MERCHANTS & MISSIONARIES:

Patenting Life, Competing International Obligations and The Proselytization of a Realistic Utopia

by

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ABSTRACT

Canadian patent legislation was recently amended to reflect a commitment in trade instruments to public health by providing developing countries access to essential medicines. Canada failed to take this opportunity to respond to the patent-human rights debate manifested in the patenting of life. Universal minimum standards for patent protection are now required of all WTO Members. This thesis considers how seemingly discordant rules under the trade and human rights regimes can be reconciled domestically and internationally in order to maximize regulatory and cultural diversity while minimizing state liability to citizens, patentees, and foreign states. A principled blend of historical, doctrinal, and interpretative textual analyses support the argument that states should not be discouraged by the threat of trade sanctions in giving human rights obligations priority over trade in domestic law and policy. A bi-furcated framework for appropriate state agency is provided. Patents have been extended to life and its building blocks by judicial fiat and administrative inertia rather than deliberate democratic parliamentary processes involving public participation. Two Supreme Court of Canada decisions obfuscate rather than clarify legal issues. A comparative examination of the Canadian context results in the first branch of the prescribed framework wherein domestic regulatory responses enabling governments to prioritize human rights consistent preferences for health over industrial policy are outlined. An anticipated international

approach is necessary to complement national strategies in case of a resulting trade dispute and constitutes the second branch. The recognition of an equitable conduct defence (ECD) by WTO decision-making bodies is a necessary legal mechanism to protect a state's right to self-determination. This defence enables states to meet their human rights obligations and fulfill duties owed to citizens while removing any real or perceived international impediments to state action in the patenting life debate. Modernity has made all measures trade-related; the future existence and legitimacy of the WTO requires the organization to act as steward of broader social values that are consistent with its own institutional history and instruments but also with political ideals of a *Realistic Utopia*. The Millennium Development Goals demand no less from our merchants and missionaries.

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In Loving Memory of My Uncle Aflatoon Adhami

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No society can surely be flourishing and happy, of which the far greater part of the members are poor and miserable.

-Adam Smith, *The Wealth of Nations*

To no one will we sell, to no one will we refuse or delay right or justice.

- Article 40, *Magna Carta*

I took one draught of life,
I'll tell you what I paid,
Precisely an existence-
The market price they said

- Emily Dickinson, Further Poems -

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TABLE OF ABBREVIATIONS

Berne	Berne Convention
CBAC	Canadian Biotech Advisory Committee
CBD	Convention on Biological Diversity
CGIAR	Consultative Group on International Agricultural Research
CIPO	Canadian Intellectual Property Office
CIPO	Canadian Intellectual Property Office
CP	Contracting Parties (to the GATT 1947)
CPA	Canadian Patent Act
CPO	Canadian Patent Office
CPRs	Civil and Political Rights
DNA	Deoxyribonucleic acid
DOE	Department of Health (U.S.A)
DSU	Dispute Settlement Understanding
EBD	European Biotechnolody Directive
ECD	Equitable Conduct Defence (also referred to as the Public Interest Defence)
ECOSOC	United Nations Economic and Social Council
ECSRs	Economic Cultural and Social Rights
EPC	European Patent Convention
EU	European Union
EPO	European Patent Office
FAO	Food and Agricultural Organization
GM	genetically modified
GMOs	genetically modified organisms
GNP	Gross National Product
GSP	Generalized System of Preferences
HD	Human Development
HGHRD	Universal Declaration on the Human Genome and Human Rights
HR	human rights
ICESCR	International Covenant for Economic Social and Cultural Rights
ICCPR	International Covenant for Civil and Political Rights
IP	intellectual property
IPP	intellectual property protection
IPRs	intellectual property rights
LMOs	living modified organisms
MDD	Millennium Development Declaration
MDGs	Millennium Development Goals
Members	Members of the WTO
MFA	Multi-Fibre Arrangement
MGL	Myriad Genetic Laboratories Inc.
MNCs	Multinational Corporations
MOPOP	Manual of Patent Office Practice (Canada)
NGOs	Non-governmental organizations

NIH	National Institutes for Health (USA)
NTB	Non-tariff barrier (to trade)
OECD	Organization for Economic Co-operation and Development
Paris	Paris Convention
PCT	Patent Co-operation Treaty
PGRs	Plant Genetic Resources
RNA	Ribonucleic acid
RRC	Round Up Ready Canola (Monsanto's)
SNPs	Single nucleotide polymorphisms
SPLT	Substantive Patent Law Treaty
TK	Traditional Knowledge
TNCs	Transnational Corporations
TRIPS	Trade Related Aspects of Intellectual Property Agreement
UDHR	Universal Declaration of Human Rights
UN	United Nations
UNC	United Nations Charter
UNCTAD	United Nations Commission on Trade and Development
UNDHR	Universal Declaration of Human Rights
UNDP	United Nations Development Program
UNESCO	United Nations Economic Social and Cultural Organization
USA	United States of America
USPTO	United States Patent and Trademark Office
VCLT	Vienna Convention on the Law of Treaties
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

Chapter One INTRODUCTION

Its peculiar character, too, is that no one possesses the less, because every other possesses the whole of it. He who receives an idea from me receives instruction himself without lessening mine; as he who lights his taper at mine, receives light without darkening me. That ideas should freely spread from one to another over the globe, for the moral and mutual instruction of man, and improvement of his condition, seems to have been peculiarly and benevolently designed by nature, when she made them, like fire, expansible over all space, without lessening their density in any point, and like the air in which we breathe, move, and have our physical being, incapable of confinement or exclusive appropriation. Inventions then cannot, in nature, be a subject of property. Society may give an exclusive right to the profits arising from them, as an encouragement to men to pursue ideas which may produce utility, but this *may or may not be done, according to the will and convenience of the society, without claim or complaint from anybody.*[1]

- Thomas Jefferson

What's past is prologue.

-William Shakespeare

1.1 Context

My high school geography teacher kept a shelved row of labeled jars containing seeds. When asked about this curiosity, he spoke apocalyptically of an approaching dystopian future when seeds would no longer have the capacity to self-propagate due to human genetic intervention. Farmers, reduced to agri-serfs, he claimed, would become dependent on large corporations (agribusinesses) that, in pursuit of greater profit, would dole out single harvest seeds at monopolistic prices under strict licences. I dismissed these doomsday comments as typical of the political hyperbole characterizing the environmental movement of the late 1980s. But the comments were ever present as the supporting evidence mounted in the following two decades.[2] Now, over twenty years later, these statements reveal a prescient awareness of the then-nascent issues that have

[1] Letter from Thomas Jefferson to Isaac McPherson (13 August 1813) in A. A. Lipscomb & Albert E. Bergh, eds., *The Writings of Thomas Jefferson*, vol. 13 (Washington: Thomas Jefferson Memorial Association, 1903-04) 333 in The Founders' Constitution, "Thomas Jefferson to Isaac McPherson", vol. 3, art. 1, s. 8, cl. 8, doc. 12, emphasis added, online: The Founders' Constitution <http://press-pubs.uchicago.edu/founders/documents/a1_8_8s12.html> [Jefferson, *Writings*].

[2] The Crucible II Group, *Seeding Solutions: Policy Options for Genetic Resources – People, Plants and Patents Revisited*, vol. 1 (Ottawa: International Development Research Centre, 2000) [Crucible II, *Seeding Solutions*], online: The International Development Research Centre < http://web.idrc.ca/en/ev-31619-201-1-DO_TOPIC.html>. The Crucible Group is a multisectoral group with representatives from industry, indigenous peoples, third world farming interests and lawyers. This document is available digitally at the IDRC (a Canadian NGO) website. See also Keith Aoki, *Seed Wars: Cases and Materials on Intellectual Property and Plant Genetic Resources* (Durham, N.C.: Carolina Academic Press, 2006).

come to dominate the debate surrounding intellectual property protection and human rights, the patenting of life (biopatenting) from genes of all species, to plant and animal varieties, and the human rights impact of growing, converging, sometimes overlapping,[3] and generally excessive intellectual property rights (IPRs) protection. Because of the number of countries affected and the scope of their application, the most significant of these IP protections are entrenched by international agreement within the multilateral trade system of the World Trade Organization (WTO).[4] WTO membership depends on implementation and enforcement of universal minimum standards for IP protection.

Meanwhile, developing countries protest these new legal and technological restrictions on their sovereign right to self-determination. They complain of an apparent hypocrisy on the part of developed countries: historically, the same developed states that today push for stronger IPRs in multilateral and bilateral agreements did not observe strict IPRs until they had reached a high level of development; an economic maturity facilitated by the liberal exchange of ideas and transfer of technology. Some developing countries assert that they would simply like to be extended the privilege to determine domestic industrial policy in accordance with other regulatory priorities and social values without potential economic costs for non-compliance with trade obligations - just as developed countries had before them.

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[3] See *e.g.* Viva R. Moffat, "Mutant Copyrights and Backdoor Patents: The Problem of Overlapping Intellectual Property Protection" (2004) 19 Berkeley Tech. L.J. 1473.

[4] Crucible II Group, *Seeding Solutions*, *supra* note 2;; E.H. Erbisisch & K.M. Maredia, eds., *Intellectual Property Rights in Agricultural Biotechnology* (Cambridge: CABI Publishing, 2004); C.M. Correa, (2000) "Options for the Implementation of Farmers' Rights at the National Level." Trade Working Paper No. 8, online: The South Centre <http://www.southcentre.org/publications/farmersrights/toc.htm>; for a useful bibliography on IPRs and plant genetic resources, see <http://www.ecolomics-international.org/bib_pgrs.htm.>. Stronger protections have been negotiated under bilateral and regional agreements (see chapter five) but are limited to negotiating parties rather than the entire WTO membership.

Deoxyribonucleic acid (DNA) provides genetic information and has therefore been referred to as the building blocks of life, the 'blue print' or 'Manual of Man', the 'Code of Codes' and the 'Book of Life.'[5] There are many arguments for and against patenting life, ranging from the economic to the ethical, which may appeal to culturally stratified citizens and their governments. At its core, the debate is about free access to genetic *information*[6] and the propriety of its regulation through market restrictions designed for *inventions*.[7] I will argue that sovereignty and the right to self-determination require that governments be able to exercise discretion to regulate the patenting of life domestically without threat of trade-related interference. Of equal compelling force are claims that health, food, education, and the right to benefit from scientific progress legitimately mandate state protection as human rights. Although there may be some ambiguity in how these social and economic rights are to be conceived, they are nonetheless human rights worthy of unfettered protection by a sovereign.

This thesis explores state agency in determining the issue and impact of patenting life. The state's role is integral to whether international human rights commitments are domestically realized. Most states are also Members of the WTO and obligated under its agreements to advance consumer welfare by helping to ensure reduced costs of

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[5] See *e.g.* Kevin Davies, *Cracking the Human Genome: Inside the Race to Unlock Human DNA* (New York: The Free Press, 2001) at 33.

[6] J.H. Reichman & Jonathan A. Franklin, "Privately Legislated Intellectual Property Rights: Reconciling Freedom of Contract with Public Good Uses of Information" (1999) 147 U. Pa. L. Rev. 875. Reichman and Franklin write of the "dual function of information" in its commodity value and its value as "the foundation of knowledge in the information economy" (at 884).

[7] Peter Drahos and John Braithwaite, in their book on the maladies of a growing intellectual property protection system, *Information Feudalism: Who Owns the Knowledge Economy?* (United Kingdom: Earthscan Publication, 2002) [Drahos &Braithwaite], observe at 4 that "[we] experience these restrictions not as a mass of individuals living in a totalitarian society, but as members of smaller communities who find strands of intellectual property law settling on and changing the customary ways in which we have accessed and exchanged information. Farmers who follow ancient practices of saving, swapping, bartering or selling seeds to each other find that these practices have to take place in the shadow of patent claims over those seeds. Just what a farmer may or may not do with plants containing patented genes becomes a lawyer's game."

consumption through commitments to eliminate trade barriers. I examine how states can exercise the right to self-determination to order domestic law and policy over biopatenting to better accord with welfare and competition promoting objectives under trade law, and the need for co-ordination between industry and health policy domestically. Measures a state can take to improve industrial policy to achieve the progressive realization of human rights such as health are, I argue, defensible even if they are trade-related and should be immune from liability under international law.

1.2 Problem

Patents, a form of intellectual property had, until recently, appropriately remained within the exclusive jurisdiction of each nation state to regulate in accordance with its own phase of social, economic, and industrial development. With some exception for United Nations based agreements under the World Intellectual Property Organization (WIPO), countries were essentially left to determine the existence and extent of their own domestic IPRs schemes. To attract protection for intellectual property, the author or inventor would have to register or otherwise comply with the legal institutional requirements within each individual jurisdiction where rights were sought. This meant that patent law was essentially country-specific and largely variable; an effective means for optimizing regulatory governance but not necessarily industry profits. With the shift to a 'knowledge-based' economy and facilitated transnational capital flows, the intellectual property generating industries successfully lobbied for a corresponding shift to negotiating substantive international IP protection within the multilateral trading regime - to secure protection and therefore returns in foreign markets- using established western IP standards as the baseline.

Not all states are at the same level of development, however; nor are they in an equal position to capitalize on the gains of the knowledge economy. The institutionalization of IP in the world trading system under the *Agreement on Trade-Related Aspects of Intellectual Property Rights* (TRIPS)[8] rewards innovation while ignoring the comparative advantage enjoyed by poorer nations in cheap labour and therefore imitation. TRIPS' universal minimum standards also ignore the historical territoriality and state derived scope of IPRs and are ostensibly at odds with the institutional history and normative welfare promoting justifications for the development of the human rights and trade regimes. Although institutionalizing IP in the WTO creates a perceived impediment to regulatory diversity, I argue that in relation to patenting life these restrictions are illusory and are rooted in misgivings of what trade obligations require or corresponding rights permit. In actuality, states continue to enjoy significant latitude with how domestic patent law may respond to the biopatenting debate of whether life- and its genetic building blocks- are or ought to be patentable.

Some governments may view biopatenting as favourable to their (economic) policy objectives and development agendas. Canada's federal government, for example, has embraced the currency of industry rhetoric and openly endorsed the global proliferation of patents on the assumption that growth in the number of patents issued is a measure of increased innovative activity that is good for the economy. Former Canadian Prime Minister (then Finance Minister) Paul Martin's Budget Speech in February 2000 emphasized the desirability of protecting private property rights in knowledge:

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[8] Agreement on Trade-Related Aspects of Intellectual Property Rights, Dec. 15, 1993, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, Legal Instruments- Results of the Uruguay Round, http://www.wto.org/english/docs_e/docs_e.htm.

> Today the strength of a nation is measured not by the weapons it wields, but by the patents it produces; not by the territory it controls, but by the ideas it advances; not only by the wealth of its resources, but by the resourcefulness of its people. It such a world, successful nations will only be those that foster a culture of innovation. They will be those that create new knowledge and bring the product of that knowledge quickly to market. Our goal as a nation must be to lead the way.[9]

Governments of developing states may, conversely, find that restrictive patent protection hampers technology transfer and knowledge dissemination critical in the early stages of an economy's development. They may find that internationally mandated strong protections pervert national cultural policies. States may have very differing rationales for preserving independent views on whether patents can issue to new subject matter such as life and the institutional parameters of IPR instruments required to provide optimal incentives for innovation. Different cultural values may even inform legal disagreement on what constitutes "life", which would have to be legally mediated through national representative governments.

The major problem confronting civil society in convincing representative governments to act on the patenting life debate to better respond to both individual human rights and the public interest in more efficient and coordinated regulatory policies is, however, the (mis)apprehended challenges that TRIPS imposes on a sovereign's unrestricted discretion to prioritize citizens' rights over the private interests of patentees. While states "have considerable freedom to choose different social policy responses to a global era,"[10] there seems to be significant reservation regarding the scope and actual restraints on this freedom due to increasingly fragmented international obligations. In some cases, governments look for legitimate means of overcoming perceived impediments to domestic policy formation while in others international obligations may

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[9] Paul Martin, Finance Minister, February 28, 2000 Budget Speech, full text online, http://www.fin.gc.ca/budget00/speech/speech1e.htm.

[10] See Keith G. Banting, "The Social Contract in a New Century: Choice and Social Cohesion in a Global Era," Donald Gow Lecture, School of Policy Studies, Queens University, 25 April 2003 at 2-3.

be resorted to by national governments as a ruse for failing to take action. Politically charged and controversial issues are instead abdicated to a judiciary often less concerned with achieving optimal patent law and policy than with the economic and political costs of divergence with American patent law.

As a result, the legal emergence of biopatenting has hitherto resulted from a patent-friendly judiciary and the exercise of administrative discretion to extend patents to life and its building blocks rather than from any legislative action whereby sufficiently robust debate could occur within a public participatory process. Where a state opposes the issue of biopatents in order to fulfill its international human rights obligations, its government may adopt domestic TRIPS-compliant measures available under current law. Governments could engage in policy reform and legislative amendment to broaden statutory exclusions and defences available and issue interpretative patent practice guidelines through offices similar to the Canadian Patent Office (CPO) as a way of establishing more stringent application of the patentability requirements. Alternative regulatory models to patent law should be considered as should the increased use of competition law to curb escalating anti-competitive behaviour.

My position in this dissertation is that life, and in particular its genetic subcomponent, is not patentable by domestic doctrinal standards in Canada. Because of the significant ethical, religious, social, cultural and economic issues, the main purpose of this thesis however is not to impose my substantive view as the norm by which all nations should adhere. Rather, my main purpose is to empower states to act in a self-determined manner to settle this debate within their own cultural and regulatory contexts. Accordingly, this thesis strives to answer a principal question that cuts across state

motivation and stratification on the biopatenting debate: *How should a state respond to competing international obligations where the patenting of life is concerned?*

In an age of deep economic integration reaching beyond borders to address non-tariff, regulatory barriers to trade, how can a state, desirous of attaining greater compliance with its *own* human rights obligations or achieving a different balance in domestic public policy, take domestic measures that may *prima facie* portend non-compliance with international trade obligations? Can a state domestically prioritize human rights, if it chooses, without finding itself defending this position as a respondent to a WTO complaint and subject, ultimately, to countermeasures by way of legitimately imposed trade sanctions?

My objective in this dissertation is to develop a prescription for an appropriate state response to competing international obligations- one that fosters democratic accountability, is responsive to the private interests of citizens over corporations, and displays fundamental respect for sovereignty. The need to establish a framework for state agency is important because international trade law provides skewed incentives for prioritizing industrial policy and trade obligations over health policy and human rights by creating cost consequences associated with defending a WTO complaint against the contested measure. Effectively, human-rights promoting measures may paradoxically be subjected to welfare-reducing trade sanctions. No similar external threat exists to influence state agency towards compliance with United Nations (UN) human rights instruments. There are no cost consequences where sovereign discretion is exercised to give trade obligations priority over human rights. The hegemony of trade and private property rights over domestic public policy and the realization of human rights have

invited significant scholarly criticism and compelling arguments in the literature on why human rights should always trump trade obligations.[11] Because of my commitment to a state's right to self-determination however, the position I take is much more modest than this unequivocal declaration. I simply ask: How can the trade disincentives for making progress in human rights protection domestically, and thus internationally, be neutralized and associated costs and risks for the state minimized? While I do not go so far as to say that all states must prioritize human rights obligations, certainly there should be no *down-side risk* for doing so. As a corollary, what is the WTO's jurisdiction and authority to respond when faced with human rights related claims and defences?[12] In prescribing a dual framework for appropriate state response, I hope to offer a new reading of international obligations as part of a common commitment to dignity and development and a coherent system of global (self) governance.

1.3 Method and Theoretical Premise

This thesis is written with the Canadian government in mind as its primary audience. Canada is a liberal democratic member state of the WTO and the United Nations (UN), a ratified signatory of the twin Covenants protecting human rights, and a potential respondent to a trade-related intellectual property complaint based on a recent

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[11] The United Nations Charter (UNC) provides for the establishment of the International Court of Justice to adjudicate on matters relating to the achievement and maintenance of the purposes and principles relating to the UN including human rights which could be carried out on either an adjudicatory or an advisory capacity. Each member pledges to comply with the decision of the court in any case to which it is a party. But the Statute of the Court annexed to the Charter made the compulsory jurisdiction of the Court voluntary to member States. Social and economic rights cannot be adjudicated before the ICJ and rely entirely on domestic means of enforcement. These reasons support my proposal for recognizing the WTO with its sophisticated dispute settlement mechanism, as steward of trade *and* other values where the latter are complained of as affecting the former. UNC, online: United Nations, http://www.un.org/aboutun/charter/.

[12] The Doha Declaration lists 'the relationship between existing WTO rules and specific trade obligations set out in multilateral agreements (MEAs)' as a topic for negotiation, see Doha Ministerial Declaration, Paragraph 31(i), adopted on November 2001, WT/MIN(01)/Dec/1 dated 20 November 2001, online:<http://www.wto.org/English/thewto_e/minist_e/min01_e/mindecl_e.htm>. See also Joost Pauwelyn, *Conflict of Norms in Public International Law: How WTO Law Relates to Other Rules of International Law*, (New York: Cambridge University Press, 2003). [Pauweln, *Conflict of Norms*].

controversy over unauthorized government use of a patented cancer-related gene and method for its diagnostic testing in the course of public health delivery. Nations poorer than Canada and in the process of developing their patent systems, however, have the most to gain from the proposals advanced for the preservation of regulatory diversity, deference to internal policy priorities, and the resolution of conflict between competing if not conflicting international obligations at the intersection of biopatents. My framework allows them to address the impact of patent policy on their development agendas.

Since the patenting of life forms has become established by the activities of proactive judges apparently endorsing industry-friendly developments in patent offices rather than by legislative fiat, this thesis also cautions judges about the potential consequences of judicial agency in extending patents to life as new subject matter and in pursuing legal harmonization removed of relevant cultural and political context. The common law extension of patents to life is consistent with transjudicial trends in domestic courts where judges seek convergence of their decisions with foreign judgments and sources of law.[13] Judicial agency has been integral to the increased patenting trend and the use of domestic standards to push for international convergence towards higher protections in all fields and in particular, in the biotechnology sector. Because of two important Supreme Court of Canada (SCC) decisions, Canada is a prime example of the unintended and undesirable consequences of judicial activism. Extending patents to life as new subject matter is controversial for the ethical, social, and legal issues involved and

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[13] See *e.g.* Anne- Marie Slaughter, "A Typology of Transjudicial Communication" (1995) 29 U Rich LR 8 at 99. Slaughter defines transjudicialism as "the communication among courts—whether national or supranational—across borders." See also Ann-Marie Slaughter "Court to Court" (1998) 92 Am. J. Int'l L 708; "Judicial Globalization" (2000) 30 Va. J. Int'L 1103; and "A Global Community of Courts" (2003) 44 Harv. Int'l LJ 191. See also the reasoning of the court in the first major case to allow patents on life in Canada, *Re Application of Abitibi Co.* (1982), 62 C.P.R. (2d) 81 [*Abitibi*].

more so when it occurs on a piecemeal basis by an unelected and unaccountable judiciary. Anxiety over judicial extension of proprietary rights to life relates to the interface of biopatents with areas of fundamental national importance for public policy: the delivery of public health, food security, protection of common and public goods including the environment, and the basic assertion of sovereignty attendant on human development, dignity, and cultural rights.

Finally, this thesis is written in a manner that may motivate NGOs and civil society. By dispelling perceived legal obstacles to the realization of human rights, I hope to invite a renewed basis for increased advocacy by appropriate state agencies. There is a very fine line between the gains to be had and the losses to be suffered if the new technology is not properly regulated within national and international contexts. Already, human rights advocates in the developed world have joined the social movements of developing countries, indigenous peoples and the global NGOs that represent them[14] in challenging the neo-liberal rhetoric that posits the primacy of private property rights[15] now entrenched under the multilateral TRIPS and bilateral TRIPS Plus agreements.

The patents-human rights relationship is geopolitically manifested as a polarized and politicized debate between the *North* and *South* or the *developed* and *developing* countries respectively.[16] The human rights interests of citizens in rich, north, developed

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[14] See generally Rosemary J. Coombe, "The Recognition of Indigenous Peoples and Community Traditional Knowledge in International Law" (2001) 14 St. Thomas L. Rev. 275-85.

[15] Peter Drahos & Ruth Mayne *Global Intellectual Property Rights: Knowledge, Access and Development* (New York: Palgrave, 2002) at 205; Susan K. Sell, "Post-TRIPS Developments: The Tension Between Commercial and Social Agendas in the Context of Intellectual Property" (2002) 14 Fla. J. Int'l L. 193.

[16] This is because the North/developed countries' liberal democracies provide more stable economic and legal environments for corporations and are, relative to the governments of South/developing countries, more likely to be subject to government capture by strong industry lobby as evinced by the history of TRIPS. For a discussion of the subversion of civil society by corporate interests through law and the profoundly undemocratic influence and existence of corporations. See *e.g.* Harry Glasbeek, *Wealth by Stealth: Corporate Crime, Corporate Law, and the Perversion of Democracy* (Canada: Between the Lines,

countries are often neglected even though these are equally at risk as those in the poor, south, or developing countries, albeit in different ways and with different consequences. Accordingly, this thesis may offer activists a new arsenal for promoting 'bottom-up' state accountability transcending the needs of the developing world by suggesting that the human rights of those in the developed world deserve no less protection by their governments from trade obligations that serve to assure corporate profit rather than the welfare promoting functions for which these obligations were designed. Civil society in rich and poor countries may come together, mobilized by a common cause, to assert the primacy of human rights and the need to account for these as part of the costs and consequences of industrial and cultural policies.

The scholarly literature on trade and human rights has typically focused on how restrictive border measures on imports such as quotas or tariffs may be used as trade sanctions to coerce human rights compliance in *other* jurisdictions (to eliminate, for example, indentured child labour in an exporting country) rather than on how trade obligations may fetter the discretion for human rights compliance in a Member's home jurisdiction. Alternatively, the focus has been to assess how monetary aid and debt relief delivered in tandem with institutional reform to the multilateral trade regime may facilitate (sustainable) "development" rather than the ways in which trade-related IP obligations may interfere with *homegrown* development that comes from imitation, transfer of knowledge and liberal access to technology. Little attention has been given to the state's role in mediating the validity of plural perspectives infusing substantive

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2002). William Quigley writes, "It is difficult to suggest that current economic arrangements, dependent as they are on large international corporations, are working for the common good." William Quigley, "Catholic Social Thought and the Amorality of Large Corporations: Time to Abolish Corporate Personhood," (2004) 5 Loy. J. Pub. Interest 46.

normative claims for IPRs that are culturally and politically located. This dissertation departs from the existing scholarship and attempts to fill the gap by prescribing and defending a pragmatic two-step procedural approach for state agency in response to these questions. If law is intended to reflect community values, how are regulatory options shaped by global regulatory trends? My answer to the "how" question is more conceptual than content driven. I believe that the content will and should invariably vary with the socio-economic conditions of a state, the political will of its constituents, and desired public policy objectives as democratically determined. Implicit in my analysis is a respect for difference founded on a liberal rights-based approach.

Legal philosopher John Rawls contributed vastly to rights discourse, emphasizing concepts of justice and rights as values superseding utilitarian conceptions of welfare maximization. In his *Law of The Peoples*, he speaks of the attainment of a "Realistic Utopia" from which this thesis borrows its title and normative framework for the dual prescriptions advanced: "[t]he idea of this society is realistically utopian in that it depicts an achievable social world that combines political right and justice for all liberal and decent peoples in a Society of Peoples."[17] In such a world, he adds,

> peace and justice would be achieved between liberal and decent peoples both at home and abroad.[18]...[The reasonably favourable] historical conditions [for a realistic utopia] include, in a reasonably just domestic society, the fact of reasonable pluralism. In the Society of Peoples, *the parallel to reasonable pluralism is the diversity among reasonable peoples with their different cultures and traditions of thought, both religious and non-religious.*[19]

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[17] *Ibid.* at 6.
[18] John Rawls, *the Law of Peoples and 'The Idea of Public Reason Revisited"* (Cambridge: Harvard University Press, 1999) at 6.
[19] *Ibid.* at 11 and 12.

Rawls' fundamental respect for regulatory and cultural diversity within certain limits – maintaining the priority of universal human rights- defers to state sovereignty.[20] A *realistic utopia* is an achievable goal where human difference is celebrated as the common characteristic of our existence. For Rawls, the justness of the theory gives it a universal appeal. To this end, he states that "[a] (reasonable) Law of Peoples must be acceptable to reasonable peoples who are thus diverse; and it must be fair between them and effective in shaping the larger schemes of their co-operation." The framework advanced in this dissertation is designed to accord with a Rawlsian understanding of international law as both the *law of peoples* and the *law of nations*.

With the proliferating reach of international agreements into sovereign jurisdiction, the lack of democratic global participatory processes, and the increasing scope and means of enforceability of international obligations, particularly in the international trade system, individual rights and public interests may be usurped by competing private economic proprietary interests of transnational corporations without an opportunity for meaningful political dialogue. The lack of a compelling global morality or political ethic makes strong national policies imperative. Consequently, sovereign discretion to respond to international human rights obligations is a *defendable* position, against trade complaints, but also a *desirable* one.

Appropriate state response may be domestic and/or international. A dual strategy is essential. An international approach needs to be anticipated to complement national

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[20] Rawls identifies a number of *familiar and traditional principles of justice among free and democratic peoples* on which he expounds and for which there is evidence in the global welfare promoting institutions of the United Nations and the WTO. These include that peoples are 1. free and independent, and their freedom and independence are to be respected by other peoples; 2. to observe treaties and undertakings; 3. equal and are parties to the agreements that bind them; 4. to observe a duty of non-intervention; 5. to observe human rights; and have 6. a duty to assist other peoples living under unfavourable conditions that prevent their having a just or decent political and social regime. *Ibid.* at 37, emphasis added.

strategies so as to protect domestic state measures from successful challenge under international trade instruments. The bifurcated framework offered here also helps to eliminate any real or perceived international limitations to state agency where patenting life is concerned and safeguards the accountability of representative governments to their respective constituent "publics" while reducing external costs for public policy preferences. Instead of a comprehensive methodology, I offer a principled blend of historical, doctrinal, and interpretative textual analysis to support my commitment to state discretion to allow human rights to trump trade obligations where the two conflict without potential sanction or liability.

Six substantive chapters follow this introduction. *Chapter 2: What's Wrong With Intellectual Property Rights?: A Not So Common(s) Approach to Genetic Information* begins by deconstructing the idea of IPRs in order to reveal their normative conceptual flaws as well as the inability of this property-based regime to appropriately address communal claims of ownership and access to genetic information. This chapter demonstrates the institutional nature of IPRs, the rationales for conferring state derived privileges, and the statutory basis by which they are defined and limited in order to impress on the reader the national identity of IPRs while displacing commonly accepted deontological theories of rights. IPRs are cultural and commercial policy instruments designed to achieve specific desired outcomes within a geopolitical territory through institutional variability. Such an understanding challenges any rights based claims for the further expansion of patentable subject matter to life and its genetic building blocks, deferring instead to regulatory policies and doctrinal analyses. On the basis of a conceptual understanding alone, we may anticipate resistance to internationally

prescribed substantive IP protection, even if they are "trade-related". Where such rights are extended to genetic information, further substantive opposition may result from its unique nature as our common heritage and its public good character as an information commons barring the legitimacy of individual claims to its appropriation and privatization under the guile of "invention."[21]

Having provided a general conceptual and historical introduction for institutional IPRs, Chapter 3, *The Promise and Perfidy of Patents,* examines the vast welfare and human rights potential of biotechnology and the disproportionately positive gains promised to the poorest and worst off in both developed and developing countries. By analytically exploring the nature of the scientific paradigm by which invention and discovery are made, and the specific collaborative projects for mapping genetic sequences, we observe a significant conceptual dissonance between the extension of a proprietary "rights" regime and the accretion nature of scientific process. In reviewing evidence of patent practice, we see how our discomfort with granting private exclusive rights to public collaborative research is exacerbated by the subject matter to which such rights attach and the faulty operation of the patent administrative system. Institutional resource deficits and patent holder greed define current patent proliferation trends and synergistically threaten biotech's human rights-promoting potential. A tragedy of the anti-commons looms large as a result of overprotection and the proliferation of poor quality patents and does not augur well for the public who subsidizes these so-called inventions. Building on the warning arising from the previous chapter's conceptual critique, this chapter argues against the further expansion of exclusive property rights in the field of biotechnology by highlighting the practical inefficiencies of our current

[21] See *e.g.* Drahos & Braithwaite, *supra* note 7 at 157.

regime in granting ex post rewards to basic research, the inappropriately lax application of patent criteria by patent offices that has allowed this to occur, and the resulting perverse secondary incentives created for patent holders, typically large multinational corporations, to engage in predatory practices. Alternative regulatory approaches are suggested as are more immediate means of patent reform. The overall emphasis made is that any expansion and strengthening of patent rights should occur through thoughtful, balanced democratic deliberation rather than by way of administrative inertia and inoperability.

In Chapter 4, *Origins of the Patented Species: Of Mice and Men and Sincerity of Invention,* I build on the prior analyses of a conceptually and institutionally flawed patent system. Against this landscape, I consider the instrumental role of a predominantly patent-friendly judiciary in extending patents to life and the regulatory responses available to a state to remedy an apparent impasse in the common law on patenting life. A review of the case law will reveal the incremental and surreptitious nature by which patents have issued on life forms and the difficulty in reconciling this outcome with the auto-activity of living matter given the legal requirements for full disclosure of patented inventions. The jurisprudence highlights the common law evolution of the patented species through the courts to the incredibly odd legal conclusion reached in two pivotal recent Supreme Court of Canada (SCC) cases. Because these decisions further obfuscate the law in this field, we can expect continued harmful inefficiencies to abound until regulatory action is taken by the Canadian government. Reform measures should be trade-compliant in order to avoid attracting patent litigation or a WTO complaint. To empower states, I outline the international obligations that must now be contemplated by

any domestic regulatory initiative for patent reform and show the textual flexibility of the TRIPS agreement specific to the issue of patenting life. Various recommendations are made for domestic responses that would allow a state to effectively balance and co-ordinate policies in a trade-consistent manner. These constitute the first branch of the framework I prescribe for appropriate state agency in this dissertation and demonstrate how the failure of representative governments to improve domestic law and policy in a manner consistent with the human rights of its citizens cannot be exclusively attributed to perceived restrictions imposed under WTO law. The chapter concludes by asserting that while there may be political pressures to have convergence towards stronger property rights extend to life in the common or statutory law, there are no international *obligations* that necessitate this outcome. To the contrary, from the evidence put forward, states have ample capacity and discretion to adopt liberal trade-consistent policies that are duly consistent with their human rights obligations reviewed in the next chapter.

Chapter 5, TRIP'ing Over Human Rights: A Legitimacy Crisis at the WTO provides a much needed institutional history of the international regimes for trade and human rights, their institutions, and their instruments in order to understand why today's globalized legal climate requires states to anticipate a trade complaint and be able to respond appropriately. Until this point in the dissertation, the need for regulatory diversity in relation to biopatenting has been framed in terms of its positive potential for achieving better domestic regulatory responses and co-coordinating strategies for policy preferences. This chapter considers how human rights obligations of a state invariably translate the universal minimum IPRs protections of TRIPS as equally "human-rights related". The historical review in this chapter reveals how the impetus for TRIPS'

inclusion in the multilateral trade regime came from a powerful private lobby fixed on internationally expanding property rights protections, marking a significant substantive departure from trade policy, theory, and negotiating processes in prior rounds. Mark Halle explains their inclusion:

> [f]or the trade world, IPRs are one of the pillars on which the entire trade edifice is built. Without widespread recognition of property rights, without considerable degree of harmony in how these rights are recognized, and without an assurance that these rights will be respected and- where necessary- enforced, the confidence necessary for international commerce is difficult to muster.[22]

IPRs are now central to the multilateral trade regime and raise important areas of domestic public policy but despite their institutional character, are IPRs also *human rights?* This question is explored in order to determine whether the discourse in patent-human rights debates should be concerned with competing *human rights* such as a right to IP and a right to health or with competing obligations of a state which pit human rights (such as the right to health) against trade obligations (the protection and enforcement of patents). After considering this question, the intersection of patents with other human rights are outlined as part of the process of determining the potential sites of vertical conflict (between domestic human-rights promoting laws and international trade rules) and the question of horizontal conflict internal to the human rights regime (between competing human rights to health and IP for example). From this analysis, I reach the conclusion that IPRs are *not* human "property" rights of exclusion (the kind critiqued in chapter two) but, if they exist as human rights, they are rights of *inclusion*, *participation* and *access* consistent with a commons approach outlined earlier in this thesis. I argue that a right of access is the only reasonable approach to treating IPRs as human rights and

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[22] Mark Halle, Project Director, IUCN Project on the Convention on Biological Diversity and the International Trade Regime, foreword to Graham Dutfield, *Intellectual Property Rights, Trade and Biodiversity: Seeds and Plant Varieties*, (United Kingdom: Earthscan Publications Ltd, 2000) [Dutfield, *IPRS, Trade & Biodiversity*].

complements rather than undermines the realization of other human rights at their intersection with patenting life. IPRs are again reduced to their institutional denomination as state interventions which significantly benefit corporate owners, now internationally, creating tensions with individual (and collective) human rights obligations. Attention is drawn to the immediacy of the sovereign right to self-determination by which all other human rights obligations undertaken by a state may be realized, vertical conflict minimized, and legitimacy of the WTO retained.

Chapter Six, *Reconciling Competing International Obligations: The Equitable Conduct Defence & Stewardship of the WTO,* considers renewed commitments to co-operation under the Millennium Development Goals and the synergy between human rights, human development, and trade. The fragmentation of international law has increased the potential sites of anticipated horizontal conflict; because of this, it becomes even more imperative for states to have a means of defending domestic regulatory measures as part of an overall commitment to a broader *system* for global (self) governance. This chapter examines how principles of treaty interpretation can be used to assist states to simultaneously make positive efforts to interpret competing obligations in a conflict minimizing manner. Requiring the grant of patents for all biotechnology creates potential conflict with human rights and other international instruments such as the Convention on Biological Diversity (CBD). But certain conflicts can be read out of international texts through proper interpretation of the rights and obligations conferred. A state desirous of prioritizing human-rights consistent obligations under ratified Conventions should do so, defending its conduct, I argue, with assertions of its right under human rights and trade instruments as well as its legal obligations to its citizens.

This is the second branch of my framework for state agency; it is consistent with international rules of treaty interpretation, Rawlsian principles of fairness and social justice, and is justifiable in equity to allow states to reconcile fragmented obligations as part of a unified international order. The WTO dispute settlement body should accept its stewardship over trade-related human rights values raised by patenting of life by remaining open to what I call an equitable conduct defence (ECD) designed to protect the public's interest. The public, incidentally, have no legal standing in the multilateral trade system's complaints process. I argue that decision-making bodies of the WTO should direct themselves to broadly accepting all legal arguments and evidence of defensible conduct when assessing a contested measure- so long as non-discrimination, the primary principle of the multilateral trade regime, is met. I conclude by asserting that my proposed framework's reconciliation of human rights and trade obligations in dispute resolution would serve the ends of social justice and restore some of the eroding legitimacy threatening the future relevance of the WTO; any proposed framework for state agency must maintain the coherence of international law.

In the course of analysis, it will become apparent that a false dichotomy of national obligations exists, classifying them as either exclusively trade *or* human rights, based on the source from which they are derived. This has in turn created a distinct duality in our socio-legal and political identities, a likely vestige of our historical past, as either *merchants* (capitalists) in pursuit of trade related gains or *missionaries* (colonialists) engaged in cultural imperialism with "charitable" forms of support aimed to convert societies - so-often by fostering dependency on foreign 'assistance' conditioned on assimilation and the obliteration of difference. Some may argue that institutionally

protected universal human rights are themselves a manifestation of cultural imperialism[23] accentuating the tenuous relationship between cultural diversity and universal claims. Yet others have no difficulty reconciling the two:

> Culture and human rights are often seen as antagonistic entities, culture positing people according to particular semantic schemes and value systems, and human rights referring to shared concerns and a universal standard of evaluation...For an anthropologist there is no contradiction between the two; anthropology itself presupposes both a shared humanity, without which the comparative study of societies and cultures would make no sense, and a sensitivity to cultural distinctions, seen as different ways of practicing universal capacities.[24]

Anthropologist Kirsten Hastrup argues that human rights culture "draws upon all kinds of ancestry" such that

> [w]hether we agree to the view of liberal justice which Rawls (1971) has identified simply as 'fairness', the international community agrees surprisingly well across differences in local culture, belief, language and metaphysics on the demands for justice and mutual benevolence, and universal standards of rights that are increasingly specific are put forward and subscribed to as part of the international legal instrumentalization. Even when governments subscribe to them with a good deal of hyprocrisy and reservation, few would openly question the basic assumption that they can further justice between people.[25]

She contends that universal declarations of human rights represent a pursuit for the 'common good' on a global scale. In fact, so too does trade liberalization although through different instruments. The historical analysis engaged in chapters 5 and 6 strives to eliminate the perceived divisibility of international institutions (and the legal identities they foster) in order to correct any misgivings about the common purpose of trade and human rights systems despite their significantly divergent approaches (the former utilitarian in focus, the latter individualized); chapters 2 and 3 demonstrate that this purpose is in fact shared by an institutionalist's understanding of industrial policy as primarily utilitarian. The multilateral trade system also espouses utilitarian justifications for welfare maximization through a state's comparative advantage which reduces

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[23] See Kirsten Hastrup, "Accommodating Diversity in a Global Culture of Rights" in Hastrup, ed., *Legal Cultures and Human Rights: The Challenge of Diversity* (USA, Kluwer Law International: 2001) at 25.
[24] *Ibid.* at 1-2.
[25] *Ibid.* at 7 and 9.

consumer costs and increases productivity while the human rights system embraces individual rights which if taken as a collective will also raise aggregate welfare. The common objective of all three regimes is to promote development agendas and personal dignity by facilitating the creation of larger and more stable foreign consumer markets without doing so at the cost of individual human rights. But, the insular expansion of trade and human rights has occurred without regard to the effects of this mutually exclusive taxonomy on (distributive) justice. The duality is misguided and leads to state malpractice by artificially limiting the jurisdiction, scope, and understanding of what states as agents should or could do to respond to private and public claims in relation to patenting life. This contrived "duality" has, until now, constrained a coherent understanding of state obligations as part of an international system of law based on social justice.

My prescribed framework for resolving potential conflict domestically and internationally, with TRIPS-compliant domestic measures supported by an equitable conduct defence before WTO jurists offers a comprehensive approach to competing international obligations; it is a framework based on equity and advanced in the interest of justice, reasonable pluralism, development, and human dignity. Patenting life raises important issues that should be navigated domestically to accord with the public interest in regulating new technology. Biotechnology promises the means for addressing the paucity and disparity of natural endowments contributing to famine and disease while underscoring important economic, cultural, religious, ethical, and human rights issues to be weighed by the regulatory governments of nation states against industrial policy objectives for defining domestic private property rights, their scope and limits.

Chapter Two

What's Wrong with *Intellectual Property Rights?* A Not So Common(s) Approach to Genetic Information

2.1 Introduction

Ideas flow freely across boundaries, particularly in a global society characterized by facilitating telecommunication and transport technology. Ideas contribute to our common stock of knowledge and expand the base for further generation of ideas. Knowledge is readily accumulated, copied, built on and transferred.[26] Its unique character means that knowledge is at once valuable to society and yet without market value absent state regulation since it is non-rival in consumption and can be reproduced or transmitted at close to zero cost despite substantial fixed costs of acquisition. Knowledge is also non-exclusive and unlike corporeal property, may be used, consumed, and possessed by multiple individuals at any given time without depriving the rights holder of any use. These benefits of knowledge to all members of the benefiting group classify it as a public good.[27] The value of knowledge in fact increases with greater dissemination because of *network gains.* For example, DNA sequences, often referred to as the 'code of life' are like any language and communicate (genetic) information. Mapping projects for DNA sequencing, however, increase the common stock of genetic *knowledge*[28] by creating networks of experts whose collaboration in mapping requires

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[26] Wendy Gordon, *Intellectual Property Theory Intensive Course Reader* (University of Toronto, 2000); Wendy Gordon, "Of Harms and Benefits: Torts, Restitution, and Intellectual Property" (June 1992) XXI J. Legal Stud. 449 [Gordon, "Harms and Benefits"].

[27] "non-rival availability of benefits to all members of the benefiting group is the essential feature of public goods, but the group has to be defined." United Nation Development Programme (UNDP), *Human Development Report 2000: Human Development and Human Rights* (New York: Oxford University Press, 2000) at xi [UNDP HR/HD Report 2000]. Biotech's promises are discussed further in chapter three.

[28] "The Knowledge Based Economy" The Organization for Economic Co-operation and Development (OECD) *Science, Technology and Industry Outlook 1996,*[OECD 1996 Knowledge Based Economy Report] online: http://members.shaw.ca/competitivenessofnations/Anno%20OECD.htm, provides some distinctions: "Knowledge is a much broader concept than information which generally represents the know-

attendant standard formation in management, retrieval, and use of genetic information and these help to identify technological needs to which innovators may respond by creating new mapping, sequencing, and analyzing technology that are expeditious, economical, and efficient.[29] Network gains in genomics can also be measured in terms of health outcomes since liberal access to genetic information (basic research) will likely increase global collaboration in research and development (R&D) for less commercially attractive applications by reducing transaction costs (i.e. the need to obtain licences for R&D of patented technology).[30] Because innovation is knowledge dependent, since 1996, the Organization for Economic Co-operation and Development (OECD) has focused efforts on quantifying and mapping the diffusion paths of knowledge and innovation as key to economic performance,[31] reporting that:

> [i]nnovation is thus the result of *interaction in a community of actors and institutions*, which together form what are termed national innovation systems. Increasingly these innovation systems are extending *beyond* national boundaries to become international. Essentially, they consist of the flows and relationships created among industry, government and academia in the development of knowledge....Of key importance is the power of the system to distribute knowledge or its capacity to ensure timely access by innovators to relevant stocks of knowledge.[32]

In short, liberal access to knowledge as a public good will have proportionately greater gains for the granting society and government policies should, accordingly, promote laws, networks or systems that can efficiently distribute knowledge and remain

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what and know-why components of knowledge...All knowledge that can be codified and reduced to information can now be transmitted over long distances at very little cost. It is the increasing codification of some elements of knowledge that has led the current era to be characterized as the information society... where a majority of workers will soon be producing, handling and distributing information or codified knowledge" (at 232).

[29] "Technologies for Genomic Mapping, Sequencing and Analysis" (March 1997) 26.8 NIH Guide.

[30] GM plant derived vaccinations provide additional network gains in that individual health gains are augmented by global (social) gains from interrupting the chain of disease transmission. Private firms, however, may be deterred from vaccination research, knowing that once produced, governments will pressure their use at manufacturing costs (possibly under compulsory licencing schemes) rather than firm determined prices which might try to recoup larger R&D costs of multiple research initiatives of the firm. See Michael Kremer, "Creating New Markets for New Vaccines" (24 May 2000), online: Harvard, <http://www.economics.harvard.edu/faculty/kremer/papers/vaccine1.pdf>

[31] OECD 1996 Knowledge Based Economy Report *supra* note 28 at 235.

[32] *Ibid.* at 233.

impervious to external (corporate) pressure for its containment. But despite widespread public benefits from sharing knowledge and its advantage to society, its unique nature means that in a free market, profits could never repay the expense of its generation and the costs of knowledge production would have to be borne privately.

Moral philosopher Adam Smith's *The Wealth of Nations*[33] first made the distinction between public and private goods in the late eighteenth century. He argued that since the market fails to provide for the existence of public goods, governments must ensure their provision. Firms would otherwise have little incentive to invest in innovation since the economic benefits would be shared by those who have not expended funds in the generation of this knowledge.[34] Smith's theory of division of labour and specialization revolutionized political philosophy and economic theory and is often cited for offering rationales for state created monopolies in knowledge, but he was first and foremost a moralist and major proponent of public education.[35] Nevertheless, for a free market proponent such as him, the public good quality of knowledge *justifies* a limited term monopoly[36] such that safeguarding Congressional power over letters patent entered debates early in the drafting of the American Constitution. Yet intellectual property

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[33] Adam Smith, *The Wealth of Nations,* online: <http://www.econlib.org/library/Smith/smWN.html>.

[34] David Vaver, *Intellectual Property Law: Copyright, Patents, Trade-Marks* (Concord, Ont.: Irwin Law, 1997) [Vaver, *IPL*].

[35] According to E. Rothschild, "Smith is insistent, from the beginning of the *Wealth of Nation,* on the equality of natural talents. The difference between the philosopher and the common street porter, he says, "seems to arise not so much from nature, as from habit, custom and education. When they came into the world, and for the first six or eight years of their existence, they were, perhaps, very much alike." Their "very different genius," as adults, is the consequence of the division of labor more than its cause. People are not born "stupid and ignorant" but are made so by their "ordinary employments"; by the simple, uniform nature of the work they can get; and by the circumstance that their parents, who "can scarce afford to maintain them even in infancy," send them out to work as soon as they can." E. Rothschild, "Apprenticeship and Insecurity" in *Economic Sentiments: Adam Smith, Condorcet, and the Enlightenment,* c 4 (Cambridge, Mass.: Harvard University Press, 2001) at 87, cited in Chartrand, *infra* note 36.

[36] See generally Harry Hillman Chartrand, "The Labour Theory of Knowledge & Its Corollary: The Knowledge theory of Capital," in *The Competitiveness of Nations in a Knowledge Based Economy*, March 2003, online: <http://www.compilerpress.atfreeweb.com/Labor%20Theory%20of%20Knowledge.htm>.

protection (IPP) is neither universal nor *essential* but is, rather, a politically determined cultural form of industrial regulation contained within the canon of laws exported to British colonies. Thomas Jefferson, a founding father of American patent law and patent board member wrote:

> England was, until we copied her, the only country on earth which ever, by a general law, gave a legal right to the exclusive use of an idea. In some other countries it is sometimes done, in a great case, and by a special and personal act, but, generally speaking, other nations have thought that these monopolies produce more embarrassment than advantage to society; and *it may be observed that the nations which refuse monopolies of invention, are as fruitful* as England in new and useful devices. Considering the exclusive right to invention as given not of natural right, but for the benefit of society, I know well the difficulty of drawing a line between the things which are worth to the public the embarrassment of an exclusive patent, and those which are not.[37]

Intellectual property "may be defined as embracing rights to novel ideas as contained in tangible product of cognitive effort."[38] Edwin Hettinger describes them as "intellectual objects."[39] Indeed, novel ideas recast as "intellectual property" are valuable only *because* the law has institutionally created artificial scarcity through the grant of exclusive "rights" to these efforts. Greater legal protection for intellectual property as a matter of social policy creates greater value in that property and therefore a more significant desire to curtail its theft and piracy. If "piracy" exists, it is only because its object has been labeled "property".[40] Intellectual property, consequently, is a cultural construct legally codified as an imaginative way to ascribe a tangible monetary exchange value (thus creating and protecting a market) to things that would otherwise be 'free as the air we

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[37] Letter from Thomas Jefferson to Isaac McPherson (13 August 1813) in A. A. Lipscomb & Albert E. Bergh, eds., *The Writings of Thomas Jefferson*, vol. 13 (Washington: Thomas Jefferson Memorial Association, 1903-04) 333 in The Founders' Constitution, "Thomas Jefferson to Isaac McPherson", vol. 3, art. 1, s. 8, cl. 8, doc. 12, online: The Founders' Constitution <http://press-pubs.uchicago.edu/founders/documents/a1_8_8s12.html> [emphasis added] [Jefferson, *Writings*].

[38] Dale A. Nance, "Forward: Owning Ideas" (2000) 13 Harv. J.L. & Pub. Pol'y 757 at 758.

[39] Edwin C. Hettinger, "Justifying Intellectual Property" (1989) 18 Phil. & Pub. Aff. 31.

[40] See generally Rosemary J. Coombe, *The Cultural Life of Intellectual Properties: Authorship, Appropriation and the Law* (United States: Duke University Press, 1998) [Coombe, *Cultural Life*]. Peter Jaszi has insightfully noted, "[o]ne might say that one nation's 'piracy' is another man's 'technology transfer'." Peter Jaszi, "A Garland of Reflections on Three International Copyright Topics, (1989) 8 Cardozo Arts & Ent. L.J. 47 at 63.

breathe' (such as ideas, relations, schemes, etc.) - simultaneously capitalizing on the fact that "all forms of capitalism are accompanied by forms of enchantment [as] markets are animated by fictions, tropes, and rhetorical forms."[41]

The significant value of knowledge as a public good[42] is surpassed by its increasing value as a private good closely connected with its legal status as *property* in domestic and subsequently international law. It is not merely the shift in industry from manufacturing to knowledge production (in entertainment, books, pharmaceuticals, biochemicals, fertilizers etc) that has augmented the market value of knowledge to a "knowledge-based economy". Rather, it is the effective efforts at gaining legal ascription of property type rights to what are actually monopoly based privileges that has unnecessarily artificially inflated the value of specific forms of knowledge (genetic) and expanded patentable subject matter (to life). Despite its name and rights-based theoretical discourse, there are good reasons for concluding that IPRs are neither *intellectual* nor *property*, and, most importantly, that they are <u>not</u> *rights*.

The deconstruction of IPRs in this chapter will demonstrate the conceptual presumptive flaws of modern dominant western IP regimes by critiquing their normative elements. The historical instrumental use of patents to encourage new trade confirms that intellectual property protection (IPP) can only find justification in institutionalist theories rather than the deontological ones commonly advanced in industry rhetoric and frequently accepted by the Courts. IPP is prescribed by statute, expands to diverse

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[41] Rosemary J. Coombe, "Legal Claims to Culture in and Against the Market: Neoliberalism and the Global Proliferation of Meaningful Difference" (2005) 1 Law, Culture and Humanities 32, online: York University <http://www.yorku.ca/rcoombe/publications/Coombe_Legal_Claims_to_Culture.pdf> [Coombe, "Legal Claims"] at 4.

[42] The public good quality of genetic and biomedical knowledge is discussed in the next two chapters.

subject matter, takes multiple forms for stratified periods,[43] and conventionally is subdivided into two main branches: copyright and industrial property. Industrial property can be further subcategorized into geographic indications, industrial designs, plant variety protection, patents, trademarks, and the common law of trade secrets.[44] The World Intellectual Property Organization (WIPO), a United Nations specialized intergovernmental organization charged with administering international IP treaties, also defines IP in terms of its instrumentality to public interest and functionality within social and economic contexts.[45] Despite common references to public rights of access within both WIPO's and domestic IP instruments, the IPRs granted are exclusive rights and necessarily restrict liberal access and use. This chapter proceeds by examining the idea of exclusion integral to western IP regimes, its centrality to how the idea of property is conceptualized (as a right to exclude) and to what it attaches (only certain forms of intellectual inputs). Next, I proceed to problematize and thereby reveal the fallaciousness

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[43] By statute in Canada, fifteen years with unlimited renewal for registered trade-marks, ten years for industrial designs, twenty years for a patents, fifty for a copyright, and by common law, twelve years for personality rights and indefinitely for a trade secret so long as it is kept a trade secret.

[44] The blunt instrument of patents sometimes is extended to the contested arena of traditional knowledge (TK). Other times TK is protected by *sui generis* regimes (plant variety protection). See Dutfield, *IPRS, Trade & Biodiversity, supra* note 22 at 65-68. Dutfield presents several case studies of US patents granted over traditional knowledge, against the protest of the original communities from which they were taken. See also Robert Howell, "The Interconnection of Intellectual Property and Cultural Property ("Traditional Knowledge")" online: http://www.fphlcc.com/assets/toolkit/artsculture/reports/the%20interconnection%20of%20ip%20&%20cultural%20property%20rg%20howell.pdf.

[45] Formed under the WIPO Convention (signed in Stockholm July 14, 1967, entering into force in 1970) WIPO replaces the two "international bureaus" constituted under the Paris and Berne Conventions for the protection of intellectual and industrial property). WIPO administers other agreements including the Patent Co-operation Treaty [PCT] (1970, amended 1979 and modified 1984), and the Budapest Treaty on the International Recognition of the Deposit of Micro-Organisms for the purpose of Patent Procedure. (1977, amended in 1980). Intellectual property is defined as "[t]he legal rights which result from intellectual activity in the industrial, scientific, literary and artistic fields. Countries have laws to protect intellectual property for two main reasons. One is to give statutory expression to the moral and economic rights of creators in their creations *and such rights of the public in access to those creations*. The second is to promote, as a deliberate act of *Government policy*, creativity and the dissemination and application of its results and to encourage fair trading which would contribute to economic and social *development*." World Intellectual Property Organization, *Introduction to Intellectual Property Theory and Practice* (Geneva, Switzerland: Kluwer Law International, 1997) at 3 [emphasis added].

of "intellectual", "property" and "rights" as requisites for the generation of intellectual objects. Despite the conceptual ill fit, I conclude by arguing that if institutionally we are to locate property in genetic information, then *that* property cannot be held exclusively by private individuals as a matter of enclosing the public domain because the nature of genetic information as our common heritage is creative and derives from communal authorship; as a matter of social policy these IPRs must necessarily be held in common with a collective right to use.

2.2 Intellectual Property Rights Deconstructed

2.2.1 The "Exclusion Thesis"

Not only is the content and substance of intellectual properties culturally articulated as an artifact of legality but, additionally, so are the very laws by which IPRs are juridically defined, limited, constituted, and mediated. For example, *what* counts as IP addresses the first point and *why* IPRs (the normative claim to IPRs) addresses the latter. Western IPRs are based on a theory of exclusion - not only in the property sense as a means of ensuring exchange market value in the underlying invention or expression of an idea, but also in the politics of excluding specific forms of works culturally incongruent with western normative legal prescriptions. For example, copyright's "fixation" requirement effectively denies traditional works of oral culture and folklore (so-called immaterial property) the IPRs enjoyed by those who appropriate them under the guise of "public-domain" inputs into their own creative efforts and subsequently reduce them to some tangible form of expression legally recognized as *valid* (material property) to which IPRs attach. Similarly, patent law has often struggled to protect traditional knowledge even though BigPharma has not experienced similar barriers when

seeking to protect such appropriated knowledge.[46] The claim to *validity* alienates the contributions of indigenous communities and renders their stories, traditional (medicinal and ecological) knowledge and contributions of (economic) value free for the taking as "public" inputs for the "private" outputs of those culturally conditioned for compliance with a legal order thus constituted. Similarly, genetic information was located within this "public domain" such that "through an act of isolation and purification, [DNA could] transform a naturally existing product into an invention...even though the purified DNA coded for the same protein as the naturally occurring sequence"[47] Consequently, property rights will vest in those who invest labour of the kind legally recognized, such as to immortalize things through documentation and archive rather than oral preservation and transmission,[48] or to purify and isolate rather than to procreate or nurture.[49] Such a legal system ignores as material a form of labour, creativity, and contribution non-existent in the mappings of (or yet to be "discovered" by) western IP law.

The dynamic has been played out repeatedly on various platforms including the (corporate) privatization of the human genome and more demonstratively the now defunct Human Genome Diversity Project (HGDP), then dubbed the "vampire project" for its capitalist drive by Western scientists to patent genomic information derived from samples taken from 722 indigenous communities without consideration of benefit sharing, consent, or alleviating the conditions that rendered these communities "vanishing isolates" worth archiving for their comparative research value.[50] The genetic samples

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[46] See for example the Turmeric example discussed in chapter five.
[47] Drahos & Braithwaite, *supra* note 7 at 157.
[48] See Bita Amani, "Fact Fiction or Folklore?: It's Time the Tale Were Told" (1999) 13.2 I.P.J. 237 [Amani, "Fact, Fiction"].
[49] See generally Bita Amani and Rosemary Coombe, "The Human Genome Diversity Project: The Politics of Patents at the Intersection of Race, Religion, and Research Ethics" (2005) 27.1 Law & Policy 152.
[50] *Ibid.* at 155. See also in text discussion in chapter three, pages 110-111.

extracted from members of these communities studied were not conceived of as property. Yet, any valuable cell-line so derived would be on the basis of the labour vested in it, once again rendering the labour of the individual in maintaining the physical self *invalid;* effectively, *"immaterial"* if property, and obviously not 'intellectual' in kind.[51]

Morris Cohen long ago argued that "*dominium* over things is also *imperium* over our fellow human beings."[52] Because property confers a right establishing a legal relation between the person not in relation to the object but in respect of it as against the world, its dominant feature of exclusion creates a form of *sovereignty* over others affecting many human rights and in particular the right to self-determination.[53] The conceptual distinction between sovereignty and property becomes significantly blurred as the latter necessarily imposes on the former through the non-consensual and coercive use of state power. Developing countries now share the angst experienced by larger and more stratified indigenous communities in resisting the appropriation, privatization, and commoditization of their traditional knowledge, often to the exclusion of the original communities whose stewardship preserved this knowledge.[54] In short, "[a]s the law creates 'property', so it may deny its existence."[55]

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[51] See *Moore v. Regents of the University of California*, 51 Cal. 3d 120, 125; 793 P.2d 479 (Supreme Court Cal., 1990), the legal precedent for this. For a detailed discussion, see Amani and Coombe, *ibid.* at 153.

[52] M.R. Cohen, "Property and Sovereignty" (1927) 13 Cornell L. Q. 8 at 13.

[53] Protection and preservation of geographic indications as true indications of source are played out with similar politics. See Graham Dutfield, "Case Study 6.1" in *IPRS, Trade & Biodiversity, supra* note 22 at 87-88. See also Bita Amani, "A Penchant for Persian Rugs Over Palatable Products: The Use of Geographic Appellations as Trade-Marks- Part I" (2000) 14.2 I.P.J. 185-218 and Part II, "A Parthian attempt to Turn Paddock to Haddock in Trademark Law or the Continued Search for the Philosopher's Stone?" (2000) 14.3 I.P.J. 313-360.

[54] See Rosemary Coombe, "Intellectual Property, Human Rights and Sovereignty: New Dilemmas in International Law Posed by the Recognition of Indigenous Knowledge and the Conservation of Biodiversity" (1998) 6 Ind. J. Global Legal Stud., 59 [Coombe, "IP, HR & Sovereignty"]; Amani and Coombe, HGDP, *supra* note 49. The InterAmerican Development Bank is supporting an experimental project, *Transforming Traditional Knowledge into Trade Secrets,* based in Ecuador on protecting traditional knowledge as trade secrets. See Dr. Gerard Bodeker, "Indigenous Medical Knowledge: The Law and Politics of Protection" (Paper presented to the Oxford Intellectual Property Institute Research

Law and communications professor Rosemary Coombe has offered a sustained and significant contribution to the cultural and anthropological identity of such legalities,[56] critiquing their colonial containment of alterity[57] through authorial cartographies[58] and proprietary mappings. Coombe writes:

> Intellectual property laws, which create private property rights in cultural forms, afford fertile fields of inquiry for considering the social intersections of law, culture, and interpretive agency. The rights bestowed by intellectual property regimes (copyright, trademark, publicity rights, design patents, and associated merchandising rights in particular) play a constitutive role in the creation of contemporary cultures and the social life of interpretive practice.[59]

Since these legal norms are necessarily culturally specific, any investigation into IPRs must remain cognizant of the cultural dimensions of the creation, recognition, and enforcement of such rights, their exclusions or exceptions, and their broader acculturation by the more powerful stakeholders into normative acceptance. IPRs are duly *cultured,* in the sense that they are the product of a social dialectic that contributes to the constitution, management, and transmission of these rights as normative due to a given cultural framework but also in that this conceptual framework has itself, in its constitutive form, developed under artificial and controlled conditions (the western neoliberal regulatory state).[60] The legal frameworks for IP regimes enable, according to Coombe,

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Seminar, 25 January 2000), online: <http://www.oiprc.ox.ac.uk/EJWP0300.pdf>; Dr. Gerard Bodeker, "Traditional Medical Knowledge, Intellectual Property Rights and Benefit Sharing" (July 2003), online: <http://www.cardozo.yu.edu/cjicl/pdf%20files/CAI219.pdf>. See also Dutfield, *IPRS, Trade & Biodiversity, supra* note 22 at 65 and Chapter 5 at 5.11.1 discussing the turmeric example.

[55] Eileen E. Gillese, Derek Mendes Da Costa & Richard J. Balfour, *Property Law Cases, Text and Materials,* 2d ed. (Toronto: Edmond Montgomery Publications Ltd., 1990) at 1:23.

[56] See *e.g.* Coombe, *Cultural Life, supra* note 40.

[57] Rosemary J. Coombe, "Critical Cultural Legal Studies" (1998) 10 Yale J.L. & Human. 463 [Coombe, "Legal Studies"] at 464, online: York University <http://www.yorku.ca/rcoombe/publications>.

[58] Rosemary J. Coombe, "Authorial Cartographies: Mapping Proprietary Borders in a Less-than-Brave New World" (1996) 48.5 Stan. L. Rev. 1357 [Coombe, "Authorial Cartographies"].

[59] Coombe, "Legal Studies", *supra* note 57 at 469.

[60] Coombe defines neoliberalism as "an ensemble of conditions that include trade liberalization, market fundamentalism, the reduction and withdrawal of state services and subsidies, the evisceration of labour rights, an acceleration of extractive industries, threats to subsistence livelihoods, and a concomitant loss of human security." Coombe believes that the renewed attention to culture in international legal circles is a priority to those who reject the current system and fear that a market driven society threatens cultural

> the reproduction and repetition of cultural forms as ever the same marks of authorial proprietorship, while paradoxically prohibiting and inviting their interpretive appropriation in the service of other interests and alternative agendas. The law's recognition and protection of some activities of meaning-making under the guise of authorship...and its delegitimation of other signifying practices as forms of piracy...create particular boundaries for cultural agency. The dialectical relationship between authorship and alterity is a significant, if overlooked, dimension of contemporary cultural politics.[61]

Legal institutions reify, assert, claim, defend, manage and preserve culture, Coombe argues;[62] a relationship not only *overlooked* in contemporary cultural politics but also ignored as a dimension in the transplantation of IP to the international arena. In globalizaing IPRs, "[w]hat was lost from the discourse", according to Professor David Vaver,

> is the obvious point that there is no single platinum standard IP law. Countries at different levels of *cultural* and *economic development* do not need or want an IP law that has been developed and refined for countries having a very different *culture* and *economy*. This point was glossed over in the globalization rush of the late 20th century, but will not go away.[63]

Technological capacities to intervene, map, and manipulate the genomic and now the atomic (with nanotechnology) structure of a given species currently exist.[64] Even if we accept cultural preferences for both scientific and legal proprietary mappings as norms, whether incentives are needed to continue with research and development in the life sciences (authorship/ inventorship), the kind of incentives that are optimal,[65] the degree

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diversity with homogeneity as well as for proponents of the system who, nevertheless, desire to maintain "meaningful social differences to feed the growth of new economy enterprise." Coombe, "Legal Claims", *supra* note 41 at 5.

[61] Coombe, "Legal Studies", *supra* note 57 at 469-70.

[62] Coombe, "Legal Claims", *supra* note 41 at 2.

[63] David Vaver, "Need Intellectual Property Be Everywhere? Against Ubiquity and Uniformity" (2002) 25 Dal. L.J. 1 at 5 [Vaver, "Uniformity"] at 10 [emphasis added]. See also William Cornish, *Intellectual Property: Omnipresent, Distracting, Irrelevant* (Oxford: Oxford University Press, 2004). Cornish focuses on the major dilemmas enmeshing the area and explains that the adjectives in his title are meant to highlight the different dimensions of these problems: "*omnipresent* - to capture the cases where IPRs appear to be spreading like a rash, particularly across new technologies, and threatening to leave few patches of unblemished, open skin; *distracting*- to indicate cases where the rights achieve little of their essential purpose, but cause persistent itching; *irrelevant* - to refer to technology which in practice seems to be rendering IP nugatory" (Cornish, *ibid.* at 1). Cornish and Vaver are not alone in these views.

[64] ETC Group, "A Tiny Primer on Nano-Scale Technologies and 'The Little BANG Theory'" (June 2005), online: ETC Group <http://www.etcgroup.org/documents/TinyPrimer_English.pdf>.

[65] See Nancy Gallini & Suzanne Scotchmer, "Intellectual Property: When Is It the Best Incentive System?" in Adam B. Jaffe, Josh Lerner & Scott Stern, eds., *Innovation Policy and the Economy,* vol. 2 (National

and duration of protection, and the kinds of technology to which it can attach[66] are all issues of domestic cultural and industrial policy. These are not issues that can be readily resolved by ascribing the label "property" in order to harmonize towards the highest standard of property protection globally available and currently provided by a member state's patent regime. The IP law of a nation remains, rather, a form of mimesis of the cultural norms that inform the stratified regulatory preferences amongst property embracing nations and render the "public interest" in IP within each state an ever critical form of legal ethnography of citizenship.

2.2.2 W(h)ither "Intellectual"...

The reference to "intellectual" in relation to all IPRs is a misrepresenting metaphor which triggers an emotional reaction through linguistic obfuscation in its rhetorical eloquence: it makes legal protection for abstract objects of mental constitution normatively *easier* to justify out of mutual respect for and dependence on human ingenuity. Although it may take some intellect to think up a good trademark for example, this field of IPRs is better conceived of as the law of protecting advertising costs since title to a mark in English modeled legal systems is *not* based on the mere *creation* of the mark but its *use* (effectively, possession) or its surrogates in the law (such as making the mark known).[67] Similarly, the extension of quasi proprietary rights to

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Bureau of Economic Research: MIT Press, 2002) c. 2, cited to PDF file online: <http://www.dklevine.com/archive/scotchmer-when-is-ip-best.pdf>. Other authors have similarly examined this issue for related IP disciplines with regard to the standards TRIPS imposes. See *e.g.* Ruth Towse, *Creativity, Incentive and Reward: An Economic Analysis of Copyright and Culture in the Information Age"* (UK: Edward Elgar Publishing, 2001).

[66] Dan L. Burk and Mark A. Lemley, "Is Patent Law Technology-Specific?" (2002) 17 Berkeley Technology and Law Journal, 1155 [Burk & Lemley] cited to PDF, online: Innovation Law <http://www.innovationlaw.org/pages/DanBurk.doc>.

[67] See *e.g.* B.W. Pattishall & D.C. Hilliard, *Unfair Competition and Unfair Trade Practices.* (New York: Mathew Bender, 1985).

protect the value of celebrity endorsement and merchandizing has very little to do apparently with the "intellect".

There are some areas within IP where the label "intellectual" is more accurate and less strained, such as with copyrights and patents - where the capacity to think abstractly or profoundly and with creativity or inventiveness, may arise.[68] But copyright arose out of the guilds to protect the right of copy[69] and even with patents, the "intellectual" is not imperative since independent invention will not necessarily protect an inventor against patent infringement actions from another inventor who has secured the patent right. In genomics, applications do engage the intellectual but *mapping* projects are not about innovation but cartography and are increasingly performed by computers. These efforts emphasize labour and investment rather than intellect. The blanket use of the label "intellectual" should be restricted, to use a trademark analysis, as it is either clearly descriptive and therefore superfluous in relation to some IPRs or deceptively misdescriptive in relation to others. If the latter, it is deliberately so and facilitates the normative claim of deontological justifications for their protection. Either way, for our understanding of the subject, "intellectual" is unhelpful, unnecessary, and a prolixity worth editing.

2.2.3 "Property"? A Challenge Exceeding Qualification

It has been stated that,

> [p]roperty is the root of all evil; and, at the same time, property is that toward which all the activity of our modern society is directed, and that which directs the activity if the world. States

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[68] Over the years, IPRs have extended through the common law to protect investment of finances, labour, or even acts of appropriation which, although industrious, engage very little intellect *per se*. See *Tele-Direct (Publications) Inc. v. American Business Information, Inc.*, [1998] 2 F.C. 22 (C.A.) for copyright protection in a compilation of facts (phonebooks). See also the turmeric example discussed in chapter six of this dissertation and in Dutfield, *IPRS, Trade & Biodiversity, supra* note 22 at 65 and the example of Taxol, *infra* in text, page 42.

[69] See *e.g.* Amani, "Fact, Fiction", *supra* note 48.

> and governments intrigue, make wars, for the sake of property....; government functionaries, tradesmen, landlords, struggle, deceive, oppress, suffer, for the sake of property; courts of justice and police protect property; penal servitude, prisons, all the terrors of so-called punishments- all is done for the sake of property.[70]

Without making a moral judgment on the existence of property, one can concede its central role and institutional nature in modern society. Property is a legal and social institution governing almost all aspects of our lives. Despite indictments to the contrary, the concept of property is generally believed to be in 'the public interest.'[71] The protective model of property[72] traditionally adopted (that individual interests once determined are protected from collective claims –including competing claims of the "public interest"[73]) has an attractive presumptive power in underlining the cultural commitment to social stability and investments in societies in which the concept of property is found but reveals no normative claim about the *content* of property rights or the objects of its attachment. There is a universal pattern of cultures forming similar categories worldwide around the concept of property and property rights, despite the variability of their content, according to anthropologist Irving Hallowell,[74] who insists that social aspects of property are a critical third element (in addition to traditional economic and legal principles) underlying the concept of property:

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[70] Leo Tolstoy, *What is to be Done* (New York: Thomas Y. Crowell and Company, 1899), cited in Laura S. Underkuffler, *The Idea of Property* (New York: Oxford University Press, 2003) at 1.

[71] For a review of the literature of 'the public interest' in property, see Underkuffler, *ibid.* For a thesis on a "process-based" approach to determining public interest, rather than a content based understanding of it, see Mike Feintuck, *'The Public Interest' in Regulation* (Oxford: Great Clarendon Street, 2004).

[72] See *e.g.* Jim W. Harris, *Property and Justice* (Oxford: Clarendon Press, 1996); Jim Harris, "Is Property a Human Right?" in Janet McLean, ed., *Property and the Constitution* (Oxford: Hart Publishing, 1999).

[73] Such as an individual's interest to use private land in a particular manner that may raise public interest claims of environmental degradation. For a comprehensive discussion of private property and how as it becomes less absolute it becomes more subject to social claims, see Joe Singer "No Right to Exclude: Accommodation and Private Property" 90 Nw. U. L. Rev. 1299 (1995-1996) and " Property and Social Relations: From Title to Entitlement, in G.E. Van Maanen & A.J. van der Walt, eds., *Property Law on the Threshold of the 21st Century,* (Antwerp: MAKLU, 1996), arguing that the traditional conception, however, "remains powerful and exerts substantial determinative force in adjudicating and developing the rules of property law" at 70.

[74] See Irving Hallowell, *Culture and Experience* (New York: Schocken Books, 1967).

> [O]ne of the most significant and far reaching conclusions that has emerged from twentieth-century anthropology is the relativity of culturally constituted values and the immense variability to be found in the specific cultural forms of different human societies.[75]

Within the property literature, the debate is unsettled whether the concept of property captures a (natural) right or is itself a mere institutional design much like I suggest IPRs are. The most operative codes of meaning occur subconsciously and are

> pre-learned through their articulation by various social and legal institutions...so well learned that they appear *natural*, which suggests that the practice of coding has been comprehensively disguised. Consider Western legal societies' use of property and contract law, or economic theories that operate as the hidden paradigm for the pedagogy of the law.[76]

My current investigation does not allow a comprehensive foray into the theoretical normative claims of *property* as "things" or as "a bundle of rights" bearing relational qualities, or as a strategic instrument of the state subject to change, although my institutionalist perspective on property might be discerned from my espousal of that framework for IPRs.[77]

Laura Underkuffler, however, offers a progressive model of the idea of property designed to explain its *relative* presumptive power (sometimes as protective and other times as non-protective) in a manner that allows for collective change based on collective

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[75] Hallowell, *ibid.*, cited in Amani, "Fact Fiction", *supra* note 48 at 244.

[76] Amani, "Geographic Appellations as Trademarks", *supra* note 53 at 201, n. 49. See also Rosemary J. Coombe, "Objects of Property and Subjects of Politics: Intellectual Property Laws and Democratic Dialogue" (1991) 69 Texas L. Rev. 1985 [Coombe, "Objects and Subjects"], noting that doctrines of law are hardly neutral in relation to their subjects.

[77] The literature that surveys protective and non-protective property models and the institutional commitment to the malleability of "property" to protect underlying interests in different legal contexts is vast but even the best scholars are unable to provide a coherent substantive idea of property. The following offer insightful discussion: James W. Harris, *Property and Justice* (Oxford: Clarendon Press, 1996); James E. Penner, *The Idea of Property in Law* (Oxford: Clarendon Press, 1997); David Lametti, "Property and (Perhaps) Justice: A Review Article of James W. Harris, *Property and Justice* and James E. Penner, "The Idea of Property in Law" (1998) 43 McGill L.J. 663; for a discussion of property as antecedent to political liberty, see Richard Pipes, *Property and Freedom* (Toronto: Random House, 2000). See Adam Mossoff, "What is Property? Putting the Pieces Back Together" (2003) 45 Ariz. L. Rev. 371 [Mossoff, "Property"] for a comprehensive review of property literature and the theories of Penner and Hohfeld. Mossoff asserts that, "[c]ontrary to the disintegrating effects of the nominalist bundle theory and the excessively narrow insight of the exclusion theory," the integrated theory of property (which locates the substance of the concept of property as possessory rights to acquire, use, and dispose one's possessions), is a more robust concept of property (at 440).

interests. Her model effectively furthers my argument about the dynamic and social construction of laws and strives to provide a framework for answering the question of how property rights should be resolved when faced with a competing 'public interest' and is a response to the tensions between private property's protective ideals and the exigencies of regulatory governance. In her book, *The Idea of Property*,[78] Underkuffler reviews the seminal work of James E. Penner and his basic proposition that the law protects private interests in things by recognizing "the interest in exclusively determining the use of things."[79] The 'exclusion thesis', according to Underkuffler, is the main pillar of property analysis in the legal system:

> It characterizes property primarily as a protected sphere of indefinite and undefined activity, in which an owner may do anything with the thing he owns. Exclusion is, furthermore, intimately tied to the idea of alienability: 'it includes the rights to abandon [a thing]..., to share it, to license it to others (either exclusively or not), and to give it to others in its entirety'.[80]

Within property discourse, Adam Mossoff critiques the exclusion thesis, arguing

> [It] cannot provide an adequate descriptive account of the evolution of basic property rules, such as the common law rule of first possession. Moreover, the exclusion theory fails to explain why we are interested in protecting some entitlements as 'property' such as the varied rights subsumed under the increasingly significant domain of intellectual property.[81]

It is similarly flawed in relation to patents since by statute, "abandoning" a patent may constitute abuse (after three years) affecting the proprietary rights of the patentee.[82] Nevertheless, the right of exclusion is the main *force de jure* behind the characterization of IPRs as property and reappears in the normative claim of "rights" which is implicit in the dominant concept of property but also explicit in the term "rights" within IPRs. Regardless of whether one conceives of property as a right, a relationship, or an

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[78] Underkuffler, *supra* note 70.
[79] James E. Penner, *The Idea of Property in Law* (Oxford: Clarendon Press, 1997), as discussed in Underkuffler, *ibid.* at 31, quote at 37.
[80] Underkuffler, *supra* note 70 at 32, quoting from Penner, *ibid.* at 103.
[81] Mossoff, "Property", *supra* note 77 at 375.
[82] See ss. 65-66, Patent Act, R.S.C. 1985, c. P-4, [CPA].

instrumental political and economic concept, the perspective is irrelevant to the quality of *exclusion* as a formal substantive requirement of that right, relationship or instrumental concept. Accordingly, *exclusion* is an institutional design of the regulatory state - in response to any number of possible factors including a conception of things, power politics, regulatory capture, utility claims, or efficiency rationales - to protect against, with IPRs, the free rider problem present in knowledge as a public good. It is not a particularly good design for the intellectual commons and as will become apparent, less so for the genetic commons. The good news is that institutional designs can be changed.

2.2.3.1 Is "Property" *Necessary?*

Rights granted under domestic statutes give the owner the power to exclude. In the case of Canadian patents it is "the exclusive right, privilege, and liberty of making, constructing and using the invention and selling it to others to be used[.]"[83] The granting of the right imposes a corresponding duty on the public not to do what is attached by statute to that right unless authorized by licence.[84] The Canadian Federal Court of Appeal (FCA)[85] has identified two main reasons for granting a patent. First, the court rationalized that patents are necessary to encourage innovation for the reasons that Adam Smith identified: ideas, knowledge and information are not naturally scarce and can be shared infinitely without being diminished or depriving the original right holder.[86] Property rights are required to protect against market failure and the *free rider,*

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[83] CPA, *ibid.,* s. 42.
[84] For greater discussion of monopoly rights in the context of plant genetic resources and agriculture, see Adam Mannon, Intellectual Property as a Tool for Social Repression, online <https://www.kent.ac.uk/law/undergraduate/modules/ip/resources/ip_dissertations/2002-03/PlantDissertationDec2002.doc>.
[85] *President & Fellows of Harvard College v. Canada (Commissioner of Patents)*, [2000] 4 F.C. 528, 189 D.L.R. (4th) 385 [*Harvard,* FCA], online at http://decisions.fct-cf.gc.ca/fct/2000/a-334-98.html.
[86] Cornish, *supra* note 63.

> to permit the recovery of research and development investment *necessary* to produce the invention and a return on that investment to the inventor, commensurate with the value purchasers place on the invention. ... Without patent protection, as soon as a product implementing a new idea is marketed, others could copy it and compete with the original inventor without having to have made the initial research and development investment. Competitors who did not have to cover such costs could drive prices down to such a level that the original inventor could not recoup the research and development investment made, let alone a return on that investment, thereby discouraging the creation of inventions.[87]

Without exclusive patent rights, a company having invested significantly in innovation would be disadvantaged by the free rider who arrives after the costs have already been borne to reap the commercial benefits. On this view, patent protection protects against competitors in order to encourage innovation by ensuring *fair* compensation through an exclusive right in order to prevent a net result of welfare loss due to the disincentives to innovate. There is a need for qualification, however, as Wendy Gordon aptly asserts:

> The issue of limits is vital...The law of intellectual property must be narrower than an entitlement to 'receive payment for all the benefits you generate'. After all, if we tried to give incentives to authors and inventors by eliminating all free riding, society would grind to a stop. Education, progress and community all depend on our sometimes being able to 'reap without sowing', just as being members of a community requires us to tolerate some uncompensated mistakes and harms.[88]

Moreover, the rationale adopted by the FCA is not explicitly supported empirically. Bronwyn Hall reports that

> [t]he Carnegie-Mellon and Yale surveys demonstrate fairly clearly that patents are NOT among the important means to appropriate returns to innovation, except perhaps in the pharmaceutical industry. Similar results have been obtained by other researchers for Europe and Japan. Arundel (2001) reports the results of the PACE survey of large European firms, accounting for more than 75% of the patenting in Europe. In both the United States and Europe, firms rate superior sales and service, lead time, and secrecy as far more important than patents in securing the returns to innovation. Patents are usually reported to be important primarily for blocking and defensive purposes.[89]

Hall's qualification for the pharmaceutical industry seems to reference traditional drug manufacturing which requires a significant *private* investment in innovation. In the life sciences, there are regrettably growing examples of (pharmaceutical) companies enjoying

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[87] *Harvard,* FCA, *supra* note 85 at para. 25.
[88] Wendy Gordon, *Intellectual Property Theory Intensive Course Reader*, *supra* note 26 at 7.
[89] See Bronywn H. Hall, "Business Method Patents, Innovation, and Policy" NBER Working Paper Series, Working Paper 9717, online: National Bureau of Economic Research<http://www.nber.org/papers/w9717> at 9, emphasis in original, citation omitted.

windfalls due to the prior public or communal investments made for the "inventions" privately claimed.[90]

The Chinese and Japanese, for example, have long known and applied the health benefits of yew extract for various medical ailments yet this did not prevent Bristol Myers Squibb (BMS) from obtaining a very lucrative patent for it.[91] James Love and Suzannah Markandya report that the Redbook average wholesale price for BMS's Taxol, was $6.09 per milligram. A generic producer reported $.07 per milligram cost of making Taxol, indicating very significant profit margins: "Did BMS spent[sic] $1 billion on Taxol research, as they now claim? That would be pretty difficult," they write "considering that:

- BMS did not sponsor any of the clinical trials used for the original US FDA approval of Taxol for ovarian or breast cancer.
- BMS signed its Taxol CRADA with the US government on January 1991, when the drug was already in government sponsored Phase III clinical trials. The US FDA approved Taxol for treatment of ovarian cancer on December 29, 1992, less than two years after BMS signed the CRADA. At this point BMS was using Hauser Chemical, the US government's contractor, to manufacture Taxol.
- The National Cancer Institute (NCI) recently estimated its costs of clinical trials for the DCP Cooperative Group Treatment Trials conducted between 1993-1999. According to this study, the average cost of a clinical trial was $169,789 to $310,563, depending upon the year, with an average per patient cost of $3,861 to $6,202 (depending upon the year). For BMS to have spent $1 billion on clinical trials, it would have to had to enrolled more than 166 thousand patients in trials, at $6 thousand per patient. How many patients has BMS actually enrolled in clinical trials? Ask BMS.
- How much does BMS earn on Taxol? Between $4 and $5 million per day. (Based on the annual sales figure of $1.592 billion, as reported by BMS in their SEC 10-K form for the year 2000.)" [92]

This example highlights a few critical flaws in the current IPRs regime. First, the patent alienates the contributions of traditional knowledge (TK) preservers for the use of plant resources and renders these *free* for the private taking by BMS. Second, BMS, itself a

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[90] See *e.g.* Brian Martin, *Information Liberation: Challenging the Corruptions of Information Power* (London: Freedom Press, 1998) online http://www.uow.edu.au/arts/sts/bmartin/pubs/98il/ilall.pdf. See also Dorothy Nelkin, *Science as Intellectual Property: Who Controls Research?* (New York: Macmillan, 1984).
[91] James Love and Suzannah Markandya, "Disputes involving Paclitaxel, a cancer drug sold under different brand names including Taxol" [Taxol] August 23, 2001, at http://www.cptech.org/ip/health/taxol/.
[92] *Ibid.*

free rider, is only able to appropriate this traditional knowledge *because* of exclusive patent rights granted. There is nothing *fair* about compensating BMS for this taking and the subsequent "exclusion" of others.[93] The courts, loyal to the incentive rationale for patents, focus on property rather than inventiveness and thereby provide perverse incentives for private parties to succeed with inverse forms of appropriation inconsistent with judicial understandings of what constitutes free riding while, at the same time, curtailing smaller transgressions that fit their cultural paradigm. Thirdly, it ignores the public funds and contributions of the National Cancer Institute involved in bringing this "drug" to the market.

The second reason the FCA identifies for providing patent protection is to encourage public *disclosure* of new technology to facilitate and expedite its transfer. The theory is that without such legal protection knowledge embodied in new inventions would likely be kept a trade secret.[94] Domestic patent law emphasizes the importance of knowledge diffusion by requiring *teachings* of the applied for invention through public disclosure. Sufficient instruction must be given by the applicant to allow a person skilled in the art to work the patent according to disclosed specifications.[95] This is an essential criterion for granting the monopoly. Failure to make sufficient disclosure to "teach" the invention can be considered a breach of the crown contract and a fraud on the public;

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[93] Gallini and Scotchmer define IP "to mean an *exclusive* right to *market* an invention for a fixed time period." *Supra* note 65.

[94] Citing dictum from the Supreme Court of Canada's decision in *Cadbury-Schweppes v. FBI Foods* [1999] 1 S.C.R. 142, at 171-172: "[A]t least one of the policy objectives underlying the statutory remedies available to a patent owner is to make disclosure more attractive, and thus hasten the availability of useful knowledge in the public sphere in the public interest." At para 26. This theoretical justification for a patent system is consistent with empirical findings using 19th century invention data from World's Fairs and Expositions. See P. Moser, (2001). "How do Patent Laws Influence Innovation? Evidence from Nineteenth Century World Fairs". UC Berkeley: working paper as cited in B.H. Hall, *supra* note 89. at 8. Moser found that inventors in countries without a patent system do not innovate more than inventors in countries with a patent system but they do tend to innovate in areas that are more amenable to protection through trade secrecy.

[95] See s. 27(3) of the CPA, *supra* note 82.

during litigation it may compromise patent validity and infringement claims. The Crown's desire to promote the transfer of technology is consistent with the institutional history of limited IPP in common law jurisdictions for import monopolies - the same jurisdictions which have, in the last two rounds of trade negotiations, championed the efforts for stronger international IPP while enjoying the economic and developmental gains achieved under less restrictive protective regimes - or often in abject denial of them.[96]

Nancy Gallini and Suzanne Scotchmer consider whether a property-based model of exclusion is required as incentive for spurring innovation or whether, in fact, overprotection through IPRs may be a *drag* on innovation. The authors review what economists have said about incentive schemes to promote research and development (R&D) and undertake an historical analysis that reveals while *some* incentive scheme is needed; the *form* need not be *property*. Prizes, government grants, simple procurement mechanisms such as auctions, and fixed price contracts have long operated as incentives to innovate. Prizes have been recommended by the World Health Organization (WHO) and World Bank (WB) to encourage the development of vaccines for developing countries where every year more than 5 million people die from malaria, tuberculosis and

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[96] "[T]he American Republic…[was born] a pirate nation. It might therefore seem hypocritical for us to insist so strongly that other developing nations treat as wrong what we, for the first hundred years of our existence, treated as right." Lawrence Lessig, *Free Culture: How Big Media Uses Technology and the Law to Lock Down Culture and Control Creativity*" (New York: The Penguin Press, 2004) at 63. Ostergard also finds that "[t]he United States, Britain, Japan, Germany, and other developed nations have all adopted foreign inventions, creations, and ideas and adapted them to domestic use, promoting their continued growth and development. However, the developing countries are now faced with the problem of these same countries imposing greater barriers to accessing technology that could help sustain development." See Robert L. Ostergard Jr. "Intellectual Property: a Universal Human Right?" (1999) 21.1 Human Rights Quarterly 156-178, at 177.

strains of HIV prevalent in Africa.[97] The initiative is to provide incentives for the development and distribution of such medicines beyond that offered under a proprietary system[98] through prizes and procurement. The National Science Foundation (2000) reports that the federal government sponsored about 30% of US research in 1998 through grant monies.[99] Daniel Greenberg outlines how, in current dollars, in the United States,

> total spending for research in universities increased annually, without exception, in good and bad economic times, starting at $273 million in 1953 to $15.5 billion...[T]here was no backsliding by federal and state governments, the major sources of external support for university-based research.[100]

Because patents grant exclusive rights to *market production*, they create incentives towards commercially lucrative R&D. Non-patent incentives may be important in reducing a growing genetic divide in which

> [m]ost research in genomics and related biotechnologies...focuses on the needs of the industrialized nations, a manifestation of the notorious '10/90 gap' whereby 90% of health research dollars are spent on the health problems of 10% of the world's population.[101]

But, as Gallini and Scotchmer detail, prizes and grant funds are also fraught with problems and, one might add, politics.[102] The race to the prize may create inefficiencies

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[97] Ed Crooks, "Prizes for Saving Lives: Drug Companies will not develop new vaccines unless they are awarded for it" *Financial Times* (25 April 2001).

[98] Michael Kremer, "Creating New Markets for New Vaccines" (13 April 2000) makes the recommendation of turning a patent into a prize in order to avoid deadweight loss. In his model, a patent authority would repossess the patent and auction it to the highest bidder. Gallini and Scotchmer caution that this model of providing a "prize" equal to the social value of an invention paid out of general revenue may be inefficient if there is more than a single researcher because it might attract other firms to race in which the firms over invest. Gallini & Scotchmer, *supra* note 65.

[99] Gallini & Scotchmer, *ibid.* at 2.

[100] Daniel S. Greenberg, *Science, Money, and Politics: Political Triumph and Ethical Erosion,* (Chicago: The University of Chicago Press, 2001) at 81. According to Greenberg, industries' share of university based research increased from $40 million in the 1960s to almost 1.9 billion in 1998.

[101] See the results of the major Canadian study conducted by University of Toronto researchers at its Joint Centre for Bioethics, A.S. Daar, H. Thorsteindóttir, D.K. Martin, et. al. "Top 10 Biotechnologies for Improving Health in Developing Countries" (2002) 32 Nature Genetics 229 [Daar et. al., "Top 10 Biotechnologies"] and references to the Global Forum for Health Research, *The 10/90 Report on Health Research 2000* (Global Forum for Research, Geneva, 2000). See generally the National Research Council of Canada Genomics and Health Initiative online: <http://ghi-igs.nrc-cnrc.gc.ca/news2003-2_e.html>.

[102] Sometimes it is gendered politics as with the long neglected role of Rosalyn Higgins in the discovery of the DNA structure by Watson and Crick. For a very insightful review of American federal funding through granting bodies and the politics of who gets funded and why, see Greenberg, *supra* note 100. He introduces his text by asserting: "Science prospers on government money, though aloof from these

but these are paralleled by patent races where market inefficiencies also result from the duplicitation of efforts and expenditures that the patent incentive encourages (evinced in biotechnology, drug development, and even mapping *races*).[103] Since patent applications essentially remain secret until made, firms may be unaware of similar R&D by other firms and unintentially undertake duplicitive research efforts. The resulting inefficiencies is compounded by a desire to patent defensively by applying early and for discoveries for which the utility is not yet known in order to facilitate continued research or favourable licencing as the case may be. Worse still, companies conducting the same research during the period before a competitor's patent issues may subsequently have to incur *unexpected* licencing costs and possibly infringement penalties for the same research they conducted in secret; these costs are not insignificant as it would have to be determined which if any of the multiple patents in a portfolio apply and whether they are valid.[104]

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activities. Success, however, came at serious costs to science. Long ago it left the cloistered laboratory to make its claims on resources in the clamor of competitive America. In the process, the veneration and pursuit of growth spawned a supportive, inventive bureaucracy that has eroded the right values of science and transformed it into a clever, well-financed claimant for money, in its own nonpolitical fashion....[W]ith persistent lobbying and overwrought alarms of dangerous neglect, science fared even better, though leaving behind shreds of integrity" (at 1). The commercialization of publicly funded research only became possible in the United State with the *Bayh-Dole Act* of 1980 which granted permission to universities, small businesses, and contract-operated government laboratories the right to patent the results of public research. See *e.g.* Arti K. Rai & Rebecca Eisenberg, "Bayh-Dole Reform and the Progress of Biomedicine" (2003) 66 L. & Contemp. Probs. 289.

[103] Patent proponents cite this reason as the justification for a long and exclusive monopoly grant for the pharmaceutical industry: "Patent races are increasingly common in the pharmaceutical industry and it is important to realize that often the resources dedicated to finalizing a patent in order to win the race are greater than a company would have put into the project under normal circumstances. Companies may therefore over invest in research and development (R&D). Effectively patentability of a product results in high returns for the innovator company and builds brand loyalty for the product in question." See Panos Kanavos & Christina Golna, *WTO And Patents: The Impact on the Pharmaceutical Industry* (London: Informa Pharmaceuticals, 2000) at 8. See also Lisa Austin and Bita Amani, "Patents on Genes: Identifying Issues and Responses." discussion paper prepared for the Provincial Advisory Committee on New Genetic Technologies. Toronto, Ontario October 2001[Austin & Amani] reproduced in Trudo Lemmens et. al. *Reading the Future?: Legal and Ethical Challenges of New Predictive Genetic Testing"* (Montreal: Les Éditions Thémis, 2007), pp 105-139.

[104] See Human Genome Project Information, "Genetics and Patenting" online <http://www.ornl.gov> .

Races will necessarily translate into redirected funds from other worthwhile endeavours for R&D investment, and are therefore a net social loss, regardless of whether the reward is a patent or a prize, and arguably more so for the former with the 20 year monopoly period.[105] Both highlight the opportunity cost of conducting research. When the estimated cost of sequencing the entire human genome was announced, for example, young researchers were particularly hostile to the initiative, because,

> [e]ven when defrayed over fifteen years, the cost of $3 billion-$1 for every letter of DNA- would necessarily deny funds for many other worthy projects. Indeed, during the late 1980s, the proportion of grants funded by the National Institutes of Health (NIH) fell from 40 percent to less than 25 percent.[106]

Competition to *get* the patent invites greater medical and technological advances to be made sooner than would be the case otherwise. It is therefore theoretically consistent with long-term health policy- but it is neither a fair way to reward efforts nor an efficient way to utilize them, particularly if the efforts are in generating upstream basic science, knowledge, data, and information rather than downstream applications. In addition, there is some indication that the system is not operating efficiently. Patent races are *worse* than prize races not only because of the "duplication" inefficiencies common to both, but also since they encourage a race to expand a firm's "patent portfolio" to secure preferential licencing arrangements and other strategic uses not available with a prize that correspond with the patent's exchange value.[107] Nevertheless, Gallini and Scotchmer conclude that though the "property system has defects", its virtues

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[105] "The incentives for the creation of new work provided by an intellectual-property system must be weighed against the deadweight loss and administrative costs of the system: the economic goal is to obtain the highest net sum." Gordon, "*Harms and Benefits*", *supra* note 26 at 450 fn 3.
[106] Davies, *supra* note 5 at 16.
[107] B.H. Hall and R.H. Ziedonis "The Patent Paradox Revisited: An Empirical Study of Patenting in the U.S. Semiconductor Industry, 1979-1995" (2001) 32 *Rand Journal of Economics* 102.

outweigh these and the regime is flexibly designed to allow for reform and other mechanisms where contexts demand.[108]

Economists Adam Jaffe and Josh Lerner more recently critique the IPR system.[109] These authors examine how the incentives created in patent law have perversely affected not only innovative firms but the behaviour of others engaged in the system including lawyers, patent officials and judges adjudicating patent cases. Their focus is on correcting incentives not only for the innovators but the unintended ones that operate on all who participate in this system. Because patent policy is too important to be left to lawyers alone, Jaffe and Lerner advocate more democratic processes including an institution for effective re-examination of a patent once granted, to better involve the affected public:

> When issues of patent policy are considered by the courts, the Congress, and the Executive branch, you can be sure that the opinions of patent lawyers and patent holders will be heard. While their arguments will often be couched in terms of the public interest, at bottom their interest is in their own profits and livelihoods, not in designing a patent system that fosters the overall rate of innovation. Even the PTO itself cannot be expected to advocate necessary reform, if such reform reduces its revenues (by discouraging bogus applications) and threatens its established mode of operation.[110]

But they too assume the propriety of patents overall. Amongst these property-supporting scholars there is a shared commitment to the regulatory state as an agent of the public interest charged with tweaking the patent institution to assure efficiency and efficacy of the property model in meeting social objectives- without compromising

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[108] Every IP regime has provisions on length, breadth and the standard for protection. The economics literature on design of IP concerns the appropriate choice of these provisions. The optimal length, breadth, and standard for protection depend on the economic environment, e.g., the shape of the demand curve, the rate at which improvements to existing technologies are developed, or the relative costs of sequential innovators." Gallini & Scotchmer, *supra* note 65 at 18.

[109] Adam Jaffe and Josh Lerner, *Innovation and Its Discontents: How Our Broken Patent System Is Endangering Innovation and Progress, and What to do About it* (Princeton: Princeton University Press, 2004).

[110] *Ibid.* at 23.

overall regulatory commitment to the property paradigm. This is not a view universally shared by scholars writing in the field.[111]

Drahos and Braithwaite examine the history of "propertyless creativity", tracing it through the flourishing end of the eighteenth century and the dawn of the nineteenth century as the greatest half-century in creativity and innovation; in music, with the works of Mozart, Haydn, Beethoven and others; in literature, with the writings of Austen, Goethe, Wordsworth, Coleridge, Byron, Hugo and others; in the sciences, with Lavoisier and Dalton's foundation of modern chemistry; James Watt's steam engine that fathered the industrial revolution; in philosophy, with the great works of Kant, Hegel, Bentham, Hume, and Adam Smith and countless others the authors reference to exemplify the point that some of our most illustrious gains as a society occurred in the absence of *any,* let alone strong, IPRs schemes:

> [W]e should be suspicious of incentive views of creativity. Seeing creativity as a supply-side problem that can be best met by meeting individual demand curves for intellectual property rights is an impoverished account, to say the least, of what motivates people to create. It is unlikely, for example, that those driven to write for a living will become more motivated by the extension of the copyright term from 50 years to 70 years after the death of the author, even if publishers seeking to protect monopolies in lucrative works invoke the authors' creative interests in their lobbying campaigns to get such extensions. People to a large extent are naturally disposed to create. Intellectual property is not irrelevant to the reward of creative work, but it is for reasons that we articulate in the next section not the most significant means that society has for supporting and rewarding such work.[112]

Property, according to Drahos and Braithwaite, is neither the essential nor greatest institution for the most phenomenal periods of creativity in human history. In fact, its occasion has invited greater assembly line productions of lesser merit (i.e. bad patents for bogus applications) for the sake of its acquisition rather than the immense creative contributions of prior-to-property times. They echo the musings of Brad Sherman and

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[111] See *e.g.* Hettinger, *supra* note 39.
[112] Drahos & Braithwaite, *supra* note 7 at 210-11.

Lionel Bently who, in their oft cited treatise, aim "to disentangle the conditions of intellectual property law's history, to de-naturalise it and to show that what are often taken as givens or as constructs of nature are, in fact, the products of a complex and changing set of circumstances, practices and habits."[113] Sherman and Bently delineate the adaptable nature of intellectual property categories and legal variability prior to the 1850s, when they finally crystallized:[114]

> While today the shape of the law is almost universally taken as a given...under pre-modern law there was no clear consensus as to how the law ought to be arranged: no one way of thinking had yet come to dominate as *the* mode of organization...[A]t least up until the 1850s, there was...certainly no intellectual property law....[P]re-modern law, which provided protection for things...was subject specific and reactive....[M]odern intellectual property law tends to be more abstract and forward looking...[I]n drafting modern legislation the law was not only concerned with the objects it was regulating, it was also interested in the shape that the law *itself* took when performing these task.[115]

Drahos and Braithwaite's suggestions are consistent with the OECD's recommendation of domestic policies geared towards promoting life long learning- a stronger educational focus and investment in knowledge diffusion networks.[116] In fact, Drahos and Braithwaite attribute much of the pre-eminence of the US as the source of invention in the twentieth century not to its IP laws, as the US was one of the latest starters of the capitalist democracies to adopt and expand its IPRs or accede to international provisions, but a "more important fount...[T]he pre-eminence of its universities."[117] They advocate the revitalization of universities as a desirable alternative to the creeping expansion of IPRs:

> It is the institution of the university itself that has been the greatest fount of innovation, not the intellectual property laws systematized in its faculties of law....People to a large extent are naturally disposed to create...[T]here are strong social interests in encouraging some individuals

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[113] Brad Sherman & Lionel Bently, *The Making of Modern Intellectual Property Law: The British Experience, 1760-1911* (Cambridge: Cambridge University Press, 1999) at 6.
[114] *Ibid.* at 2-4, 61-100.
[115] *Ibid.*
[116] Drahos & Braithwaite, *supra* note 7.
[117] *Ibid.* at 212.

> to work in institutional settings that reward them, but allow the expression of their creative endeavors to remain a public good.[118]

The current emphasis on property is a cultural preference that has penetrated international society through the hegemony of the capitalist corporate imperative undermining other passionately held commitments to public health and public education. Its export to the international trade arena has been based on a form of legal and cultural imperialism, the politics of which have falsely translated property as a *necessary* system of ordering (incentives) for the creation of (bio)technology- the magical panacea for all of the maladies that pervade human existence including healthcare, food shortages and environmental degradation discussed in the next chapter. Property's claim as the *zeitgeist* of modernity reflects a general ignorance of the significance of cultural diversity for progress, development, peace, and prosperity.[119] Clearly, there is nothing *essential* about property for encouraging the creation of 'intellectual objects'.[120] If the concept of property is not necessary as an incentive for innovation *ex ante,* is it nevertheless appropriate as an *ex post* reward or are IPRs simply another manifestation of the tyranny of 'property' within our intransigent western belief system?

2.2.3.2 Is "Property" *Appropriate*?

The short answer is that property is not appropriate for intellectual objects as these fundamentally differ in kind from traditional understandings of objects to which property attach. The longer answer is nuanced and depends on certain variables to determine whether property may be appropriate in some contexts. Within the property model, the question of property's propriety prompts the antecedent (institutional)

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[118] *Ibid.* at 211.
[119] See UNESCO *Universal Declaration on Cultural Diversity*, 31st Sess. of the General Conference of UNESCO, Paris, 2 November 2001[UNESCO UNDCD] and discussion infra at page 324.
[120] Hettinger, *supra* note 39, defined at 34.

question: how much property (scope and depth) attached to what (basic/applied research; upstream/downstream applications; invention/discovery), and how held (privately or communally). This question invariably raises issues of space, control, and management central to debates about the commons underling public interest claims to knowledge as a public good while highlighting the political deliberative construction of property's individualist legal identity. Although the commons has had "various histories, from property to shared spaces to notions of democratic ideals,"[121] if we conceive of the information commons (in particular the genetic information commons) conceptually as a hitherto unrecognized form of collective property then the debate is about the "legitimacy of [private proprietors in] enclosing properties owned communally."[122] Hess and Ostrom have argued that

> [c]ommon-pool resources may be owned by national, regional, or local governments, by communal groups, by private individuals or corporations, or used as open-access resources by whomever can gain access. Each of the broad types of property regimes has different sets of advantages and disadvantages, but at times may rely upon similar bundles of operational rules. Examples exist of both successful and unsuccessful efforts by governments, communal groups, cooperatives, voluntary associations, and private individuals or firms to govern and manage common-pool resources. Thus, no automatic association exists between common-pool resources and common-property regimes -- *or, any other particular type of property regime.*[123]

Privatization by individual stakeholders authorized by the law through the regulatory institutional framework of IPRs is a form of a *taking*[124] of common-pool resources although not widely recognized as such. Instead, compulsory licencing, a public interest

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[121] See Charlotte Hess and Elinor Ostrom, "Ideas, Artifacts, and Facilities: Information as a Common-Pool Resource" (2003) 66 Law & Contemp. Probs. 111 [Hess & Ostrom] at 115, online: <http://www.law.duke.edu/journals/lcp/articles/lcp66dWinterSpring2003p111.htm>.

[122] *Ibid.* See also Lessig, *supra* note 96.

[123] Hess & Ostrom, *supra* note 121 at 120-21 [emphasis in the original].

[124] "IP (specifically trade secrets) has been the subject of taking cases, and moral rights protections also can be analyzed from a takings standpoint." See e.g. *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986 (1984); *Philip Morris, Inc. v. Reilly,* 312 F.3d 24 (1st Cir. 2002); *Pharmaceutical Care Management Association v. Rowe*, 307 F. Supp. 2d 164 (D. Me. 2004). Cf. *Zolteck Corp. v. United States*, 58 Fed. Cl. 6888 (2003) as cited in Robert Rosenthal Kwall, "Why Intellectual Property Belongs in the First Year Property Course" (2004) 54 J. Legal Education 504-510 at 505. See also Lawrence Lessig, *Free Culture: How Big Media Uses Technology and the Law to Lock Down Culture and Control Creativity* (New York: The Penguin Press, 2004 .

safeguard integrated into patent regimes to restore access and use of a public good is however, recognized by stakeholders as a governmental *"taking"* albeit justified in specified contexts despite vehement general opposition by industry.

There is a notable difference between the tangible, whose theft deprives the owner of the good, and the intangible, whose "theft" still leaves the owner in possession of the invented idea, the poem, the song, the information coded in our DNA, despite its use by others. These points suggest that the concept of property is inappropriate for 'intellectual objects'. Moreover, it confirms that genetic information simply cannot be "intellectual" as an "object" given its very real manifestation in the *physical subject*- a conveniently omitted criticism of modern-day expansion of patent rights to genes. But, if there is to be the concept of property for genetic information, it must be renegotiated in terms of the collective's claim to the (genetic) knowledge commons which, although distortable into property paradigms, is better left in search of new, less monolithic, conceptual frameworks. As Nagan states,

> When law intervenes in the process to protect what is yours and what is mine, the tendency to reify rights and duties relating to things means that these rights and duties become abstracted from operative reality. Of course, law wishes to conserve entitlements in the form of rights and in doing so it runs into the paradox of intellectual property. From an observer's perspective, intellectual property stretches as far as the human, inventive imagination extends. Thus, the logical paradox is that all is property or all is not property. More realistically, from a legal perspective, property is a cluster of complex, conditional, relational interests which are recognized as differing from one legal culture to another.[125]

Property law, like any law, is both artifact and infrastructure for the provision of further goods. Although there is an uncomfortable fit, Underkuffler, for example, has no hesitation in tautologically characterizing IPRs as subject to the presumptive power of

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[125] Winston P. Nagan, "International Intellectual Property, Access to Health Care, and Human Rights: South Africa v. United States" (2001-2002) 14 Fla. J. Int'l L. 156 at 184.

property.[126] Nor does she have any reservation, incidentally, in extending that same recognition to individuals in their personal genetic information, acknowledging however that the traditional understanding she brings to property claims,

> does not deny, in any way, the possibility that all of these claims or their underlying values could - as a societal matter - be otherwise understood. All individual and public claims are subject to dispute, discard, evolution and change, as socially constructed understandings.[127]

Once a normative claim is made, universality of its terms seems imperative to its legitimacy so that any object to which the descriptor "property" extends should bear the social hallmarks of its socio-legal dimensions. Intellectual objects seem to create a formidable challenge to this principle because of their non-rivalrous and non-excludable nature. If a particular right falls within the concept of property, to what degree is it protected? Here the exclusive right to devise, possess and use are the usual incidents of corporal property, and certainly some of these attach to IPRs. While stringency variation within property is not uncommon when comparing real property to personal property, the dissonance of IPRs as property comes from the fact that doctrinally in some cases treatment as property has occasionally meant the *loss* of rights.[128] Underkuffler believes

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[126] Underkuffler, *supra* note 70 at 90-92. I say tautologically because her conclusion that "if a patent has been validly granted, the claimed right it creates is a claimed property right, and has clear presumptive power...[and] those rights cannot simply be abrogated, without legal consequence, in favour of the ordinary or routine goals of government" (*ibid.* at 91) is based on the fact that this is the "Current" or "traditional" understanding to patent claims. Underkuffler's commitment to the presumptive power of patents is based on the fact that they issue and thereby confer "particular relations between those claims and competing public interest [that] will follow" (*ibid.* at 93).

[127] *Ibid.* The social constructs operate within the conception of property as well. Penner's theory of the idea of property in law, Underkuffler writes, fails to account for important pieces of the property puzzle: "For instance, although property may indeed involve rights to exclude others from separable things- thus providing, in effect, understandings of the theoretical and spatial dimensions of property- critical questions remain unanswered. With what *stringency* are these rights protected forever? Or does their content, or enforceability, vary in time? If we are to be aware of *all* the normative choices that property involves...we must remember all of the dimensions of property...and how [the idea of property] operates, and should operate, as a protective force in law" (at 33). The four dimensions she identifies and refers to are 1. a theory of rights; 2. space or area of field; 3. stringency of protection and 4. time.

[128] For example, prior to legislative amendment, the common law of trade-marks would not allow licencing or assignment as it would undermine the claim to distinctiveness of the mark as coming from one trade source essential for the continued validity and protection of a trade-mark.

that *time* is also a necessary dimension "for any legally cognizable conception of property[.]"[129] This dimension asks when the property right, as defined by law, attaches and whether these rights are fixed in time or allowed to change in their content with its passage to address the needs of 'the public interest':

> Few would deny that regimes of private property, as generally conceived *include considerations of the public's interest.* To the extent that individual property rights are collectively conceived and collectively enforced, they will (almost certainly) consider not only the interests of property owners but also the interests of others in the community. With the consideration of collective needs, however, comes the question of collective change.[130]

IPRs fail to accord with more traditional protective conceptions of private property on which they were modeled. This may be because socio-legal dimensions, while *necessary* for a concept of property, are not necessarily *sufficient* in all cases as indicia to constitute property. If property in genetic knowledge is to be appropriate, it will require a renewed understanding of the property paradigm as a culturally sensitive institution divested from the shadow of an individualist atomistic culture of "self" conceptually central to its articulation; property will have to invest in communal ideologies of existence.

2.2.3.2.1 The Tragedy of the Commons and Anti-Commons

Literature on the commons grew out of the seminal classic of Garret Hardin, *The Tragedy of the Commons*,[131] in which Bentham's utilitarian "greatest good for the greatest number" thesis was criticized for its failure to recognize that "a finite world can support only a finite population...."[132] In the absence of a private property regime,

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[129] Underkuffler, *supra* note 70 at 28.
[130] *Ibid.* at 30.
[131] Garret Hardin, "The Tragedy of the Commons" 162 *Science* 1243 (13 December 1968).
[132] *Ibid.* at 1243. "Picture a pasture open to all. It is to be expected that each herdsman will try to keep as many cattle as possible on the commons...[T]he inherent logic of the commons remorselessly generates tragedy.... Adding together the component partial utilities, the rational herdsman concludes that the only sensible course for him to pursue is to add another animal to his herd. And another...But this is the conclusion reached by each and every rational herdsman sharing a commons...Each man is locked into a

Hardin warned, the privilege of use would lead to rational overuse and underinvestment in the commons resulting in the tragedy of depleted environmental resources. The absence of the right to exclude would ultimately detrimentally affect everyone's use.

Michael Heller and Rebecca Eisenberg drew a different conclusion in relation to biomedical research. They were among the first to draw attention to the growing transaction costs of doing such research due to private enclosure *vis-à-vis* letters patent. Unlike the tragedy of the commons, the anti-commons are characterized by too many rights to exclude without corresponding rights to use.[133] In their compelling 1998 article, "Can Patents Deter Innovation: The Anticommons in Biomedical Research"[134] the authors argue that biomedical information may effectively become underutilized by rational individuals acting separately under the exclusive rights patents confer. This in turn may effectively cause a collective *waste* of scarce resources. The dangers of over-patenting, they argue - particularly in basic biomedical research – arise from the need to bundle multiple licences, raising the barriers to entry, and increasing transaction costs, with long term deleterious effects on downstream (applied/developmental) innovation:

> Under the commons model, the federal government sponsored premarket or "upstream" research and encouraged broad dissemination of results in the public domain. Unpatented biomedical discoveries were freely incorporated in "downstream" products for diagnosing and treating disease. In 1980, in an effort to promote commercial development of new technologies, Congress began encouraging universities and other institutions to patent discoveries arising from federally supported research and development and transfer their technology to the private sector...Privatization can go astray when too many owners hold rights in pervious discoveries that constitute obstacles for future research...The result has been a spiral of overlapping patent claims

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system that compels him to increase his heard without limit—in a world that is limited. Ruin is the destination toward which all men rush, each pursuing his own best interest in a society that believes in the freedom of the commons. Freedom in the commons brings ruin to all." *Ibid.* at 1244.

[133] Michael A. Heller and Rebecca S. Eisenberg, "Can Patents Deter Innovation? The Anticommons in Biomedical Research" *Science* 280:1364 (1 May 1998) 698-701 [Heller & Eisenberg], online: Science Magazine <http://www.sciencemag.org/cgi/reprint/280/5364/698.pdf>. See also Michael Heller, "The Tragedy of the Anticommons: Property in the Transition from Marx to Markets" online <http://www.bus.umich.edu/KresgeLibrary/Collections/Workingpapers/wdi/wp40.pdf>.

[134] Heller & Eisenberg, *ibid.*

> in the hands of different owners, reaching ever further upstream in the course of biomedical research. [135]

Effectively more IPRs would translate into fewer useful products for improving human health. Excessive fragmentation of patent rights in the technological base for commercially oriented biomedical innovation, especially when held by large corporate actors in merging agrochemical and biotechnical industries, may deter (smaller) private competitors from investing in follow-up innovation, as Heller and Eisenberg suggest. More importantly, greater transaction costs may be disproportionately felt by the very institutions- universities- whose mandate hitherto has been to do property-less research. As a public institution, the new costs of conducting research may be too prohibitive to pursue, slowly transforming universities into teaching schools (dissemination sources) of private labs under licence.[136] Already there is evidence of this.

"Patent or parish" has replaced the traditional "publish or perish" imperative for university researchers. Stronger and overlapping IPRs continue to pose a significant "obstacle to academic researchers' rapid access to informational inputs necessary for their work."[137] Patents are less user-friendly as a means of knowledge dissemination in content and form than academic literature published in scholarly scientific journals

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[135] *Ibid.* at 698. They posit that privatization of biomedical research must be more carefully deployed to sustain both upstream research and downstream product development; "otherwise, more intellectual property rights may lead paradoxically to fewer useful products for improving human health" (*ibid.* at 701).

[136] For example, "some universities and other nonprofit research institutions have balked at terms DuPont Corporation has offered for licenses to use patented oncomouse and cre-lox technologies, although others have acquiesced to the license terms. These patents cover genetically engineered mice useful in research that could result in products falling outside the scope of the patent claims. DuPont has offered noncommercial research licenses and sublicenses on terms that seem to require licensees to return to DuPont for further approval before any new discoveries or materials resulting from the use of licensed mice are passed along to others or used for commercial purposes. DuPont thereby gains the right to participate in future negotiations to develop commercial products that fall outside the scope of their patent claims. In effect, the license terms permit DuPont to leverage its proprietary position in upstream research tools into a broad veto right over downstream research and product development." *Ibid.* footnotes omitted.

[137] David, "Commons", *infra* note 147 and accompanying text. David, posits that the property ethos perverts the open culture of sharing by encouraging researchers to refrain from disclosing findings as quickly as possible through publication in order not to preempt a patent application on the basis of novelty, even in publicly funded universities (at 8 and fn 8).

because unlike the latter, the former are drafted by lawyers and patent agents trained in using obfuscating language to secure maximum legal protection. Also, the scientific community generally enjoys greater knowledge of accessing and navigating through relevant academic publications than legal ones. The perverse effect is to reduce rather than increase public disclosure of the underlying technology with further frustrating consequences for science. The intellectual commons are different from Garret Hardin's non-renewable resource commons (of land and the environment) because the former require participation rather than exclusion for re-generation. The science paradigm relies on publication so that findings can be tested by other scientists as a means of ensuring validity of results and maintaining quality of science and its 'progress'. Genomic patents create poor science and may impede testing the genetic/diagnostic tests for quality and utility.[138] In addition, scientists must now communicate with commercialization departments of other universities, which most major resourceful institutions have, for data sharing and licence procurement.[139] Academic withholding in genetics, so that a patent can be obtained and profits realized when the technology is licenced, translates into more funding for university based research even though it simultaneously raises the costs of doing such research when pursued by all institutions. Regrettably, the direction of future research, whether publicly or privately pursued will likely be steered towards

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[138] Dr. Ron Carter, a Hamilton genetic specialist criticized Myriad's patents over the BRCA1/2 and diagnostic testing method, asserting that "You have to do the test their way with their equipment at their site and you get their answer." See Karen Palmer, Public Health Reporter, "Battle over cancer gene test U.S. company's patenting claim called 'abhorrent'" Organic Consumers Association, 01/09/2003 online www.organicconsumers.org/Patent/010903_patent.cfm. See also Jon F. Merz, Antigone G. Kriss, Debra G.B. Leonard, & Mildred K. Cho, "Diagnostic testing fails the test: The pitfalls of patents are illustrated by the case of haemochromatosis" (2002) 415 *Nature* 577. Questioning whether patents invite development of diagnostic tests or impede their development through access, these authors cite evidence of clinics disengaging from important research once a patent had issued to another firm

[139] Eric Campbell and Dr. David Blumenthal's 2002 survey reported in the *Journal of the American Medical Association"* "The Selfish Gene: Data Sharing and Withholding in Academic Genetics" May 31, 2002, online http://sciencecareers.sciencemag.org; Brad Everson, "Competition Hampering Gene Studies, Survey Says" *National Post,* January 23, 2002: A3.

further patentable and commercially viable invention, corrupting the traditional politically free sphere of our public institutions.[140] The institutional provision of IPRs is government intervention striving to correct against appropriation (free-riding) with the trade-off of short term exclusivity for long term increases to the common stock of knowledge. Other instruments could perform the same task.[141]

Peter Drahos and John Braithwaite argue that IPRs regimes are more political than a mere regulatory response and serve to entrench power disparities. The *information feudalists* (mostly corporate capitalists), they argue, push the agenda for the private enclosure of knowledge through stricter and stronger IPRs and are overly simplistic in their mantra that more IPRs mean more innovation:

> Information feudalism is a regime of property rights that is not – economically - efficient, and does not get the balance right between rewarding innovation and diffusing it. Like feudalism, it rewards guilds instead of inventive individual citizens. It makes democratic citizens trespassers on knowledge that should be the common heritage of humankind, their educational birthright. Ironically, information feudalism, by dismantling the publicness of knowledge, will eventually rob the knowledge economy of much of its productivity.[142]

Hope Shand, Research Director with the non-governmental organization ETC (formerly known as RAFI), echoes these concerns and warns of their unintended adverse effects:

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[140] See Members Press Release Report on the second Annual Survey on University Technology Transfer Activities by Nottingham University Business School (NUBS), the University Companies Association (UNICO), and The Association for University Research and Industry Links (AURIL). The study found an increase of 19% of inventions disclosed and 59% growth in patents issued. The study found that "For every $100 billion in GDP, the US allocates over 30% more than the UK on research expenditure, and Canada nearly 22% more. Comparisons of experience in the UK, US and Canada show that after adjusting for differences in GDP and research expenditure between the three countries: UK universities create more spinout companies compared to US and Canadian institutions, UK universities executed more licences compared with US and Canadian institutions, but had far fewer licences yielding income, and earned less gross licence income than either country. The UK performs less well than US in terms of number of patents issued, but better than Canada." Online: < http://www.isis-innovation.com/about/news/annualsurvey-nov03.html>. See also Bruce Clayman, "Addendum to Technology Transfer at Canadian Universities: Fiscal Year 2001 Update" Report for the Canada Foundation for Innovation, July 31, 2003.

[141] Regulatory models to improve incentives and access to genetic information are discussed in. "Policy Implications of Commercial Human Genetic Research in Newfoundland and Labrador" A Report of the Newfoundland and Labrador Department of Health and Community Services, January 2003, online <http://www.nlcahr.mun.ca/research/>.

[142] Drahos & Braithwaite, *supra* note 7 at 222.

> Over time, intellectual property regimes have grown into mechanisms that allow corporations (not individual inventors) to protect *markets* rather than idea. This trend complicates, makes more expensive and slows the pace of scientific advancement in agriculture and health care. If one company "corners the market" with a strong monopoly patent, competitors may logically decide to orient their R&D sights elsewhere.[143]

Yet, the OECD is comfortable relying on patent numbers as a "knowledge indicator",[144] confusing their primary utility to spur *production* rather than *innovation*. According to Drahos and Braithwaite,

> [l]ike many simple messages, this obscures much. Copying and imitation are central to our process of learning and the acquisition of skills. As children we copy the artwork of others and imitate our sporting heroes. Copying and imitation never leave us, and without it a lot of socially valuable information would never be transmitted or learnt. The creator of innovation is *always* the borrower of ideas and information from others. Intellectual property rights put a price on information, thereby raising the cost of borrowing. Raising the costs of borrowing through the imposition of very high standards of intellectual property will progressively choke innovation, not increase it.[145]

Management of genetic information, essentially data, can take different, preferably complementary, forms. Paul A. David, thinks IPRs can work well as incentives for creation but,

> [a] variety of market and non-market institutional mechanisms may be deployed to address the so-called "appropriability problem," and, typically, several among these are found to be deployed simultaneously by modern states, in order to encourage the provision of public goods in the shape of scientific and technological knowledge.[146]

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[143] See Hope Shand, "Gene Giants: Understanding the "Life Industry"", in Brian Tokar (ed.) *Redesigning Life? The Worldwide Challenge to Genetic Engineering"* (Canada: McGill-Queen's University Press, 2001) [Shand, Gene Giants] at 230.

[144] OECD 1996 Knowledge Based Economy Report, *supra* note 28 lists 4 knowledge indicators, noting they are less comprehensive than traditional economic ones: expenditures on research and development, employment of engineers and technical personnel, patents, and international balance of payments for technology (at 243-44).

[145] Drahos & Braithwaite, *supra* note 7 at 2 [emphasis added].

[146] Paul A. David "A Tragedy of the Public Knowledge 'Commons'? Global Science, Intellectual Property and the Digital Technology Boomerang" at 2, online: http://ideas.repec.org/p/wpa/wuwpdc/0502010.html [David, "Commons"], responding to the EC, *Directive 96/9/EC of the European Parliament and of the Council of 11 March 1996 on the legal protection of databases*, [1996] O.J. L. 077/20 . The European Community's *sui generis* systems are perceived to threaten the scientific commons and the conduct of open collaborative science. See also fn 2 referring to Paul A. David, "Knowledge, Property and the System Dynamics of Technological Change" in L. Summers & S. Shah, eds., *Proceedings of the World Bank Annual Conference on Development Economics: 1992*, (Suppl. to the *World Bank Economic Review*) (Washington, D.C..: International Bank for Reconstruction and Development, 1993) [David, "Technological Change"] at 215-48 and particularly at 226.

David's premise is that a functional system would balance the use of the different institutional mechanisms (patronage, procurement and property)[147] in accordance to need as defined by context;

> [N]o one (among the several means available for coping with the public goods "appropriability problem") should be permitted to encroach upon the spheres in which the others function most effectively. The design of each should be re-evaluated and modified where necessary in order to accommodate, rather than undermine, the viability of complementary institutional mechanisms.[148]

David argues that property rights have gone too far and have "unbalanced" the system's fragile stability by displacing other mechanism like *patronage* (and institutions like universities) for the production of science as a public good.[149] The consistent policy preference has been to subsidize national scientific and industrial development through patent rights to the exploitation of new knowledge creating a *new* "tragedy of the commons". Exclusive control and access to genetic information erects artificial cost barriers to knowledge production and industrial applications because of unbalanced pressure to extract greater economic rents resulting in "over-fencing".

"Must we," James Boyle asks, "privatize the public domain to avoid a 'tragedy of the commons,' or can the technologies of cheap copying and global networks actually make common pool management more efficient than legal monopolies?"[150]

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[147] *Patronage* stands "for the institutional arrangements for awarding publicly financed prizes, research grants based on the submission of competitive proposals for scientific peer review, and other subsidies to private individuals and organizations engaging in discovery and invention – in exchange for full public disclosure of their findings. 'Patronage' characterizes the pursuit of open scientific inquiry and is the dominant institutional and social mode of organization associated with the conduct of academic research in the democratic societies of the West." David, "Technological Change", *ibid.* at n. 2. See also Paul A. David, "Common Agency Contracting and the Emergence of 'Open Science' Institutions" (1998) 88:2 The American Economic Review 15 [David, "Open Science Institutions"].

[148] David, "Commons", *supra* note 146.

[149] See *e.g.* Ann Louise Monotti & Sam Ricketson, *Universities and Intellectual Property: Ownership and Exploitation,* (Oxford and New York; Oxford University Press, 2003).

[150] James Boyle, "Forward: The Opposite of Property?" (2003) 66 L. & Contemp. Probs. 1 at 2 [Boyle, "Opposite of Property"].

The constant drive to extend the term and scope of IP protection in order to keep such knowledge from entering the public domain has been referred to as the *Second Enclosure Movement*[151] by law professor James Boyle. The second enclosure is not unlike the first that dealt with real property and was characterized by the imperialist appropriation of public land for private benefit. Like the first enclosure, the second enclosure re-engages familiar issues over the protection of the "public domain" and 'the public interest' polarized and dichotomized by the encroachment of private property rights.[152] The "other side" of IPRs, the "public domain"[153] is a continued source of debate, characterized at either extreme as a "virtual wasteland of undeserving detritus or the font of all new creation".[154] Mark Rose, an English professor and eminent historian of intellectual property, reiterates the power of eloquence in framing public domain discourse:

> [A]s we attempt to argue for the value of the public domain, we need to understand that we are fashioning a rhetoric as well as a politics of the public domain. Casting a defense of the public domain on the model of the environmental movement seems promising. As Boyle notes, before the movement, the environment was in effect invisible. Likewise, one element of the task today is to make the public domain visible—to develop an affirmative discourse that will make it a positive and prominent part of the social and cultural landscape...*Rhetoric is crucial.*[155]

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[151] James Boyle, "Second Enclosure Movement" (2003) 66 Law & Contemp. Probs. 33 [Boyle, "Second Enclosure"]. For a conference on the Public Domain, see Duke University. Webcast (9 -11 November 2001), online: <http://www.law.duke.edu/pd/realcast.htm>. See generally James Boyle, *Shaman, Software, and Spleens: Law and the Construction of the Information Society*, (USA: First Harvard University Press, 1996). For an insightful analysis of the implications of Boyle's cultural environmentalism metaphor on our socio-legal understanding of traditional ("poor people's") knowledge, see Madhavi Sunder, "The Invention of Traditional Knowledge" UC Davis Legal Studies Research Paper No. 75, (February 24, 2006), online: SSRN, <http://papers.ssrn.com>, [Sunder, "Invention of TK"].

[152] For a comprehensive discussion of how the public interest is determined and arguments supporting the thesis of a democratic vision of the Public Interest, see Feintuck, *supra* note 71.

[153] See *e.g.* David Lange, "Recognizing the Public Domain" (1981) L. & Contemp. Probs. at 147; Jessica Litman, "The Public Domain" (1990) 39 Emory L.J. 965.

[154] See Pamela Samuelson, "Mapping the Digital Public Domain: Threats and Opportunities" (2003) 66 L. & Contemp. Probs. 147 and references to authors on each side of the debate, online: <http://www.law.duke.edu/journals/lcp/articles/lcp66dWinterSpring2003p147.htm#B1>.

[155] Mark Rose, "Nine Tenths of the Law: The English Copyright Debates and the Rhetoric of the Public Domain" (2003) 66 L. & Contemp. Probs. 75 at 87. The central role of rhetoric as essential to the mediation of legal spaces is emphasized throughout this dissertation. The eloquence of rhetoric is captured in metaphor. See also Robert A. Baron, "Reconstructing the Public Domain (Metaphor as Polemic in the Intellectual Property Wars)" (23 March 2002), online: <http://www.studiolo.org/IP/VRA-TM-StLouis-

The difference between a "public domain" and an "intellectual commons" is important for reasons Boyle expounds: "the term 'public domain' is generally used to refer to material that is unprotected by intellectual property rights, either as a whole or in a particular context, and is thus "free" for all to use - a term that is itself susceptible to multiple meanings in this context, ranging from costless access, through political liberty, to free trade."[156] He advocates for a "legal realism of the public domain". The "intellectual commons," on the other hand, draws from theories of the commons and common source pools to try and understand innovation. Boyle has long been a proponent of the view that the public domain is an integral input into creative works. In his more recent work, he problematizes the colloquial collapse of the two concepts- the public domain and the intellectual commons- and the assertion within IP policy of a conceptual scheme that

> portrays 'intellectual property' as a monopoly and the 'public domain,' as its conceptual opposite—a realm vaguely defined 'freedom.' In contrast, the commons literature gives us a conceptual scheme in which property, seen as a regime of individual, legal, market-based control is juxtaposed to its conceptual opposite—the well-run commons, a realm of collective, and sometimes informal, controls that avoids the tragedy of the commons without a need for single party ownership. The former juxtaposes monopolies against freedom, the latter juxtaposes individual formal controls against collective, and often informal, ones. Both give us a realm of property and a realm in which its opposite, or alternative, are offered. Despite these similarities, the two are by no means identical. Yet the two terms, public domain and commons, are often used as if they were interchangeable.[157]

2.2.3.2.2 The Comedy of the Commons

Carol Rose's *The Comedy of the Commons* offered a formidable reply to Hardin. Rose exposed Hardin's thesis as an oversimplification by discussing occasions when

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PublicDomain.htm#Ch001>. Baron explains the vitality of metaphor: "Use of metaphor in the language of persuasion, while instinctive, is frequently crafted neither innocently nor naively, and when called upon to serve as an instrument for the benefit of ideological conflicts, is rarely employed dispassionately; it readily charges itself with the weight of self-righteousness and implied damnation, seizing ready-made figures and examples from the rich traditions of our common heritage. Metaphor used in this way recasts conflicts so that what might have begun as a contest of principles, in the end turns out to be a struggle for dominance and vindication based upon the consequences and potency of the imagery employed."

[156] Boyle, "Opposite of Property", *supra* note 150 at 30.

[157] *Ibid.* at 8 [footnotes omitted].

collective management of a resource produced *greater* social efficiencies than individual private ownership.[158] Effectively, many individuals using a resource will increase its usefulness; this is especially true with knowledge because its non-rivalrous character means that people can become better educated without making others more ignorant.[159] Take for example a telephone. The greater number of people with such telecommunication, the greater its social value- after all, a single telephone would hardly be effective for its purpose; who would you call? Similarly, the more people have access and use to an intellectual object or information the greater welfare gains for society since knowledge is necessary for bettering the human condition, for achieving sustainable development, eliminating poverty, and contributing to discursive cultural exchange. Presumably, people are rational and self-interested thinkers such that even Hardin's tragedy could be averted if only those participating in the commons are educated on the results of overuse, the need for efficient and fair management, and the importance of *care* for ensuring a viable commons to be enjoyed by future generations (sustainable development). The incentive would arise from the shared knowledge of the undesirable reality that collective inaction would inevitably foster and the common desire to avoid it.

Sharing knowledge makes it arguably the single most important factor in alleviating the gap between the world's haves and have-nots in developed and developing countries because it speaks to correcting *structural* inequalities rather than the paucity of natural endowments/assets that are perpetuated in economic terms by want of education,

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[158] Carol Rose, "The Comedy of the Commons: Custom, Commerce, and Inherently Public Property" (1986) 53 U. Chicago L. Rev. 711, as discussed in Boyle, "Opposite of Property", *supra* note 150 at 7.

[159] This is tied to the network effects of that resource that creates scale returns with positive network externalities. For a comparative discussion of open access to infrastructure resources with network effects, see Brett M. Frischmann, "An Economic Theory of Infrastructure and Commons Management" (2005) 89.4 Minnesota Law Review 917.

lack of know-how, and failings of governments in any given society.[160] The ancient Chinese proverb, "give a man a fish and you feed him for a day; teach a man to fish and you feed him for a lifetime"[161] reflects a conventional wisdom about knowledge as a public good and about empowering the subject to future independence with due regard for intergenerational obligations that transfer of technology and know-how bring, rather than the food and medical aid that charity brings.

Elinor Ostrom further revised Hardin's thesis with these insights, arguing that control enabled by private property was not the only form of governance or control over the commons.[162] That is, the dichotomy need not be classified as IP with the public domain as its opposite (a classification based on the "owned" versus the "free"). Rather, *common* property in intellectual space may be a classification that considers collective, formal and informal, control as the opposite to individual control and ownership. Hess and Ostrom[163] have written that formal and informal regulatory regimes operate on the

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[160] Nancy Birdsall, "Asymmetrical Globalization: Global Markets Require Good Global Politics" (October 2002), online: Centre for Global Development <http://www.cgdev.org/files/2775_file_cgd_wp012.pdf> at 8-10. Knowledge is critical for the attainment of vast other public goods. Where there is an undersupply by the market, we look to government for their provision. Peter Drahos writes: "Public goods range from those that are constituted by norms (peace, order and good government) to those physical goods that provide a collective benefit independently of any norms (forests and algae that consume carbon are two examples)....Government, itself a public good, allows for the creation of binding arrangements for the provision of public goods." See Peter Drahos, "The Regulation of Public Goods" (2004) 7.2 J. of Int'l Econ. L. 321-339 [Drahos, "Public Goods"] at 321 also published in Keith Maskus and Jerome Reichman, eds. *International Public Goods and Transfer of Technology Under a Globalized Intellectual Property Regime,* (USA: Cambridge University Press, 2005). Conference paper webcast online: Duke University <http://www.law.duke.edu/trips/webcast.html>.

[161] It explains why initiatives of the OECD since 1996 have focused in part on quantifying and mapping the diffusion paths of knowledge and innovation in the knowledge-based economy as key to economic performance. Also, according to the OECD 1996 Knowledge Based Economy Report, *supra* note 28, "Learning on the part of individuals and firms, is crucial for realizing the productivity potential of new technologies and longer term economic growth." (at 235-237).

[162] Elinor Ostrom, *Governing the Commons: The Evolution of Institutions for Collective Action* (New York: Cambridge University Press, 1990).

[163] Hess & Ostrom, *supra* note 121.

commons[164] and others have since provided rejoinders to Hardin's thesis drawing from case studies within collective societies and indigenous groups.[165] These investigations demonstrate historically successful group management of a commons based on a combination of methods of regulation that work to resolve the quandary of Hardin tragedy[166] while questioning its presumptive universal generalizability.[167]

If "property", rather than other regulatory mechanisms, is located in this commons space, then taking from the commons is "theft" from the community. Such an approach has the desirable result of not only refuting any legal claim within science to property in genetic, atomic, or biological information, but by the same defining qualities of its conceptual framework, judicially renders these "biopiracy"[168]- a theft from the biosphere. However, such an assertion may be equally overly simplistic in meeting the nuanced policy objectives of a state. The governance task of the state, according to Salter and Frewer, may be "to manage the tension between the protection of the public interest

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[164] Drahos adds that "the kinds of arrangements which are made to regulate the access of individuals to the commons would affect creativity in different ways. Restricting access to the commons would probably have a negative impact on creativity; at least for those individuals denied access." See Peter Drahos, *A Philosophy of Intellectual Property,* (USA: Dartmouth Publishing Company, 1996) [Drahos, *A Philosophy*] at 63.

[165] See *e.g.* Drahos, *A Philosophy, ibid.*

[166] See Margaret McKean, "Management of Traditional Common Lands (Iriaichi) in Japan," in Bromley *et al.*, eds., *Making the Commons Work: Theoretical, Historical, and Contemporary Studies* (San Francisco: Institute for Contemporary Studies, 1992), cited in Boyle, "Opposite of Property", *supra* note 150 at n. 21.

[167] See Hess & Ostrom, *supra* note 121 at 118.

[168] "The commercial development of naturally occurring biological materials, such as plant substances or genetic cell lines, by a technologically advanced country or organization without fair compensation to the peoples or nations in whose territory the materials were originally discovered." *The American Heritage Dictionary of the English Language*, 4th ed., *s.v.* "biopiracy". The NGO, the ETC Group, explains it as follows: "Biopiracy refers to the appropriation of the knowledge and genetic resources of farming and indigenous communities by individuals or institutions who seek exclusive monopoly control (patents or intellectual property) over these resources and knowledge. ETC group believes that intellectual property is predatory on the rights and knowledge of farming communities and indigenous peoples." See http://www.etcgroup.org/key)defs.asp.

and the support of the new industry in the knowledge that its activities are being shadowed by the informal governance mechanism of consumers and market."[169]

When thinking about genes as the building blocks of life and life in general, Boyle's insistence that we retain the fine distinction between the public domain, where content is free for appropriation, and the commons, where content is communal, is fundamental because of its implications for the politics of *care* and co-operation that underlie genome-related projects and biodiversity conservation efforts. The commons creates both a right and a duty of care on each individual participating within its community. The public domain, conversely, only offers free resources to be pillaged for individual purposes, which if conforming to institutional prescriptions, will give rise to exclusive rights but no corresponding duties other than on the public not to interfere with them. Boyle explains,

> Since the key to the well-run commons is frequently that it has informal systems of collective control that mitigate the inevitability of Hardin's tragedy, those who use the term "commons" are more likely to celebrate forms of control than those who write about the public domain.[170]

Jessica Litman believes, on the other hand, that:

> [t]he concept of public domain is another import from the realm of real property. In the intellectual property context, the term describes a true commons comprising elements of intellectual property that are ineligible for private ownership. The contents of the public domain may be mined by any member of the public.[171]

Herein lies the problem of conflation: for Litman, the public domain is a commons and commons by definition are marked by an absence of property whereas for Boyle, and Ostrom, the public domain is an area marked by the absence of property and control to be contrasted with the idea of a commons which is subject to some form(s) of governance, care, and control, whether defined by property or not. Litman's analysis notwithstanding,

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[169] Salter & Frewer, *supra* note 212 at 27.
[170] Boyle, "Opposite of Property", *supra* note 150 at 31.
[171] Litman, *supra* note 153 at 975.

as a matter of patent doctrine, gene patents should always be defeated on statutory grounds but failing that, if we locate genetic knowledge in the information *commons,* the subjective determination and juridical boundaries operating to allow the patent despite objections about novelty and obviousness are removed on the basis of pre-existing (often property) rights belonging to the community ("our common genetic heritage")[172] which take precedent over new claims to private property.

IPRs should not attach to genetic information for doctrinal reasons explored later in this dissertation but also because the arguments advanced in this chapter conceptually support the location of such knowledge in the information/intellectual *commons* rather than the public domain. In short, if we accept our knowledge and our life, including our common genetic heritage as part of the public domain, through the eloquence of our classification we render these subjects objects that may be taken, appropriated, and privatized for exclusive use in accordance with western intellectual property schemes.[173] If we leave them in the commons, the claim remains that these are part of the common-pool resources belonging to society as a collective community and not within the proprietary authority of any of its individuals; the requirements for patentability, such as novelty, are no longer definitive for the privatization of this public good. This is the "public" whose "interest" laws should govern; not the unauthorized public who has no right to what is ironically referenced as *the public domain* and is helpless before the corporate imperative of its ownership. Boyle crystallizes the difference. Whereas IP has at its core individual exclusive rights of ownership and control, the "free" public domain inferred as its opposite, the intellectual commons recognizes that just because property is

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[172] See Human Genome Project Information, *Understanding Our Genetic Inheritance: The US Human Genome Project,* online: <http://www.ornl.gov/sci/techresources/Human_Genome/project/project.html>.
[173] *Moore v. Regents, supra* note 51.

not privately held, does not mean that it is not commonly held in an intellectual commons. "Rather, it is individual versus collective control or sometimes, more confusingly, the presence or absence of a right to exclude" that differentiates the commons from the public domain.[174] Locating forms of knowledge in the "commons" allows for communal rights of access and participation while warding off individualist attempts at appropriation through erroneous rhetorical reference to the "public domain". Drahos explains:

> It is incomplete at best to say that creativity is exclusively an individual act or alternatively that it is the manifestation of greater forces outside of the individual. The first view ignores the importance of tradition. Creativity is tied to tradition...Equally a story about creativity which sees it as an outcome of tradition or other social forces ignores the capacity of individuals to step outside of social norms....A better way about thinking about creativity is to say that it involves individuals in dual and contrary roles. When the act of creation is complete, the individual steps forward to claim the role of inventor, pioneer, innovator, genius and so on. Yet the link between tradition and creativity suggests that, in the creative process, individuals play out another role, that of the borrower and copier. When intellectual property rights are claimed, right holders often lose sight of the *duality of roles* they have occupied, preferring to think of themselves exclusively in terms of creator and demanding protection against other borrowers and copiers. Intellectual property law, because of its focus on individual ownership, helps in fact to embed an individualistic notion of creativity.[175]

2.2.3.2.3 The Human Genome: Our Common Heritage

In the genetic commons, creativity literally produces reproduction (copy), mutation (change), and adaptation (improvement in the Darwinian sense) through natural (re)generative processes. Creativity in the genetic commons is expressly based on a common heritage (tradition) that is procreative and thus inherently collaborative. This communal contribution to our genetic information makes it different from other intellectual objects subject to IPRs and overtly resistant to *individual* privatization, commodification, and exclusion based on misplaced claims of authorship framed as

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[174] Boyle, "Second Enclosure", *supra* note 151 at 31.

[175] Drahos, *A Philosophy, supra* note 164. Mark Rose also laments the arbitrary legal distinction. He writes: "What is striking to me is the poverty of our paradigms for explaining ourselves to ourselves. Authorship is one such paradigm. The notion of authorship is implicit in the way we explain a vast range of *generative* activities from the way game shows are created to the way babies are made." See Mark Rose, "Mothers and Authors" (1996) 22.4 Critical Inquiry 613.

"invention".[176] DNA encodes genetic *information* that is significantly different from an *invention.* The metaphor of the body as information or data analogous to other health information is garnering increased international support.[177] Gene patent opponents argue that shared information is collective property, belongs to the information commons, and should be excluded from patentability.[178] The human genome mapping projects (discussed in chapter three) and any population based genomics research on gene mutation variation within discrete cultural identities highlight additionally the *cultural* identity of such communal property. As cultural property belongs to the culture from which it is derived, genetic information, even in terms of naturally occurring genes that have been isolated and purified, should not be subject to individual IPRs exclusively held by a patentee.[179]

Every living organism is born with essentially the same genetic blueprint; it is a bounded set of information with a finite number of 3.1 billion base pairs. Genomes, whether of mice or men, do not get bigger, "almost all (99.9%) nucleotide bases are exactly the same in all people". True inventions are limited only by the imagination. Thus, "mapping" the genome, be that of a mouse or man, is not about object(s) *invented* any more than discovery of new a Continent was-unless we define discovery

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[176] The individualist claim to creativity, according to Drahos, "does not gain wide currency until the 20th century. It does not appear as a fully fledged notion until the Romantic movement of the 18th century. Until that period man's status was that of labourer while the role of creator is exclusively occupied by God. According to Locke, the clear implication is that men are workers and labourers in the commons, rather than creators. With Marx...the creativity of humans is fully recognized, but the full expression of that creativity only occurs *outside* of private property rights and capitalism." See Drahos, *A Philosophy, supra* note 164 at 61 [emphasis added] and Mark Rose, *supra* note 175.

[177] See Australia Law Reform Commission "Essentially Yours: The Protection of Human Genetic Information" March 2003, online http://www.austlii.edu.au/au/other/alrc/publications/reports/96/. See R. Hoedemakkers and W. Dekkers, "The Ontological Status of Human DNA: Is it not first and foremost a biological "file-self"? (2002) 23 (4-5) *Theoretical Medicine & Bioethics.* 377-95.

[178] Geraldine Chin, "Is Gene Patenting in the Interests of Public Health? A Study of the Ethical and Public Policy Implications of Patenting Genetic Sequences" (1999) ALSA Academic Journal 1 at 5.

[179] See Austin & Amani, *supra* note 103.

colonially.[180] This is why the patenting of life, and in particular human genes, has been critically labeled *biocolonialism*, by indigenous communities under the Human Genome Diversity Project (HGDP) for the stark resemblance borne to colonialism- except now the state sanctions mining people and biological resources instead of land.[181]

Letters patent have been used to mark these real and intellectual spaces as "public domain" rather than information commons and thus "free" for the taking, staking, and laying of proprietary claims. According to National Geographic, more than 4,000 of the approximately 24,000 human genes have been claimed in U.S. patents- that's 20% of the human genome patented, 63% of which are assigned to private firms as compared to 28% to universities.[182] Yet, "the functions are unknown for over 50% of *discovered* genes."[183]

From the preceding analysis we can conclude that there need not be property in genetic information, but if there is, it is inappropriate for it to be held singularly or to accord conceptually with the exclusion thesis attendant with dominant conceptions of

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[180] See *e.g.* Hillary Cunningham, "Colonial Encounters in Post-Colonial Contexts: Patenting Indigenous DNA and the Human Genome Diversity Project" (1998) 18 *Critique of Anthropology* 205; Debra Harry, "Biopiracy and Globalization: Indigenous Peoples Face a New Wave of Colonialism" (International Forum on Globalization Teach-in conference, New York City, February 2001), online: <http://www.geneticsforum.org.uk>. "When Columbus stumbled upon a land new to him, he was carrying 'letters patent' from the king and queen of Spain. Those documents made the discovery and exploitation of a whole "New World" possible, legal and rewarding....[W]hat was necessary for the invasion and exploitation of other people's land, what was essential to the colonization, was to have a means of declaring inhabited land "empty"- void of true human beings." See Beth Burrows, "Patents, Ethics, and Spin" in Tokar, *supra* note 143 at 238.

[181] See HGP, *supra* note 172.

[182] Stefan Lovgren, "One-Fifth of Human Genes Have Been Patented, Study Reveals" National Geographic News, October 15, 2005, online: National Geographic, <http://news.nationalgeographic.com/news/2005/10/1013_051013_gene_patent.html>.

[183] Online: <http://www.ornl.gov/sci/techresources/Human_Genome/project/info.shtml>, emphasis added. Drahos and Braithwaite write that the extension of patents drew on the ill-fit metaphor of engineering: "One could liken the synthesis of new compounds to invention in mechanical engineering. The use of the metaphor becomes more problematic in the case of organic chemistry where the chemist finds molecules that exist in nature and have useful properties. In the case of patent claims over DNA instructions and their corresponding proteins...[i]t is hard to claim an entitlement to the DNA code on the basis that it had been engineered. It, after all, had been in existence for thousands of years before the genetic engineer and corporate laboratories. It had been uncovered or found rather than designed and built." Drahos & Braithwaite, *supra* note 7 at 157.

property.[184] Biodiversity preservation is commonly attributable to the collaborative efforts to preserve traditional (ecological and environmental) knowledge within (indigenous) communities. Putting aside cultural and theological arguments about whether man is at the top of a chain of being and thereby able to claim superiority, primacy, and therefore property in plants and animals,[185] the *human* genome at least, is the property of all humankind; this accords with the Declaration on the Human Genome and Human Rights[186] (HGHRD).

HGHRD was unanimously adopted together with a resolution for its implementation by the United Nations Economic Social and Cultural Organization (UNESCO) whose purpose is to "contribute to peace and security by promoting collaboration among the nations through education, science and culture in order to further universal respect for justice, for the rule of law and for human rights and fundamental freedoms".[187] It was the first universal instrument in the field of biology and confirms the status of the human genome as a "common" heritage to which we all have claim. Article 1 confirms that the "human genome underlies the fundamental unity of all members of the human family, as well as the recognition of their inherent dignity and diversity. In a symbolic sense, it is the heritage of humanity." Article 4 of the HGHRD posits that the "human genome in its natural state shall not give rise to financial gains."

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[184] See Heller & Eisenberg, *supra* note 133.

[185] Animals are patentable in the U.S. and Japan but not in the European Union. See H. Lawton Smith, "Regulating Science and Technology: The Case of the UK Biotechnology Industry" 27 L. & Pol'y 189 at 208. Animals are not patentable in Canada, see *Harvard College v. Canada (Commissioner of Patents),* [2002] S.C.J. No. 77, 4 S.C.R. 45, File No. 28155 [*Harvard* SCC].

[186] *The Universal Declaration on the Human Genome and Human Rights,* ESC Res. 27 C/5.15, UN ESCOR, 29th Sess., (11 November 1997), online: <http://portal.unesco.org/en/ev.php-URL_ID=13177&URL_DO=DO_TOPIC&URL_SECTION=201.html> [HGHRD].

[187] (Article 1.1). UNESCO strives to "promote the free flow of ideas by word and image" (Article 1.2). UNESCO *Manual of the General Conference*, texts adopted by the General Conference at its 31st session, (2002) at 8. Constitution of UNESCO, online <http://www.icomos.org/unesco/unesco_constitution.html>.

Article 12(a) provides that "[b]enefits from advances in biology, genetics and medicine, concerning the human genome shall be made available to all, with due regard for the dignity and human rights of each individual." In addition, the *Inter-Parliamentary Union, Resolution on Bioethics and Its Implications Worldwide for Human Rights Protection* (1995), adopted the year before TRIPS came into force also affirms the common genetic heritage of humankind, the right to share in the benefits of scientific progress and its applications, and the urgent need to

> develop an international corpus of common principles which respect diversity of culture, belief, spiritual values and historical heritage; prohibit all financial gain from the human body or parts thereof, subject to exceptions provided for by law; ban the patenting of human genes; provide for genuine health security at the international level; ensure equitable sharing of the knowledge and advances resulting from scientific research and new medical practices, in particular with regard to the developing countries, so as to correct imbalances in this field between them and the developed countries. [188]

If genetic information is indeed our common heritage and rights to it communally characterized, these instruments suggest that any economic and health benefits of genetic mapping research should return to the community from which they are derived with equity of information access; community must invariably be defined broadly to include all of humanity. In fact, it has recently been argued that full implementation of three UNESCO governance instruments will provide a significant means for bridging the genomic divide and help ensure equitable sharing of the benefits of research related to our common heritage.[189]

The claim that commercialization will bring more benefit than otherwise might be enjoyed without the IPRs is legitimate but the degree of benefits that flow back, how they

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[188] Resolution adopted by consensus at the 93rd Inter-Parliamentary Conference, Madrid (1 April 1995), online: <http://www.ipu.org/conf-e/93-2.htm>.

[189] These are: "the 1997 Universal Declaration on the Human Genome and Human Rights (UDHGHR), the 2003 International Declaration on Human Genetic Data (IDHGD) and the Draft Declaration on Universal Norms on Bioethics (DDUNB). All three contain articles that call for cooperation between developed and developing countries in knowledge sharing and capacity building." See Adèle Langlois, "The Governance of Genomics Science and Technology: Prospects for Development" IKD Working Paper 9 (20 May 2005).

are shared under the parameter, terms, and institution of 'property,' and the necessary balancing of interests must remain within the sole discretion of the regulatory state to negotiate and mediate in terms of its public's interest as a governance issue. This is because the regulatory state alone is at once obligated and accountable to both its constituency and the international juridical and political order.[190] State agency is imperative because it is the state that has sanctioned IPRs as a market intervention to ensure against failure for the production of knowledge as a public good, defined by the "public" within which they are located and benefit.[191] According to Peter Drahos, an additional advantage of a regulatory approach to public goods is that it can be related to theories in regulatory literature that extend the debate beyond the overly simplistic polarity of state versus market and allow for an understanding of a public good not as a singular good, "but an effect with complex antecedents made up of a set of complementary goods (private and public) and different type of social actors."[192] From this perspective, the nation state continues to have sufficient capacity to regulate human interactions and is required under international instruments to do so more coherently.[193]

Until recently, policy development in regulating biotechnology has been ad hoc and incremental "responding to the latest biotechnological research and development to

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[190] Brian Salter & Lynn Frewer, "The Changing Governance of Biotechnology - The Politics of Public Trust" (2002) Working Paper funded by the ESRC as part of its Innovative Health Technologies Programme, online: University of East Anglia, http://www.uea.ac.uk/~x514/research/governance/BIOGOV3.pdf>.

[191] Democratic representative governance is the best way of discerning consumer regulatory preferences as voters reveal support for politicians whose platform of policies (tax and spending) best accords with their wishes (an issue of public choice): "With mandatory acceptance of political outcomes, consumers have an incentive to reveal their preferences, suggesting an efficient provision of public goods." Inge Kaul *et al.*, eds., *Providing Global Public Goods: Managing Globalization* (Toronto: Oxford University Press, 2003) at x.

[192] *Ibid.* at 323.

[193] See the discussion of available regulatory responses in chapters three and four of this dissertation.

arrive at a point of economic and social impact or to an international regulatory initiative."[194] Salter and Frewer contend that

> [i]n the field of biotechnology, as in other fields such as nuclear science, public trust is a statement about the legitimacy of the activities that take place within it. The duty of the state is to protect the public's interest in that field where it sees those interests as being threatened. Thus the state's role may range from non-existent (in situations where there is no perceived threat), through the sponsorship and encouragement of self-regulation by those institutions promoting the technology, to direct regulatory controls.[195]

Political success, Salter and Frewer argue, can be measured in part by the degree of public trust and confidence "not only in the area of activity being regulated but also in the regulatory procedures themselves." Moreover, "[i]f the state fails and public confidence in a particular arena declines, there will be costs to pay in terms of the political exposure of the regulatory institutions, the economic vulnerability of the industrial sector concerned and the likely escalation of critical media interest."[196]

An erosion of confidence and legitimacy is occurring in relation to biotechnology because of the abnegation of governance. Where there is regulation, its politically captured forms stand in contrast against the communitarian conception of our common heritage and the various international declarations protecting individual and public access to genetic information. The spillover effects are directly felt as negative externalities undermining the legitimacy and global welfare improvement claims of the WTO as evinced by the controversy over trade in GM food and crops, patenting life, and provision of essential medicines. Routine discoveries of existing genetic information, made in ways that are now also obvious to those in the field, continue to be patented however, based on misconceived, though widely held, ideas of individual "rights".

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[194] Salter & Frewer, *supra* note 190 at 3.
[195] *Ibid.* at 4.
[196] *Ibid.*

2.2.4 The *Wrong* with *Rights:* Theoretically Good Justifications for Patent Privileges

Despite the challenges of justiciability, cultural relativism, and contested universality, there are two essential criteria of rights: true rights do not *expire* and are not conditional (on the payment of fees).[197] The greatest incongruence between intellectual objects and the normative claim to "rights" is the varying terms of protection afforded the different sub-categories of IPRs - it is unimaginable to conceive of the right to life, or liberty, or security as having a fixed term that is institutionally variable. Even in the seemingly insular field of real property where the concept of right is implicit once property is legally recognized, the term "right" is increasingly under challenge.[198] Adam Mossoff, however, believes it is too soon to eulogize the concept of property because a historical pattern reflects cyclical trends in its popularity always survived by the concept.[199] Having argued the position that the property label does not appropriately apply to IP and in particular the information (genetic) commons that belong to all of humanity (and are lacking in individualized inventorship of the kind recognized by patent law), we need not explore the rights debate internal to property.

The idea of personal rights outside of the internal conception of rights within property, suggests an inalienability in that, if I have a human right to food, I cannot divest myself of that right and give it to you (for example through an assignment). You would

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[197] Section 73(1) of the CPA, *supra* note 82 provides that the patent will be deemed abandoned if prescribed fees are not paid within regulatory time frames.

[198] "Today the concept of property in land may well denote no more than a temporary licensed form of utility or user privilege which may be extended, varied, or withdrawn at the sole discretion of the state and on terms dictated by it....So distant is this perception from the classical liberal image of property as a self-interested claim of unfettered power that some American commentators have now begun to predict wholesale reconstruction...of property [in land] in terms of 'socially derived' privileges of use." See Kevin Gray & Susan Francis Gray, "The Idea of Property in Land" in Susan Bright & John Dewar, eds., *Land Law: Themes and Perspectives* (Oxford: Oxford University Press, 1998) cited in Underkuffler, *supra* note 149 at 3 and n. 9.

[199] Mossoff, "Property", *supra* note 77 at 374.

not demand it of me nor need it as you too have the same right- assuming equality in rights distribution. This is not always the case with IPRs.[200] Moreover, I cannot aggregate and accumulate a single insular right, although aggregating different rights may be possible. That is, if my civil and political rights have been recognized, I may advocate for the equal recognition of my social and economic rights, but once I start aggregating my IPRs, severing some parts of the statutory exclusive rights (such as the right to use) while retaining others (like the right to manufacture or sell), what is really occurring is the penetration of rights discourse by the hegemony of property. I would be treating the 'right' (whatever it may be, but in this case the right to intellectual property) as if *it* were property and thereby aggregating property (conceived reflexively as a 'right') in the right itself. It would be as if we considered all rights attaching to humans as though they belonged to them in a property sense whether or not the underlying right was itself a substantive right to property. The absurdity of this is overshadowed by the current reality that what is valued today *is* the patent for its own sake ("assets"), rather than an IPR in the patented *invention* based on the commitment to property rather than *rights.* The words "property" and "rights" in IPRs are pedantically superfluous and ornamental since the interpretation of that "right" is traditionally in terms of a conceptual claim to it as property. To summarize, the word "right" in IPRs is in reference to a normative claim to how the idea of property should be understood: as a right individually held instead of any other property formulation. Re-imagine the breakdown as "intellectual" "property right" rather than "intellectual" "property" "right". Clarification of referential language helps negate any private claims to such IP as a human or natural right while simultaneously allowing collective claims to access, benefits, and thereby the ability to exert informal

[200] Employee contracts, for example, routinely assign patent rights to the employer.

control on the commons as either a property right absent exclusivity, a cultural right commonly held by a group,[201] or, when asserted individually, a sort of human right *other* than property (such as the right of creative participation explored in chapter five). Patents are often normatively justified by deontological theories of natural rights based on one's creative genius or one's labour[202] despite their predominantly corporate ownership.

Justice Yates, in the 1769 case of *Millar v. Taylor,* rejected a Lockean conception of a natural right to intellectual objects, stating "mere *labour and study* of the inventor, how intense and ingenious soever it may be, will establish *no property* in the invention, will establish no right to *exclude others* from making the same instrument, when once the inventor shall have published it."[203] If IP was a true right, mere publication would not destroy it. The (Benthamite) *Westminster Review* fittingly declared in 1829 that "to talk of the natural rights of an inventor is to talk nonsense."[204] Contrary to the dicta, as Mossoff argues, contemporary ideas of the natural rights philosophers did nevertheless influence the early development of patent law, their rhetoric penetrating the courts and

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[201] For a discussion of IP as a HR culturally defined, see Coombe, IP, HR & Sovereignty, supra note 54.
[202] Locke's natural rights arguments are based on property-creating labour while Hegelian natural rights are based on the extension of personhood. Hegel's theory of property is an integrated part of a sophisticated metaphysical system and essentially articulates two forms of property: that which is a fungible commodity and that which arises from the individual's personhood and self-expression. The moral connection between a person and his work is the basis of moral rights in copyright law adopted in France and Canada and the Berne Convention. *Berne Convention for the Protection of Literary and Artistic Works,* 9 September 1886 and amended 28 September 1979. For theoretical discussions, see Drahos, *A Philosophy, supra* note 164.
[203] See *Millar v. Taylor*, 4 Burr. 2303, 2387, 98 Eng. Rep. 201where the absence of any natural right to inventions was grounds for finding that authors do not possess a natural right to their written work, as cited in Adam Mossoff, Rethinking the Development of Patents, 52 Hastings L. J. (2001) 1255 at 1257 [Mossoff, "Rethinking"]. See also the discussion of this case in Sherman & Bently, *supra* note 113 at 13-14. *Donaldson v. Becket,* (1774) 17 *Parliamentary History* col. 953, the House of Lords confirmed that there was no (natural) right to copyright in voting "twenty-two to eleven in Donaldson's favour, against the right of common law perpetual copy-right." (Sherman & Bentley, *supra* note 113 at 14).
[204] Mossoff, "Rethinking, *ibid.* at 1256.

contemporary society with the theoretical understandings of the piety of property arising in the products of one's labour from Locke's *Second Treatise.* [205]

To simplify, Locke's theory of property posits that individuals own their bodies and therefore their own labour as a capital asset. As a result of mixing one's labour with existing resources, the individual alone owns the material things (objects) so produced.[206] Two important provisos exist, however, to limit this natural right to property over merged resources and labour. First, the amount of property that can be appropriated from the commons is conditioned on the person leaving as much and as good for other commoners and, second, the person cannot take more out of the commons than they can use to advantage. Lockean theory produces a number of problems for IPRs protection. It ignores the parliamentary and institutionalist variations of IPRs generally, and patent rights specifically. Not all inventions or discoveries are patentable - only those that meet the statutory definition of "invention", and some things, like abstract theorems and scientific principles, are precluded by statute while other things, like methods of medical treatment, may be precluded or included as the case may be under the common law of different jurisdictions. Second, these exclusions from patentability and the specific definition of "invention" are safeguards protecting society against artificial scarcity by denying monopolies that are mischievous to the state, harmful to social welfare, and of general inconvenience even though they may involve significant labour and/or ingenuity. Third, it creates awkwardness for independent labour by rewarding only the first to file

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[205] Mossoff's argues rights rhetoric did *influence* patent doctrine development but did not commit to justifying IPRS: "The former is a factual determination made on the basis of the historical record, and the latter is a philosophical determination that can only be made on the basis of normative principles:" *Ibid.* at 1321.

[206] Peter Laslet, ed., *John Locke: Two Treaties on Government,* (Cambridge: Cambridge University Press, 1988).

despite that simultaneous invention is a phenomenon common to science.[207] Fourth, it equally ignores complications posed as a result of the incremental, cumulative, and communal contributions to one's labour in inventing (be it modern public education, health, and other institutions taken for granted as tacit contributors to the inventive process or more explicit codified incremental substantive contributions by colleagues, or even the contributions of the individual himself in maintaining his life from which DNA specimens are extracted, manipulated and sequenced).[208]

Robert Nozick's analysis of Locke's labour theory, in *Anarchy State and Utopia,*[209] suggests that there is no moral imperative necessitating the loss of the existing commons resource to allow ownership in the merging of the object with one's labour, rather than the loss of one's labour. He cogently asks: if one pours tomato juice into the ocean, does one then have a property right to the ocean?"[210] Furthermore, asks Drahos, "labour creates the property right, but what identifies the object of that property right?"[211] The problem was not apparent at the time as the objects in reference to which Locke wrote were tangible objects with natural boundaries.

Mossoff conversely argues the moral imperative of rights is integral to his historical review of patent doctrine development: "if natural rights ideals influenced the development of modern patent doctrine...the provenance of patents indicates that the argument for an inventor's moral right to the property substantiated in his invention should complement these [constitutional, institutional and economic] analyses...The

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[207] Examples are offered within chapter three's discussion of the scientific process.
[208] See Moore v. Regents of the University of California, 51 Cal. 3d 120, 125; 793 P.2d 479 (Supreme Court Cal.,1990) discussed in chapter 4 of this thesis and in Alexandra George, *Property in the Human Body and Its Parts: Reflections in Self-determination in Liberal Society.* (M. Jur. Thesis) University of Sydney (2000) online http://www.iue.it/PUB/law01-08.pdf.
[209] (Oxford: Basil Blackwell, 1974) at 174-178, discussed in Drahos, *Philosophy*, *supra* note 164, 51-69.
[210] See R. Rozick, *Anarachy, State, and Utopia, Ibid.*
[211] Drahos, *Philosophy*, *supra* note 164 at 51.

moral claim to the product of one's labors should not be ignored." Lockean labour theory has hardly been "ignored" in IP literature or by the courts in expanding IPRs to life forms and in fact confuses the purpose of patent legislation which is to reward *ingenuity,* not *effort.* Some ingenuity may take very little labour and yet no amount of ardent and arduous hard work can guarantee "invention". Moreover, even by a labour analysis, Mossoff's conclusion fails to account for the political determination of *whose* labour matters while reflecting a common discomfort amongst property theorists with accepting a purely instrumental conception of IPRs as parliamentary tools deployed strategically for internal social and economic development.[212] The moral imperative for IPRs is not critical for my thesis on appropriate state agency regarding the patenting of life but reviewing the arguments as I have done helps foster appreciation for the power of normative claims made for the very existence of IPRs and the ease by which these policy tools have been proselytized as instrumentally essential for the (moral) recognition of natural rights of authors and inventors.

Edith Penrose long ago rejected the natural rights theory of patents, opting to characterize them instead as a matter of national "social policy" that takes into account the costs and benefits to a given society.[213] This is fundamentally a utilitarian approach to rationalizing government grants of limited term monopolies and focuses less on the interests staked by the inventor and more on the broader interest of society, with welfare gains for the greatest number. It is consequentialist in asserting that laws should be

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[212] There may be different normative claims to intellectual contributions acknowledging the incommensurability of IPRs in a poem or a book with those in our genes or a phonebook. The latter require significant labour, which can be well paid for by other means, but very little creativity. IPRs should be calibrated according to the degree of ex ante incentives or ex post rewards needed in each field.

[213] See Edith Penrose, *The Economics of the International Patent System*, (USA: John Hopkins University Press, 1951).

measured by the consequences they produce and utilitarian (Benthamite) in the mandate to produce the greatest good for the greatest number; from this perspective patents are instrumentally essential as a policy tool for maximizing social welfare. This is the alternative rationale for IPRs cited by the courts. The utilitarian perspective rationalizes the grant of limited term monopolies for "inventions" on the basis that these ultimately serve the public interest; rights, if any are deduced from welfare-maximizing principles. In Canada, for example, the Supreme Court in *Cadbury-Schweppes* v. *FBI Foods* looked not to traditional *rights* rhetoric but to the *bargain* theory with the Crown:

> A patent is a statutory *monopoly* which is given in exchange for a full and complete disclosure by the patentee of his or her invention. Accordingly, at least one of the policy objectives underlying the statutory remedies available to a patent owner is to make disclosure more attractive, and thus hasten the availability of useful knowledge in the public sphere *in the public interest.*[214]

The "trade-off" is worthwhile for society because otherwise the inventor would want to keep the invention a trade secret and the monopoly is limited in term. But the gains come from increased innovative activity as well as the post-expiry use of patented inventions which improve social welfare in the long term which is in the public's interest. The majority of the Federal Court in *Harvard* made a similar finding and concluded that "the object of the *Patent Act* is to promote the development of inventions in a manner that benefits *both* the *inventor* and the *public.*"[215] Utilitarianism conforms to "our sense of social responsibility; that is, the idea that the well-being of humans matters, and moral rules must be subjected to tests for their consequences on human well-being."[216] Such testing will allow for institutional reform.

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[214] [1999] 1 S.C.R. 142 at 171-72. As Rothstein J.A. noted, this was not a patent case, but the Court discussed patent protection in order to distinguish it from the law of breach of confidence (at para. 26).
[215] *Supra* note 85 at para. 26. See also Austin & Amani, *supra* note 103.
[216] See Canadian philosopher Will Kymlicka, *Contemporary Political Philosophy: An Introduction* (Oxford: Clarendon Press, 1990) at 11 as cited in Ostergard, supra note 96 at 163.

Sir Neil MacCormick's institutionalist theory for understanding the idea of intellectual property is consistent with the history of patents as crown granted *privileges* of limited duration with a utilitarian function. MacCormick contends that the positive law for IP protection requires three kinds of provisions to explain the extent and nature of the rights of IPRs holders. IP protection exhibits a triadic rule-structure that MacCormick believes is characteristic of legal institutions according to the Institutionalist Theory of Law. To summarize: first, the law must prescribe the circumstances in which and the means by which the named IPRs comes to exist and vests in a person as property; second, the law must define the scope of the right by providing what privileges and other rights belong to the holder of the IPR. This would include licensing powers and the conditions precedent for authorized uses and the nature of the trespassory rules that define infringement of the right and restrict the conduct of all others; finally, the law must prescribe how and when the right is extinguished, transferred, or expired. The nature and scope of an IPR is therefore entirely dependent on the particular legal regime which constructs it, the interpretation of the conditions from which it will arise, the extensiveness of the trespassory rules recognizing infringement, and the number and scope of exceptions that qualify the right.

A historical review by Adam Mossoff is consistent with the institutionalists' account of a "bargain theory" for patent grants. Mossoff writes:

> The history of patents does not begin with inventions, but rather with royal grants by Queen Elizabeth (1558-1603)...that advanced her economic and industrial policies. Approximately 200 years after the end of Elizabeth's reign, however, a patent represents a legal right obtained by an inventor providing for exclusive control...What accounts for this radical shift from a grant by royal prerogative to common-law property right?[217]

[217] Mossoff, "Rethinking", *supra* note 203 at 1255.

Crown granted *privileges*[218] were a strategic instrument of the Crown that served to encourage the importation of foreign or unknown (new) technology and its dissemination (to educate a labour force in the trades through tutelage).[219] They were limited in term within a limited territory and provided lead time to industrialists for first mover advantage. Less than fifty-five monopolies were granted between 1561-1603; twenty one of these went to foreigners.[220] The first letters patent granted was for a *manufacturing monopoly* in England as a means of stimulating domestic production of raw materials and manufactured goods. Its elements were characteristic of the Queen's prerogative:

> Under the early grant of letters patent, a patentee was supposed to: (i) work the patent, i.e. bring a foreign industry into the realm, (ii) not be inconvenient to other subjects, i.e., not interfere with established industries, and (iii) train apprentices, i.e., create a self-sufficient industry within the realm through which English subjects can make a living. Insofar as a patentee met all three conditions, the crown would exercise its prerogative and issue a letter patent for a monopoly in the respective trade.[221]

Non-inconvenience to subjects was framed in terms of anti-competitive behaviour:

> ...a monopoly cannot displace an existing trade within the realm...[T]wo rules that derived from these arguments- no monopoly patents either for trades existing at the time of the grant or for mere improvements upon such existing trades constituted the only real limitation imposed upon the early patent monopolies.[222]

An inventor shared in common with the importer the introduction of a new industry and thus patents for inventions earned royal favour with the rights of the inventor derivative of the importer's right. Crown discretion was to be exercised narrowly, "subject to Magna Carta and the common law, both of which were aimed in

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[218] Some writers protest the recasting of IP *rights* as *monopoly,* since substituted goods may reduce the price of the IPR below classic monopoly pricing, "still, no one may sell, copy or manufacture...without the authorization of the owner...[B]ut for those rights there would be competition in delivery of that good. Thus, economic conditions under which these non-rival and largely non-excludable goods are distributed look considerably more similar to a monopoly...." See Boyle, "Opposite of Property" *supra* note 150.

[219] "...King Edward III began issuing letters patent of protection for foreigners willing to come to England to train his subjects in their respective trades....function[ing] like passports..." Mossoff, "Rethinking", *supra* note 203 at 1258.

[220] One demanded that the patent be practiced within two months, failing which it would be void, another required that the French patentees train Englishmen in his trade, Adam Mossoff, "Rethinking", *supra* note 203 at 1230.

[221] *Ibid.*

[222] *Ibid.* at 1231.

terms of ideals, at the protection of the negative liberties of subjects."[223] Therefore, the Crown grants were not to unduly restrain trade or the customary right to work.[224] In fact, the *Statute of Monopolies* of 1624 limited patents to a term of less than fourteen years and excluded from patentability inventions that were "mischievous to the state by raising prices or commodities at home, or hurt of trade, or [were] generally inconvenient."[225]

With time and power came abuse of the royal prerogative. Many patents issued, much like today, "regardless of whether an industry was new to the realm or not,"[226] eventually extending over manufactures and sales.[227] Earlier conditions waned and original justifications surrendered to monopolies based on political capture impinging on the individual liberties of others. To overcome patronage and abuse, these privileges became juridically circumscribed[228] and ultimately transformed from discretionary royal grants (an institutional privilege) to statutorily-created contractual arrangements between

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[223] Drahos, *A Philosophy*, *supra* note 164 at 30.

[224] "As long as the patentee was not infringing upon the customary right to work in one's trade, i.e. as long as a patentee was not attempting to "put a new button on an old coat" or to "taketh away a mans trade," then he was accorded the status of "inventor" insofar as he was the *first* to establish (or re-establish) his respective trade within the realm." Mossoff, Rethinking. *supra* note 203 at 7. See also discussion in chapter 4 of this thesis.

[225] *An Act concerning Monopolies and Dispensations with Penal Laws, and the Forfeitures thereof* 1623 (U.K.), 21 Jac. I, c. 3. s. 6. David Vaver observes that the "agnostic stance of Canadian patent law is not a necessary feature of it"....Elizabethans, for example, feared the social disorder high unemployment might bring and so deemed it "inconvenient" to patent machines that would throw workers out of jobs." Commonwealth states, such as Australia, that "retain the *Statute of Monopolies'* criteria test the patentability of medical or surgical treatments for public 'inconvenience.'" Vaver *IPL*, *supra* note 34 at 120.

[226] Mossoff, "Rethinking", *supra* note 203 at 1263.

[227] The Hudson Bay Company and the British East India Company are examples of Crown patents used in colonial exploitation for human and natural resources. The British East India Company received a 21 year monopoly on all trade with the East Indies and reaped large profits from its Indian exports. It established local factories in India which helped the Company gain a foothold there strengthened through the acquisition of governmental and military functions. In the American colony, the 1773 "Boston Tea Party", was a precursor to the American Revolution for Independence. A political organization, The Sons of Liberty, dumped 9,659 worth in Sterling of Darjeeling into the sea at Boston Harbour in protest to British tax policies as well as a withdrawal of support "for commerce that depended on indentured or slave labor." Robert Stumberg & William Waren, "The Boston Tea Party Revisited: Massachusetts Boycotts Burma," online: http://www.ncsl.org/programs/pubs/599burma.htm,

[228] See *Darcy v. Allen (The Case of Monopolies)* in Coke's Reports as cited in Mossoff, "Rethinking", *supra* note 203 at 1264-66. *Darcy* was first to enounce the "common-law rule for adjudicating the *legitimacy* of a grant of monopoly privileges" and the limitation on the use of patents as odious monopoly.

the inventor and the crown serving as agent for society; a form of *social contract* giving rise to claims of individual *rights* void of discretion. The question of whether the law should consider qualitative aspects of the invention, according to Sherman and Bentley, was converted over time into a "fear of judgment" and a "fear of making qualitative judgments." It was believed that the law should resist making determinations of aesthetics and value and, "intellectual property law thus came to echo modernism's fear of being tainted by politics, morality and judgment."[229] This choice, however, was itself political in establishing the template for our current patent system that all but abandons any ideal of *quality* patents:

> [w]hile present-day commentators tend to be obsessed with the number of patents (design or trade marks) registered, during much of the nineteenth century it was the quality of what was registered that mattered most. Indeed, the multiplication of patents was seen as an evil that needed to be avoided. To this end, attention was given to increasing the cost of registration and to the introduction of an examination system as ways of ensuring that inventions of a trivial or undeserving nature were not patented. [230]

One way of containing the "evil" of such artificial monopolies was to try and limit the term of their existence as Thomas Jefferson[231] did in the United States in advocating stridently for a constitutionally limited term of only 12 years within the Progress clause. Article I, Sec. 8, cl. 8 of the American Constitution gives Congress the power "to promote the Progress of Science and the useful Arts, by securing for limited Times to

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[229] Sherman & Bently, *supra* note 113 at 178 [footnotes omitted]. This argument was also made by Harvard's counsel in the Canadian litigation over the oncomouse discussed in chapter 4 of this thesis.
[230] *Ibid.* at 177-78 [footnotes omitted].
[231] See *e.g.* Edward C. Walterscheid, "The Use and Abuse of History: The Supreme Court's Interpretation of Thomas Jefferson's Influence on the Patent Law" (1999) *IDEA* 195. Jefferson's writings have typically been interpreted to support the greater expansion of IPRs based on the view that 'ingenuity should receive a liberal encouragement.' But Jefferson "was never enamored of the patent system and throughout his life displayed a marked ambivalence toward it... A highly relevant point the Court has chosen to ignore totally is that [Jefferson]...expressed considerable skepticism concerning both its usefulness and its effectiveness. He clearly did not believe that patents promoted the progress of the useful arts...[he] privately believed that the patent system more often served to permit patentees to obstruct rather than promote the progress of useful arts." (At 196).

Authors and Inventors the exclusive Right to their respective writings and discoveries."[232] Jefferson failed, however, and patent term was left to be institutionally determined under legislation.[233] Malla Pollak looks at the Progress clause to determine the definition of "progress", empirically investigating the public usage of the word in the United States of 1789. She finds the term used to mean "dissemination", "distribution", and "spread" consistent with Mossof's historical European account, as opposed to qualitative or quantitative improvements in the knowledge base. This insight is offered in order to doctrinally authorize a "judicial trimming of Congressional over-protection":[234]

> [t]o the extent that Congress chooses not to act under this clause, the default position is that each person in the United States has a *property right not to be excluded from publicly accessible knowledge and technology.* Congress has only a very limited power to create private quasi-property, i.e. rights to exclude the rest of the commoners. Congress may only create temporary individual rights for "authors" or "inventors" to exclude from use of "their respective writings and discoveries" when such individual rights "promote" the spread of knowledge (Science) and technology (useful arts) [235]

2.3 Alternative Models for Regulating Knowledge Creation/Dissemination

If the dissemination of the objects to which IPRs attach is the main purpose for having this institution, then one line of inquiry pursued by critics of the current regime is whether alternative models of regulation can serve this purpose more efficiently. Wendy Gordon makes comments on the property model as follows:

> patent[s] take the form of ordinary property...[D]oes this similarity of form mask inconsistency of function? Justifications for tangible property typically refer to the internalization of both positive and negative effects, but justification for intellectual property tend to be more one-sided.[236]

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[232] U.S. Constitution, online: <http://www.house.gov/Constitution/Constitution.html>.
[233] See Malla Pollack, "The Democratic Public Domain: Reconnecting the Modern First Amendment and the Original Progress Clause (A.K.A. Copyright and Patent Clause)" (2004) 45 Jurimetrics J. 23.
[234] Malla Pollack, "What is Congress Supposed to Promote? Defining 'Progress' in Article I, Section 8, Clause 8 of the United States Constitution or Introducing the Progress Clause, online: <http://cyber.law.harvard.edu/openlaw/eldredvashcroft/progress.html#Footref12>.
[235] First emphasis added. See also Margaret Chon, "Postmodern "Progress": Reconsidering the Copyright and Patent Power" (1993) 43 DePaul L. Rev. 97, 102-03 (arguing for the existence of a constitutional right of access to information). In Canada, Parliament has the power under s. 91 of the *Constitution Act 1867* (U.K.), 30 & 31 Vict., c. 3, reprinted in R.S.C. 1985, App. II, No. 5 to make laws in relation to patents for inventions and discovery without any similar reference to the purpose for such power.
[236] Gordon, "Of Harms and Benefits" *supra* note 26 at 449-450.

So far I have established that property is an inappropriate metaphor for regulating intellectual objects and that normatively speaking, it should *not* attach to genetic information because the DNA sequences that code for such information exist in nature and are not invented "intellectual" objects or products of human ingenuity but an informational commons to which we all have claim. If the issue is to provide adequate incentives for knowledge production by ensuring fair compensation, then as international law and trade scholars Michael Trebilcock and Robert Howse have correctly acknowledged,

> [p]roprietary entitlements over one's creative product are, however, not the only form in which such compensation may be provided. For instance, in many countries, a large percentage of inventors or creators work in government laboratories and universities, and even literary and artistic activity is subsidized by the state. Invention and creation may be regarded as a salaried occupation like any other.[237]

Reform solutions may lie *outside* of the IPR structure entirely and require us to ask: to what extent should other instruments be used as forms of incentives to promote innovation instead of patent policy- these might include subsidies, R&D tax incentives (credits) while minimizing the social and economic costs of the policies adopted for the use of inexhaustible goods?[238]

Such policies may work equally well in tandem or independent of the patent system, providing incentives for basic research while reserving the patent system if necessary for applied research and development. Reforming incentives for genomics

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[237] Michael J. Trebilcock & Robert Howse, *International Trade Regulation,* 3d ed. (London and New York: Routledge, 2005) at 398. Iran's flourishing biotech sector offers a good example. Iran is neither a WTO Member nor adherent to a strong IPR regime. Nevertheless, the country continues to experience a scientific boom in the *absence* of so-called *necessary* incentives that patents provide, demonstrating again the importance of a strong public (university) education system. See cover story, Richard Stone, "An Islamic Science Revolution?" (2005) 309 *Science* 1802-1804 online: Science <http://www.sciencemag.org/cgi/content/summary/309/5742/1802>.

[238] For a good discussion on alternatives to intellectual property as incentives and the environments appropriate for these, see Gallini and Scotchmer, *supra* note 144; see also W. Norhaus, *Invention, Growth and Welfare: A Theoretical Treatment of Technological Change* (Cambridge: MIT Press, 1969) discussing the optimal design of intellectual property (in terms of having a fixed and finite length).

research may require governments to think "outside of the box" by considering alternative legal models and entirely *different* legal mechanisms. Having deconstructed the flawed conceptual understandings of IPRs it may be appropriate to ask whether property is entirely the wrong model conceptually for ensuring against harms that could better be addressed by compensatory systems under liability rules for example.

Jerome Reichman,[239] Wendy Gordon[240] and other legal academics have considered alternatives to the proprietary or quasi-proprietary protections that IPRs afford by turning to other Western legal models such as liability (where the owner - be it an individual or collective - has a right to receive a revenue stream from those who want access but cannot refuse access) and restitutionary models (based on unjust enrichment, unfair competition, and misappropriation). These conceptual frameworks, although needing further exploration than this dissertation allows, are helpful in overcoming the threat of the exclusion-thesis[241] in the life sciences that can lead to abuse and anti-competitive behaviours if the patent holder acts unreasonably.

For countries in the process of developing domestic IP regimes, there is a lot to be learned from the foregoing discussions. Alternative models may additionally provide more efficient and optimal means for governments to achieve industrial and competition policy objectives and advance economic growth based on open access to intellectual public goods without the current attendant costs of a strong proprietary exclusion based

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[239] See J.H. Reichman, "Of Green Tulips and Legal Kudzu: Repackaging Rights in Subpatenable Innovation" (2000) 53 Vand. L. Rev. 1743.

[240] Wendy Gordon, *supra* note 26. See also W.J. Cordon, "On Owning Information: Intellectual Property and the Restitutionary Impulse" (1992) 78 Virginia L. Rev. 149.

[241] Guido Calabresi & A. Douglas Malamed, "Property Rules, Liability Rules, and Inalienability: One view of the Cathedral" (1972) 85 Harv. L. Rev. 1089 stress the right of exclusion over that of alienation by emphasizing the essence of a property rule regime as the holder's right to name the price of access which if not paid, will allow the property right holder to exclude others.

system.[242] However, these alternative models, if imposed top down by some international order, may be subject to the same cultural imperialism criticism made by developing countries against the importation and normative presumptive power of any developed world's legal regime (property, liability, or otherwise) to dissonant foreign contexts. Still, alternative models help distance the economic claim for some regulatory oversight from the normative force of exclusion defining property as a concept integral to IPRs and may achieve a better balance of interests with compensation that is commensurate with the innovation for which it is rewarded - the question of which is constantly reflected in the debate on the appropriate period for protection and the tireless efforts by industry for extension of monopoly terms. "Once we have established that the issue is actually the *level* of compensation to which a creator is entitled," write Trebilcock and Howse, "then it is clear that at least implicitly the creator's claims are being balanced against other social interests."[243] In the interim, more immediate reform options lie *within* the existing property paradigm and relate to practical considerations for improving the institutional system by which patents are issued and administered, and in this manner regulated, by accounting for the quality and quantity of monopolies granted.

2.4 Conclusion

Government created law allocating "rights" in intellectual objects derogate from the default position of openly accessible information commons and undermine the public good character of (genetic) knowledge in which the public has a significant common interest (demonstrated in this chapter) and a personal (human rights) interest (discussed in

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[242] See also Jerome Reichman and Tracy Lewis, "Using Liability Rules to Stimulate Local Innovation In Developing Countries: Application to Traditional Knowledge" online. http://www0.gsb.columbia.edu/ipd/pub/Reichman_Lewis.pdf.
[243] Trebilcock & Howse, *supra* note 237 at 398.

chapter five). Despite theoretical underpinnings related to natural rights ideas, some government intervention may be necessary to ensure *private* knowledge production given the character of knowledge as a public good[244] consistent with institutionalist theories for the provision of IP protections. The current conception of the *kind* and *extent* of such state intrusion in the free market (in terms of western standards of IPRs) is flawed and overreaching due to inappropriate metaphors of "intellectual" "property" "rights". These terms, as they apply to intellectual objects, equivocate social understandings that dominate discourses around IPRs away from an activity institutionally encouraged as a matter of regulatory preference (innovation) to what assets can be acquired (inventory) based on misplaced deontological ideas of *rights* in natural law. By focusing on the *proprietary rights* of the *intellectual*, IPRs inappropriately divert attention away from the equal interests of society, users, and the public in the institutional design and operation of the industrial regulatory regime and its content, creating criminals and trespassers in the process. IPRs are distributive and must be justified by the state creating them with more than mere metaphors conceptually inappropriate in relation to our common genetic heritage. The idea of exclusion that is imported by IPRs to genetic information simply cannot apply to something so commonly (collaboratively) maintained as our genetic makeup; one cannot exclude that which is so fundamentally and universally shared by nature.

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[244] For a comprehensive discussion of the relationship between IPRs and public goods, see *International Public Goods and Transfer of Technology Under a Globalized Intellectual Property Regime Conference,* April 4-6 2003, Duke Law School. Webcast online: TRIPS Webcast http://www.law.duke.edu/trips/webcast.html [Duke IPG], articles published in book by same title, Keith Maskus and Jerome Reichman, eds. (USA: Cambridge University Press, 2005). See also Conference on the Public Domain, Duke Law School. November 9-11, 2001 [Duke CPD]. Papers available online: http://www.law.duke.edu/pd/papers.html.

The balancing of competing interests is integral to institutional IPRs as recognized by utilitarian, economic, and institutionalist theories, the U.S. constitutional "Progress clause", Canadian court dicta, as well as the public goods literature that requires states to justify market intervention as a means of promoting rather than hindering public interest objectives. Such intervention necessarily resides in the jurisdiction of the legislative branch with the propriety of its exercise to be checked by courts and citizens. Consequently, whether the property metaphor is in fact appropriate necessarily remains within the exclusive regulatory state's discretion so that intellectual property law and policy may be *institutionally* nuanced against the balance of other public policy objectives and regulatory instruments (such as prizes and patronage) within a given geopolitical territory. Reform, however, is not limited to the substance of patent law, but also the form it has taken and the means by which the property rights are operationalized. Patents were extended to genes by an exercise of administrative discretion, in the absence of balancing stakeholder interests or policy outcomes. The next chapter will explore evidence indicating an inefficient and faulty patent administration that threatens to further exacerbate the realization of public welfare gains promised by the new technology. Expanding private property rights "is of course always public spirited."[245]

[245] Lessig, *supra* note 96 at 6.

Chapter Three

The Promise & Perfidy of Patents

Promise: *a reasonable ground for hope and expectation, especially of future excellence and satisfaction*
Perfidy: *the act of violating faith, trust...; treachery*[246]

3.1 Introduction: The Genetic Revolution

> Using new biological tools, researchers have developed a wide range of possibilities for using living organisms, or parts of living organisms, to produce new products or processes. Biotechnology has applications in many sectors, including healthcare, agriculture, environmental protection, and aquaculture. In healthcare, for example, research based on biotechnology has resulted in new diagnostic tools and treatments for cancer, atherosclerosis, osteoporosis, asthma and AIDS. In agriculture, the industry has created disease resistant plants that are helping developing economies respond to the food needs of their growing populations.[247]

Biotechnology has expanded what is possible through molecular engineering and emancipated us with promises for a better *geneticized*[248] future. Biotechnology can be defined as "any technique that utilizes living organisms (or parts of organisms) to make or modify products, to improve plants and animals or to develop micro-organisms for specific purposes."[249] The definition includes traditional cross breeding methods and does

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[246] *Funk & Wagnalls Standard Dictionary, s.v.* "promise"; "perfidy". An early draft of this chapter, under the title "The Promise and Perfidy of Patents: Biotechnology, the Genetic Revolution, and the invention of 'invention'" was presented at the conference, *Intellectual Property and Biotechnology in an Age of Globalization: Challenges, Opportunities and Risk,* University of British Columbia, Faculty of Law, September 19-20, 2003, Vancouver, and is forthcoming in Ikechi Mgbeoji (ed.) *Intellectual Property and Biotechnology in an Age of Globalization,* (British Columbia: UBC Press, 2007).

[247] Ronald Hirshhorn and Jock Langford, "Intellectual Property Rights in Biotechnology: The Economic Argument" prepared for The Canadian Biotechnology Advisory Committee [CBAC] Project Steering Committee on Intellectual Property and the Patenting of Higher Life Forms, March 2001 at 12.

[248] Abby Lippman coined "geneticized" to pejoratively reflect the reduction of all qualities to a function of genetic codes. See A. Lippman "Prenatal Genetic testing and screening: Constructing needs and reinforcing inequities"(1991) 17:1 AJLM 15-50; A. Lippman "Worrying—and worrying about—the geneticization of reproduction and health" in G. Basen, M. Eichler, and A. Lippman , eds., *Misconceptions: The Social Construction of Choice and the New Reproductive Technologies* v.1 (Ottawa: Voyageur Press, 1993) 39; Melanie Rock, "Genetic norms, eugenic logic and UNESCO's International Bioethics Committee, (1997) 7 Eubios J. of Asian and Int'l Bioethics 108: "Geneticization builds upon medicalization, whereby people come to perceive the body in conformity with biomedical categories...[and] relies on notions of normal and pathological to frame the understanding of risk associated with this knowledge, thereby functioning as a mode of social control." But see A .Robertson, "Procreative Liberty in the Era of Genomics" (2003) 29:4 Am. J. L. & Med. 439.

[249] US Office of Technology Assessment, "Commercial Biotechnology, An International Analysis" quoted in Henk Hobbelink, *Biotechnology and the Future of World Agriculture,* (London: Zed Books, 1991) at 25, cited in Victoria Tauli-Corpuz, "Biotechnology and Indigenous Peoples", in Tokar, *supra* note 143 at 253. Karl Ereky was first to use this term in early 20th century, defining it "to characterize any interaction of

not necessitate molecular genetic manipulation, although the growth of the industry is certainly linked to that capacity and its corresponding private commercial enclosure.

There has been a "surge" in patenting in all fields.[250] The proliferation of patents in the biological, biomedical, and life sciences (biopatenting), however, is more profound; since the process of discovery is often cumulative and the subject matter is contentious, raising significant moral, ethical, and human rights considerations. Additionally, opposition comes from those who observe the growing anti-competitive uses of patents when treated as assets[251] rather than instrumental tools of the state for promoting imports, and later welfare enhancing innovation, as they were intended.[252]

Since knowledge is both consumable as a good and a necessary input in the creation of more knowledge, patent portfolios serve to block new competition in the particular R&D field of the patent holder; they enable coercive rent extraction by creating the need to secure technology licencing; and are a means of leveraging more favourable terms in cross-licencing negotiations (defensive patenting).[253] Today, there are "patent

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human technology and biology....[it] can be defined as the use or exploitation of a biological system, or parts thereof, for a productive end...Any process that attempts to tap the power contained within biological systems can be properly deemed to be biotechnological." Mark J. Fecenko, *Biotechnology Law: Corporate-Commercial Practice* (Canada: Butterworths, 2002) at 4.

[250] S. Kortum and J. Lerner, "What is behind the surge in patenting? (1999) 28 Research Policy 1, argue it is a result of friendly courts, fertile technology, and regulatory capture.

[251] As assets, patents are then used as security in attracting R&D, venture capital, and skilled employees or to secure promotion and tenure in public (academic) institutions. Companies are formed and merged based on IP 'assets'. See *e.g.* Curtis Cook, *Patents, Profits & Power* (USA: Kogan Page, 2002) at 142. Gary Rebak, a prominent American IP lawyer contends the institutional design failures make it complicit in promoting anti-competitive behaviour: "[t]here are those who view the patent system as the seedbed of capitalism—the place where ideas and new technologies are nurtured. This is a romantic myth. In reality, patents are enormously powerful competitive weapons that are proliferating dangerously, and the U.S. Patent and Trademark Office (USPTO) has all the trappings of a revenue-driven, institutionalized arms merchant." See Gary L. Rebak, "Patently Absurd: Corporations are increasingly converting the Shield of Patent Protection into the Sword of Unfair Competition", *FORBES ASAP* 169:14 (June 24, 2002) 44.

[252] Ironically, today patents can act as a restriction on imports. See discussion of Special 301 and section. 337 of US Trade Act, in text below commencing at page 258.

[253] See Stuart Macdonald, "When Means Become Ends: Considering the Impact of Patent Strategy on Innovation" (2004) *Information Economics and Policy* 16:1, online: Information Economics and Policy <http://else.hebis.de/cgi-bin/sciserv.pl?collection=journals&journal=01676245&issue=v16i0001>. See

development firms, intellectual property licensing enterprises, even trading exchanges for patent licenses – "there's plenty of money to be made when the "product" itself is intellectual property."[254] Strengthened patent law with weakened administrative application expanding property rights to life without public debate merits further scrutiny; neither the subject matter of genetics nor the consequences of biopatenting are commensurate with private monopolies traditionally held in "art, process, machine, manufacture or composition of matter"[255] because these are neither built nor invented, as Drahos and Braithwaite assert,[256] but also because of the unique nature of this knowledge. Geneticist and science writer Kevin Davies asserts:

> [w]ithin a decade or two, we may be carrying this [genetic] information on our own personal DNA DVD, replete with information on our genetic susceptibility to disease and our tolerance to drugs. Clinics will be able to select genetic traits in human embryos by screening DNA before implantation and employ novel gene-based therapies to replace or repair faulty genes to cure inborn illnesses and cancer. And by the end of the game, we may know even enough about the secrets of our own genome to associate genes with elements of human character.[257]

In the last chapter we considered the historical treatment of patents as crown privileges, their use as domestic policy tools for encouraging new industry and technology transfer, the influence of rights based theories in transforming discretionary crown privileges to "rights" entitlements and the impropriety of such a model for intellectual objects, and in particular discovered natural phenomena belonging to our common heritage. This chapter considers the promise of biotechnology as framed in human rights vocabularies and how these promises may be betrayed by the perfidy of patents. The chapter is divided into five parts. After the introduction, section 3.2

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also G. Rivette and David Kline, *Rembrandts in the Attic: Unlocking the Hidden Value of Patents* (Boston: Harvard Business School Press, 2000) at 4.

[254] Rivette and Kline, *ibid.* at 10.

[255] Section 2 of the CPA, *supra* note 82, defines "invention" as "any new and useful art, process, machine, manufacture or composition of matter" or any new and useful improvements to these.

[256] See *supra* fn. 183 of this dissertation.

[257] Davies, *supra* note 5 at 9.

outlines the promises of biotechnology, drawing attention to its public good character as well as the vast human rights and public interest promoting potential of this new technology. The historical discovery of genes and the various collaborative international genomics "mapping" projects that have facilitated biotech's promises are reviewed. These demonstrate that scientific discovery is incremental, co-operative, and that some of the most significant contributions arise from public funds which extend the promises of biotechnology for the benefit of all. Two important points are emphasized: science is based on an open sharing communitarian ethic and the idea of an individual scientist having an independent Eureka! moment of invention, a normative assumption for patent law, is rare and deceptive particularly in genomics where collaborations have been the defining feature of research. Section 3.3 provides a brief introduction to Canadian patent law as a bench mark by which we can doctrinally gauge "invention" claims (in this chapter) and the propriety of major court decisions (in the next chapter) instrumental in creating the current law in this field. To critique the application and interpretation of patents, we must first understand what a patent is. Section 3.4 outlines the perfidies of patents that will undermine biotech's promises should the current model continue unabated. These will range from practical observations of overprotection (leading to underutilization) to evidence in the literature that points to a flawed administrative system that warns against maintaining the status quo while moving full speed towards further privatizing life and its building blocks. Examples of 'bad patents' are offered to evidence the low threshold by which patents are being issued in order to suggest current patent policy is less than optimal, patent practice inefficient and regulatory oversight ineffective. I will argue, in closing this chapter, patent policy should be assessed with due

consideration of its operation, alternative policy instruments, and conceptual paradigm. The nature and extent of public policy co-ordination reflecting a public's regulatory preferences in a fully informed democratic society should determine whether biotech's promises become patent perfidies.

3.2 The Promise of Biotechnology

Biotechnology promises to feed the world and ail the ill, extending the quality and quantity of our lives. Scientists have heralded genetic and biological manipulations that enable genetic diagnosis, gene therapies, plant derived edible vaccines[258] and biopharmaceuticals that will tailor medical health treatment to an individual's biological needs and thereby improve metabolism and treatment efficacy. The allure of these promises is strengthened through the medical mantra of diagnosis and treatment to which bioethical centres contribute.[259] Biotech also promises nutrient enriched,[260] more resilient and highly adaptable crops as 'improved' varieties. More efficient use of decreasing land through drought and pestilent-resistant agriculture[261] is made possible to produce

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[258] See *e.g.* Karen Lynn Durrell, "Intellectual Property Protection for Plant Derived Vaccine Technology: Here they Come are we Ready or Not?" (Winter 2006) 10.3 *Lex Electronica,* online:http://www.lex-electronica.org/articles/v10-3/durell.pdf

[259] See *e.g.* Daar et. al., "Top 10 Biotechnologies", *supra* note 101, and other publications from researchers belonging to the University of Toronto's Joint Centre for Bioethics. For a comprehensive review of the issues related to new genetics and why genetic information is special, see Trudo Lemmens et. al., *supra* note 103.

[260] Products of biotechnology and genetic engineering that are almost here "...include oranges with higher vitamin C content, broccoli that contains higher levels of chemical believed to protect against cancer and caffeine-free coffee beans. A potato that contains a vaccine that fights against a killer diarrheal disease has also been developed, with the idea it could prevent a disease that affects millions of people in developing countries [although] ...there are still questions of dosing, and...the fact that the vaccine is lost if the spuds are cooked." See Pippa Wysong, "Breaking Ground" *Financial Post* (13 November 2000) E1at E-2. For a discussion of food insecurity, nutritional deficits, and biotechnology's response, see Ellen Messer, "Food Systems and Dietary Perspective: Are Genetically Modified Organisms the Best Way to Ensure Nutritionally Adequate Food?" (Fall 2001) 9:1 Ind. J. Global Legal Stud, (Symposium on Sustainable Development, Agriculture, and the Challenge of Genetically Modified Organisms) 65-91.

[261] See *e.g.* Wysong, *ibid.* Critics claim the problem is unrelated to production capacity, arguing that it is a political and not market failure that sufficient food is produced to feed the world but is not appropriately distributed: "Taken as a whole, the world produces enough food to feed everyone – but much of it is simply in the wrong place. Especially in countries with undeveloped transport infrastructures, geography restricts

tastier, healthier, hardier, and otherwise *desirable* food for the market. Researchers at the Science University of Tokyo are using a new breed of genetically modified (GM) rice plants to develop the hepatitis B antibody to produce immunity to a virus that has over 300 million carriers worldwide. In the past, the inoculation for this epidemic had to be manufactured using blood from hepatitis B carriers.[262] Jo Chiba, a university professor and the team's leader, believes this is a great discovery since it will reduce manufacturing costs, decrease the chance of other viruses entering the products, and increase access by developing countries that may lack the funds to purchase costly antibody products.[263] Genetically engineered crops include vitamin A enriched rice, known as golden rice, designed to reduce massive annual child deaths and cases of blindness in the third world, since for many poor countries food means rice. The patent is held by Monsanto.

The West African Rice Development Association (WARDA) with the support of partners including the United Nations Development Program (UNDP) has developed new rice varieties that combine the best qualities of African and Asian species (New Rice for Africa- NERICA).

> [These] can yield up to 50 per cent larger crops without fertilizer...In addition to the significant gains in production, the new varieties also mature 30-50 days earlier than the currently grown varieties...is also substantially richer in protein, more tolerant to disease, drought and acid soils, resists some of the most damaging insect pests in West Africa, and can out-compete weeds. Because the rice was designed for resource poor farmers, it can help farmers reduce poverty and save developing countries millions of dollars in rice imports.[264]

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food availability as dramatically as genetics promises to improve it [and] biotech has its own "distribution" problems." See Bill Gates, "Will Frankenfood Feed the World? Genetically modified food has met fierce opposition among well fed Europeans, but it's the poor and the hungry who need it most" (June 19, 2000) v.155 Vision 21 No. 25 [Gates] online, <http://www.time.com/time/magazine>. For a comprehensive literature review, see Mark Sagoff, "Biotechnology and Agriculture: The Common Wisdom and Its Critics" (Fall 2001) 9:1, Ind. J. Global Legal Stud., Symposium: Sustainable Development, Agriculture, and the Challenge of Genetically Modified Organisms, at 13-35.

[262] Daily Yomiuri, "Hepatitis Antibody made from GM Rice" (November 1, 2000), online: Crop Biotechnology News <http://www.agbios.com/static/news/NEWSID_1763.php>.

[263] *Ibid.*

[264] United Nations Development Program, Press Release, April 4, 2001, online http://www.undp.org/dpa/pressrelease/releases/2001/april/4apr01.html. UNDP official Peter Malton worked on the project and contends "NERICA is an excellent example of how science can be put to work

In short, the argument advanced by industry and scientists is that biotech allows for sustainable agriculture[265] where traditional agricultural production methods are not tenable for sustaining population growth and affords positive solutions for human health outcomes through medical applications and by improving food security in the face of limited land resources.[266] Biotech improves the prospects for development and thereby reduces reliance on foreign aid. Human health requires food and is inextricably linked with nutrition. Biotech promises further gains in both at the population level and is therefore an important consideration for governments in developing public health policy.

Biotechnology as the means to resolve resource disparities in the world is industry's narrative and it is supported by the technical capacity to engineer transgenic organisms custom-designed to express adaptable traits of one or both of the species, such as a tomato with flounder, corn with firefly, or rice with bacteria. The long history of plant and animal husbandry confirms that genetic manipulation is not new in food and agriculture;[267] nor is the related concern over the impact of such manipulation on

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for poverty reduction. It is already having a real impact on improving poor farmers' incomes and increasing their food security."

[265] A plurality of perspectives on what this means were offered at the Agrarian Law and Sustainable Development Conference attended by some 200 delegates from more than 20 countries held at Porto Alegre in southern Brazil from May 19-22 1998. See Lynda M. Warren, Conference Report "Agrarian Law and Sustainable Development: *Fifth World Congress on Agrarian Law*" (1998) 1 *Biosciences and the Law*, 411-412 where it is observed that "The difficulty lies in knowing how the sometimes conflicting environmental and human interests should be balanced....The overall message coming from the papers presented was the need to keep things as simple as possible for the farmer."

[266] The world's population is an estimated 6 billion and, "by 2050, the U.N. estimates, it will probably near 9 billion. Almost all that growth will occur in developing countries. At the same time, the world's available cultivable land per person...will decrease by half over the next 50 years..." The International Service for the Acquisition of Agri-Biotech Applications (ISAAA) cited in Gates, *supra* note 261.

[267] Vegetables as different as broccoli, brussel sprouts, cauliflower, and cabbage all resulted from traditional hybridization of the simple mustard plant. See J. Howard Beales III, "Modification and Consumer Information: Modern Biotechnology and the Regulation of Information" (2000) 55 Food & Drug L. J. 105.

biological diversity.[268] Such efforts and their consequences were, nonetheless, invariably limited by Mother Nature's rules of propagation. Today, however, the routine isolation of genes and determination of sequence functions of all species is coupled with the ability to transplant genes from one organism into another organism of a completely *different* species with often unknown consequences.[269] How did this capacity developed?

3.2.1 The Discovery of the DNA Structure: A Comment on the Scientific Process

If you steal from one author, it's plagiarism; if you steal from many, it's research.[270]

Mapping technologies and the discovery of the structure of DNA was essential for advancements in molecular genetics and the growth of the biotech industry. DNA, short for deoxyribonucleic acid, is "the fundamental hereditary material of all living organisms,"[271] comprised of amino acids arranged in sequences that code for genes, the basic functional and physical units of heredity that in turn contain coded information necessary for understanding the functions of proteins (the study of proteomics); they affect everything from intelligence and physical appearance to the propensity to develop

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[268] See "How Humans Invented Animals" June (2003) CBC Radio One Interview, archived at http://www.cbc.ca/ideas/features/invented-animals/index.html, tracing the history of animal domestication and its contribution to decreasing biological diversity and raising the risks for species extinction.

[269] See *e.g.* Jared Babula, "Transgenic Crops: A Modern Trojan Horse" (1999) 3:1 J. of Law and Soc'l Challenges at 131. Transgenic organisms have had at least one other species' DNA inserted into their own through genetic engineering, reflecting the unique preternatural inter-species capacity for genetic manipulation belonging exclusively to biotech. It should be noted that the capacity to create "synthetic genes" coding for "synthetic proteins" is also already underway. See *e.g.* Joe Cummins, "Synthetic Genes in Food Crops", Institute of Science in Society, 01/09/04, online: < http://www.i-sis.org.uk/sgigmc.php>, arguing for greater regulatory oversight and risk assessment of synthetic genes routinely used as surrogates for naturally occurring genes in crops. The author argues that this is because "the genes actively expressed in bacteria or humans are not very active in crop plants" but warns that the synthetic are not "substantially equivalent" and may have unforeseen consumer effects, such as toxicity. See also Roland Pease, "Artificial Life Comes Step Closer" December 18, 2004, online: <http://news.bbc.co.uk/1/hi/sci/tech/4104483.stm>.

[270] Wilson Mizner, as cited in Cook, *supra* note 251 at 93.

[271] Purves *et, al., Life: the Science of Biology* vol. 1, The Cell and Heredity 5th ed., (USA: Sinauer Associates Inc., 1998) Glossary.

specific diseases, differentially metabolize drugs, or respond to environmental or social changes such as diet and exercise:[272]

> Each new gene is a potential target for drug development -- to fix it when broken, to shut it down, to attenuate or amplify its expression, or to change its product, usually a protein. Finding a gene gives investigators a molecular handle on problems that have proven intractable.[273]

In 1953, James Watson and Francis Crick discovered that the structure of DNA was a double-stranded helical molecule characterized by complementary base pairings of nucleotides fixed with hydrogen bonds and with the capacity to self-replicate.[274] It earned them the Nobel Prize. "Discovering the nature of the gene 'was the most important objective in biology.'"[275] The actual discovery came, however, after a long on-and-off process during which other necessary and cumulative scientific advancements were made by leading scientists in the field.[276]

Watson and Crick were not motivated by letters patent although by today's standards their discovery would have been a patentable invention. They were driven, rather, by what has motivated scientists throughout history and across borders: the search

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[272] "Genes are responsible for directing the biological development and subsequent activity of the human body's 100 trillion cells… [, are] the physical basis for the [intergenerational] transmission of the characteristics of living organisms...[and] account for only about ten percent of each cell's DNA." Fecenko, *supra* note 249 at 10.

[273] Dr. Robert Mullan Cook-Degan, "Origins of the Human Genome Project", online http://www.piercelaw.edu/risk/vol5/spring/cookdeeg.htm.

[274] The two base pairs, Adenine to Thymine and Guanine to Cytosine were "identical in shape". Victor McElheny, *Watson & DNA: Making a Scientific Revolution* (Basic Books: New York, 2004) at 56.

[275] *Ibid.* at 34, endnotes omitted.

[276] James Watson attended a life altering conference where Maurice Wilkins, a scientist who had left physics for biology, was lecturing on the study of crystalline nucleoproteins in living cells and was presenting an X-ray diffraction photograph of DNA fibres he had taken and believed to be of help in determining gene structure. On his way back to Copenhagen, Watson "stopped off in Geneva and there heard of Linus Pauling's great achievement of finding large stretches of the amino acid subunits of the complex proteins arranged in what he called the alpha helix. Helices were in the air." *Ibid.* at 29. The "Paulingesque model-building approach of Crick and Watson was virtually the opposite of the very slow, methodical way that Maurice Wilkins and Rosalind Franklin were working at the Medical Research Council-supported biophysics lab of King's College London, not far from the Strand…" *ibid.* at 37.

for scientific truth.[277] Thomas S. Kuhn, in his seminal work, *The Structure of Scientific Revolutions,*[278] offers insight on what drives scientists:

> if failure to come near the anticipated result is usually failure as a scientist- then why are these problems undertaken at all?...To scientists...the results gained in normal research are significant because they add to the scope and precision with which the paradigm can be applied. That answer, however, cannot account for the enthusiasm and devotion that scientists display for the problems of normal research...Bringing a normal research problem to a conclusion is achieving the anticipated in a new way, and it requires the solution of all sorts of complex instrumental, conceptual, and mathematical puzzles. The man who succeeds proves himself an expert puzzle-solver, and the challenge of the puzzle is an important part of what usually drives him on.[279]

Watson had a similar impression; he once said that "I quickly lose interest in a scientist if I discover that he lacks the virtual monomaniacal interest in his work."[280] This characterization significantly differs from that promulgated by the patents as incentive narrative which posits that monopolies are necessary to stimulate creativity and innovation.[281]

Global activist Vandana Shiva, Director of the Research Foundation for Science, Technology, and Ecology and one of the leaders of the International Forum on Globalization, contends that the 'patents as incentive' myth[282] is based on a false construction of knowledge disconnected from any temporal, spacial, or social specificity,

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[277] "[Watson] thought of himself as the only one in Cambridge who 'lived solely to understand how DNA functioned as the gene, and who had first-hand practical experience in using bacterial viruses to get close to the self-replication of the gene.' McElheny, *ibid.* at 33.

[278] Thomas S. Kuhn, *The Structure of Scientific Revolutions,* International Encyclopedia of Unified Science, v. 2 No. 2 (The University of Chicago Press Ltd., London: 1962).

[279] *Ibid.* at 36-37. He adds, "[p]uzzles are, in the entirely standard meaning here employed, that special category of problems that can serve to test ingenuity or skill in solution....Though intrinsic value is no criterion for a puzzle, the assured existence of a solution is." (*Ibid.*).

[280] James D. Watson, May 26, 1982 as quoted in McElheny, *supra* note 274 at 179.

[281] In fact, Kuhn believes that "A man may be attracted to science for all sorts of reasons. Among them are the desire to be useful, the excitement of exploring new territory, the hope of finding order, and the drive to test established knowledge....What then challenges him is the conviction that, if only he is skilful enough, he will succeed in solving a puzzle that no one before has solved or solved so well.....On most occasions any particular field of specialization offers nothing else to do, a fact that makes it no less fascinating to the proper sort of addict." Kuhn, *supra* note 278 at 38.

[282] For a discussion of this myth in the protection of agricultural innovation and the initiation and elaboration of industrial property laws affecting plant breeding under the 1883 Paris Convention for the Protection of Industrial property, see Michael Blakeney, "Stimulating Agricultural Innovation" draft paper presented at Duke IPG, *supra* note 244 at 10.

even though the nature of knowledge, as the Watson and Crick example demonstrates, is a collective and cumulative enterprise based on the dialectic between scientists and their community. "Science", Shiva asserts, "cannot be used to refer only to modern western science. It should include the knowledge systems of diverse cultures in different periods of history."[283] The spirit of science is "communitarian" and open, requiring access to the knowledge and techniques it creates.[284] Kuhn's observations on the scientific paradigm, which sets the parameters for the puzzles to be solved, led him to conclude that "normal science is...a highly *cumulative* enterprise, eminently successful in its aim, the steady extension of the scope and precision of scientific knowledge."[285] Yet patents are granted for private "intellectual" contributions "built on the fiction of totally individualistic scientific innovation."[286]

The concept of 'development-by-accretion' makes the job of science historians difficult in chronicling exact dates, or ascribing to specific scientists, the process of scientific progress.[287] In fact, the trend in science is towards regional technology and

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[283] Vandana Shiva, *Protect or Plunder: Understanding Intellectual Property Rights* (Halifax: Fernwood Publishing Ltd., 2001) at 20.

[284] See *e.g.* the classic work of R. Merton, *the Sociology of Science: Theoretical and Empirical Investigations,* (Chicago: University Press, 1973). For a discussion of the importance of open science for progress in molecular biology see Horace Judson, *The Eighth Day of Creation: Makers of the Revolution in Biology* (New York: Cold Spring Harbor Laboratory Press, 1996).

[285] Kuhn, *supra* note 278 at 52.

[286] Shiva, *supra* note 283 at 22. See also Graham Dutfield, "The Public and Private Domains: Intellectual Property Rights in Traditional Knowledge" (2000) 21 Science Communication 274-295 on the indigenous/traditional vs. Western/scientific distinctions often drawn in the literature on the proprietary protection of IPRs and the need for western IP systems to accommodate the protection of traditional knowledge as an exception to the general recommendation to curtail the further use of IPRs from eroding the public good through enclosure of the intellectual commons; Dutfield, "Intellectual Property Rights and Biodiversity: Conflict or Synergy?" in *IPRS, Trade & Biodiversity, supra* note 22 at 40-61; Ikechi Mgbeogi, "Patents and Traditional Knowledge of the Uses of Plants: Is a Communal Patent Regime Part of the Solution to the Scourge of Bio Piracy?" 9.1 Ind. J. of Global Legal Stud., 163 on the relationship between the *Convention for Biological Diversity,* patent law, and the protection of biocultural knowledge.

[287] "As chroniclers of an incremental process, they discover that additional research makes it harder, not easier, to answer questions like: when was oxygen discovered? Who first conceived of energy conservation? Increasingly, a few of them suspect that these are simply the wrong sorts of questions to ask.

knowledge based clusters[288] whereby innovative gains can be realized by the synergy of tacit and codified knowledge that develops through collaboration and team work.[289] As Richard Gold, Director of McGill University's Centre for Intellectual Property Policy has astutely observed, however, the patent system is more focused on encouraging commercialization than innovation. It only rewards the final codification, according to specific institutional prescription, of prior existing or newly emerging knowledge.[290] If the patent system was truly focused on spurring inventions through the recognition of the individual's right to the products of his genius or his labour as the case may be, then independent inventors would share the benefits and, as with the law of copyright, enjoy exclusive rights that are good against everyone save other independent authors/inventors of the same "work"- especially since the paradigmatic structure of the scientific process means that simultaneous independent invention is not uncommon:

> To see how closely factual and theoretical novelty are intertwined in scientific discovery examine a particularly famous example, the discovery of oxygen. At least three different men have a legitimate claim to it, and several other chemists must, in the early 1770's, have had enriched air in a laboratory vessel without knowing it....[291]This pattern of discovery raises a question that can be asked about every novel phenomenon that has ever entered the consciousness of scientists. Was it Priestley or Lavoisier, if either, who first discovered oxygen? In any case, when was

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Perhaps science does not develop by the accumulation of individual discoveries and inventions." Kuhn, *supra* note 278 at 2.

[288] The Biotech Belt is built around Duke University in North Carolina, and Canada's own technology triangle (CTT), which is a system of four networked municipalities (Cambridge, Kitchener, Waterloo and Guelph). See Jeffrey Roy, "Canada's Technology Triangle" in *Local and Regional Systems of Innovation*, (The Hague: Kluwer Academic Publishers, 1998) at 239-255.

[289] Watson and Cricks' decision to emulate Pauling's cardboard models for their structure, for example, benefited from "know how"- his skills, capacity, and methodology for executing a task, as well as "know-who", in working with each other and other experts who may have assisted (un)intentionally. This tacit knowledge is as beneficial as the substantive knowledge written up in a science journal but is limited by proximity, an important factor in reaping its benefits. The OECD describes that a "fundamental aspect of learning is the transformation of tacit into codified knowledge and the movement back to practice to develop new kinds of tacit knowledge." See OECD 1996 Knowledge Based Economy Report at 229-256. See generally, Michael Gibbons *et. al. The New Production of Knowledge* (London: Sage, 1994) Chapter 1 "Evolution of Knowledge Production" at 17- 45.

[290] E. R. Gold, "Biomedical Patents and Ethics: A Canadian Solution" (2000), 45 McGill L.J. 413. See also Ikechi Mgbeogi, *Global Biopiracy: Patents, Plants, and Indigenous Knowledge* (Canada: UBC Press, 2006).

[291] Referring to the classic discussion of oxygen's discovery, A.N. Meldrum, *The Eighteenth-Century Revolution in Science- the First Phase* (Calcutta, 1930), Chap. V. in Kuhn, *supra* note 278 at 53.

> oxygen discovered?...As a ruling about priority and date, an answer does not at all concern us. Nevertheless, an attempt to produce one will illuminate the nature of discovery, because there is no answer of the kind that is sought...The fact that it is asked- the priority for oxygen has repeatedly been contested since the 1780's- is a symptom of something askew in the image of science that gives discovery so fundamental a role....Clearly we need a new vocabulary and concepts for analyzing events like the discovery of oxygen. Though undoubtedly correct, the sentence, 'Oxygen was discovered,' misleads by suggesting that discovering something is a single simple act assimilable to our usual (and also questionable) concept of seeing. That is why we so readily assume that discovering, like seeing or touching, should be unequivocally attributable to an individual and to a moment in time. But the latter attribution is always impossible, and the former often is as well.[292]

In an economy where knowledge is capital, privatizing the ownership of knowledge and "discovery", whether of naturally existing oxygen or DNA, translates into a number of inequities creating discomfort and frustration for many academics, scholars and public interest groups.[293] Canada has a first to file requirement[294] for recognizing invention which has a 'winner-take all affect.'[295] David Vaver articulates the anomaly created by the patent rules:

> The decision on who gets the monopoly right where two or more persons invent something independently, without knowing of the other's work, is often more a matter of *luck* than anything else: the history of science and invention suggests that the phenomena of simultaneous discovery is the rule, not the exception. *The sower who first turns up at a patent office will reap; the other sower will rue.*[296]

Juxtaposing the nature of scientific development with the legal atomistic view of the patent system draws attention to two main points. First, the failings of our current

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[292] Kuhn, *supra* note 278 at 55.

[293] See *e.g.* Richard R. Nelson, "The Market Economy, and the Scientific Commons" LEM Working Paper Series 2003/24, November 2003, online < http://www.lem.sssup.it/WPLem/files/2003-24.pdf>. Market stimulated and guided invention is often "dependent on the strength of the science base from which they draw. This science base largely is a product of publicly funded research and the knowledge produced by that research is largely open and available for potential innovators to use....While the privatization of the scientific commons up to now has been relatively limited, there are real dangers that unless halted soon important portions of future scientific knowledge will be private property and fall outside the public domain." *Ibid,* at 2.

[294] See s. 28.1, of the CPA, *supra* note 82.

[295] Paul Edward Geller, "An International Patent Utopia" (2003) 85 J. Pat. & Trademark Off. Soc'y 582 proposes an interim patent system to overlay national first-to file and first-to-invent systems with a first to post (on the internet) system into a globally distributed database searchable for prior patent files publicly laid open and subject to a global novelty determination to overcome the 'winner-take-all effects.'

[296] Vaver, *IPL, supra* note 34 at 7, footnotes omitted. This criticism can extend to prizes as well if we recall how the contributions of Rosalind Franklin to the DNA structure discover was only later acknowledged. See "DNA Basics" Genome Canada, online http://www.genomecanada.ca.

regime warn against taking a primarily Western conception of science and intellectual property rights,[297] with internal flaws best resolved nationally, and transplanting them to international fora, as standards to which *all* countries must adhere. Rosemary Coombe cautions:

> The maps imagined and inscribed by the global harmonization of intellectual property rights—level playing fields upon which equal partners reciprocally exchange rights recognized in homogeneous jurisdictions—have obvious distributional consequence (which...adversely affect the creative works of indigenous peoples, women, and the vast majority of peoples in the Third World generally)....Not only has the author/work relation been expanded in scope, but just as significantly, authorial rights have been exported *without* the defenses, the exemptions, or the constitutive role of the public interest that provided their historical justification.[298]

Second, we should be wary of racing to provide more, stronger, and increasingly restrictive protection paradigmatically incongruent and cognitively dissonant with the scientific process. Richard Nelson expresses grave concern over the eroding scientific commons. Keeping scientific findings in the public domain, tying the reward of the scientist to the acclaim of fellows, providing public funding of research based on peer review of the scientific promise of both the proposal and the scientist are all important parts of an incentive and control system for fostering productive science.[299] He argues two policy arenas bear on this issue of preserving an appropriately wide area of public scientific knowledge: intellectual property law and policies of universities, public labs, and the government regarding their research findings. According to Frederick Abbott, "societies, for centuries, evolved on the basis of informal transfers of knowledge and

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[297] For a critical examination of law as a form of cultural appropriation, see Coombe, "Authorial Cartographies", *supra* note 58: "The very tropes of discovery, invention, naming, and originality that animate modern intellectual property laws emerge from a historical era in which Europeans mapped the world in their own image—ignoring the human ecologies of others and denying the value to the pre-existing worlds of meaning in which such phenomena figured ontologically and spiritually....We can see the same processes at work in contemporary political debates—in the so-called "New World Order" – as authorial tropes are deployed to legitimate new forms of social domination. Emergent elites naturalize their claims to represent the global "we"—protecting "our" biodiversity and preserving "our" gene pool – while attaching their own signatures to the mappings they effect."

[298] *Ibid.* at 1365.

[299] Nelson, *supra* note 293.

technological advances in know-how, from masters to students, from fathers to sons, from mothers to daughters."[300] Coordination of regulatory policies to maximize welfare gains would have to entail a review of public education institutions and existing national and international "reward" systems for scientists because knowledge production and transfer has historically been the essence of universities.

The DNA structure was discovered in the course of doctoral research during a time when property and profit were not yet fully subsumed in the hegemonic imperatives that define the current *zeitgeist.* DNA offered little insight into the messages encoded in the double helix or how to read them but was critical for future understanding of its function in conveying genetic information, mutation, and self-replication.[301] It was the discovery of the structure that effectively instigated the genetic revolution. Amongst the scientific community, it was widely anticipated that biotech would enable the improvement of human, social, and health conditions; global multisectoral collaborative projects were organized towards this end.

3.2.2 The Human Genome Project, HGDP, HAPMAP & GAIN

The next stage of genomic R&D was characterized by private/public competition and commercialization issues relating to the identification of genes coded by DNA sequences.[302] The Human Genome Project (HGP),[303] a conglomerate of coordinated efforts by international scientists to map the entire human genome was initiated in 1988

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[300] Frederick Abbott, Thomas Cottier & Francis Gurry, eds., *The Making of the International Intellectual Property System* (The Hague: Kluwer Law International, 1999) at 130.
[301] See *e.g.* Davies, *supra* note 5.
[302] Genes are contained in chromosomes. Only 2% of the human genome is compromised of genes, the "specific sequences of bases that encode instructions on how to make proteins....The remainder consists of noncoding regions, whose functions may include providing chromosomal structural integrity and regulating where, when, and in what quantity proteins are made." Online: <http://www.ornl.gov/sci/techresources/Human_Genome/project/info.shtml>. See also "Cracking the Code" *TIME Magazine* 156:1 (3 July 2000) ["Cracking the Code"].
[303] Online: <http://www.ornl.gov/sci/techresources/Human_Genome/faq/faqs1.shtml#HGP>.

and formally commenced in 1990. Eighteen countries with national human genome programs participated with the common goal to complete the sequence for the three billion DNA subunits (bases) and to share these results for further study to the mutual benefit of all. With Watson directing the US project, the government approved a 15 year $3 billion dollar plan for the effort with funding coming from the U.S. National Institutes of Health (NIH) and the Department of Energy (DOE).[304] Watson resigned after only a few short years due to disagreement with Bernadine Healy, the Director of NIH over gene patenting. Kevin Davies explains:

> Healy strongly supported a controversial NIH decision to seek patents for hundreds of gene fragments identified by NIH scientist Craig Venter, if for no other reason than to obtain clarification from the Patent Office on the legitimacy of patenting genes of no known function....To add insult to injury, Healy asked Venter to consult on the future of human genome research at the NIH while instructing Watson not to go public with any further criticisms.[305]

In 1992 Craig Venter established his own non-profit research institute, The Institute for Genomics Research (TIGR),[306] as the NIH would no longer fund his genetic research.[307] By 1998, near the halfway point of the HGP, only 3% of the targeted sequencing in the HGP was completed. Craig Venter abandoned the public project and formed Celera Genomics to pursue a rival private for-profit effort to map the human genome with a "shotgun" technique and a smaller budget of $300 million for 3 years. His motto, "Speed matters. Discovery can't wait." With the NIH establishing the

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[304] The link with the Department of Energy is clearer now. Engineered "food" can also be used as industrial based stock, such as genetically modified corn for use as a fuel source. The American government has initiated new policies for encouraging biotech genetic research to "produce enzymes that will convert agricultural biomass or waste into fuels, plastics, and other bio-based products." The U. S Department of Agriculture and the Department of Energy have allocated $250 million for such projects and one possibility is to use "genetically engineered plants that contain higher than normal sugar and starch contents or make plastic precursors in their stalks." Fecenko, *supra* note 249 at 34. Some accounts relate the birth of the HGP with creating a funding opportunity, see Daniel S. Greenberg, *Science, Money, and Politics: Political Triumph and Ethical Erosion,* (Chicago: The University of Chicago Press, 2001).

[305] Davies, *supra* note 5 at 31.

[306] Online: The Edge Foundation <http://www.edge.org/3rd_culture/bios/venter.html>.

[307] "The Top 25 Managers of the Year" (2001) online: Business Week, <http://www.businessweek.com/2001/01_02/b3714007.htm>.

dangerous precedent of DNA patentability, Venter knew that biotech would be big business and genetic information its currency;[308] he saw for himself a ripe business opportunity.

In the meantime, Watson was succeeded at the NIH by medical geneticist Francis Collins, a devout believer in the public good quality of genomics and open access to the results.[309] Although too late for legal purposes, by this point the NIH had changed its position on patenting DNA in the interests of promoting science, medical progress and new scientific collaborations. Davies comments on the early dynamic of the relationship between the for-profit Venter and not-for profit Collins:

> Venter's intent was for his company, Celera Genomics, to sequence the human genome years before expectation (leaving thousands of gaps if need be), to be able to patent hundreds of genes and sell precious information about the genome sequence for a gene king's ransom to the pharmaceutical industry. Collins's task was to kick-start an unwieldy federal program to keep pace with Venter's private effort and deliver the complete, gold-standard sequence years earlier than projected, all the while releasing its DNA data every night to make the human genome unpatentable.[310]

In the summer of 2000, for political reasons related to maintaining the integrity of science and in order to "restore a measure of dignity to the quest for the human genome", the race "was declared over" [311] and Collins stood together with Venter in a ceremony at the White House as President Clinton announced "[t]oday we are learning the language in which *God created life.*"[312] Still, no contribution is deemed more divine than that of a few select men such that by 2001, Venter was named one of the top 25 managers of the year in the United States; his company Celera Genomics went on to generate $43 million

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[308] "The human genome...contains riches of almost inestimatable value." See Davies, *supra* note 5 at 33.
[309] Francis Collins reiterated this position recently as keynote speaker at a conference on Public Health Genomics at which I presented a poster of my Equitable Conduct Defence (see chapter 6 of this dissertation). Francis Collins, "Genomic Medicine: Opportunities and Responsibilities", Genomics and Public Health: 4th International DNA Conference, Montreal, June 4-7, 2006.
[310] Davies, *supra* note 5 at 6.
[311] *Ibid.*
[312] *Ibid.*, emphasis added.

dollars not through drug related revenue, but by selling subscriptions to its online database of sequenced DNA. Customers included drug companies, universities, medical centres and the Australian government.[313] Venter took for granted the public community based efforts that preceded and enabled his success. His story reminds us of the discordant policy of the patent system to reward the "first to sow" without considering who cultivated the land. He could not have done it, however, without the faulty operation of the administrative system that generously "rained" on him by exercising its statutory discretion to expand the private rights of patent holders and reward labour, not innovation, expended to discover naturally existing genetic sequences - even where their utility was admittedly unknown or if known, was linked only with the *propensity*, not the actuality, of developing a related illness. The public HGP was completed in 2003 and the "full, finished sequence of the genome was deposited in public databases and made available to all."[314]

The Human Genome Diversity Project (HGDP) was a subset of the HGP and was approved by the Council of the Human Genome Organization (HUGO) in 1994. Anthropologists, geneticists, doctors and linguists undertook the HGDP in order to expand the focus of the HGP to determine the genomic variation amongst a greater diversity of the world's peoples by broadening the scope of populations studied. The HGDP was to provide a database for the further study of human biological and migratory histories but failed for funding reasons tied to the significant controversy it garnered based on poor politics in sanctioning mapping efforts targeted primarily at "isolated *indigenous* communities", without proper protocols for informed consent, proposals for

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[313] *Ibid.*
[314] Collins, *supra* note 309, abstract of speech.

benefit sharing, and means to manage patent controversies.[315] The HGDP did draw attention to the need for regulatory instruments to sort out the social, ethical and legal issues relating to the scope and implication of this new knowledge; particularly because of its special nature which holds the key to our future but also "carries the secrets of our past". Davies explains:

> Studies of the variation in the genome sequence between human and primates will reveal our evolutionary journey over the past 5 million years. Genome studies also shed light on the movement of populations out of Africa and across the globe over the past 100,000 years, revealing hidden truths about our identity as a population and as a species. DNA sequence variations also provide a unique molecular fingerprint of the living and the dead....[316]

In response to the HGDP, common principles of understanding emerged internationally regarding genetic knowledge, its accrual, use, and access in order to ensure that the inherent power of genetic information would be harness for *all* of the world's peoples.[317]

The HAPMAP project (haplotype map) grew out of the HGP and effectively replaced the HGDP. It began with $100 million in funding and involved a new consortium of nine research groups from both private and public labs in five countries using blood samples from people in Nigeria, Japan, China, United States and Europe. Its aim was to understand how the 3 billion bits of DNA in the genome are organized into

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[315] See Amani and Coombe, *supra* note 49 at 179-80 and WIPO Magazine, "Bioethics and Patent Law: The Cases of Moore and the Hagahai People" Issue 5, September 2006 regarding controversy over the patenting of a cell line infected with a Papua New Guinea Human T-Lymphotropic Virus (HTLV) variant, and to vaccines for human-related diseases. The cell line was derived from blood taken from a member of the Hagahai, an isolated indigenous tribe in Papau New Guinea who enjoyed immunity from leukemia, even though they carried a gene that predisposed them to it, because of the presence of a T-lymphotrophic virus. The patent was later abandoned. Online: WIPO Magazine, <http://www.wipo.int/wipo_magazine>.

[316] Davies, *supra* note 5 at 9. See also "Of Jaws and Man: Initial decoding of elephant shark genome helps uncover ancient DNA in human genome" Press Release, December 21, 2006, online: J. Craig Venter Institute < http://www.venterinstitute.org/press/news/news_2006_12_21.php>.

[317] Amani and Coombe write that "[m]odel ethical protocols were eventually developed for the Project, but until these are enshrined in legislation, they have little legal weight, except perhaps as "customary norms" that might be appealed to in domestic courts as relevant international law. Principles of informed consent, maximizing benefit, minimizing harm, confidentiality, and the avoidance of conflict of interest became accepted as guiding principles amongst the regional committees of the Project." *supra* note 49 at 166. See also discussion in text, *supra,* pages 70-74.

sequence variations – 10 million of them common to all called SNPs[318] – which cluster in neighbourhoods described as haplotype blocks; these genes are closely grouped together and are usually inherited as a group such that variation within the group might explain diseases inherited from that genetic source. Collins reports:

> A significant recent addition to the genomic tool box is the completion of the International HapMap Project, a flagship effort launched in 2002 to begin translating the wealth of data generated through the [HGP] into knowledge and tools applicable to understanding human health. The fundamental goal of the HAPMAP project was to provide scientists around the globe with the tools necessary to fast-track analysis of the 0.1% of human DNA that varies between individuals by making the data produced through the Project *freely available.* It is this small percentage of the total DNA complement that conveys the genetic basis for observed differences in disease susceptibility, as well as differential responses to therapeutic drugs, toxic substances, and environmental factors. With the application of HAPMAP to carefully phenotyped case-control studies, we are poised to identify the genetic variants that contribute to common disease such as diabetes, mental illness, and heart disease.[319]

Single letter insertions or deletions in the 3.1 billion base pairs can eliminate an entire gene or act as disease causing mutation. There are some 3,000-4,000 hereditary diseases that are related to errors in the genetic code including cystic fibrosis, muscular dystrophy, and specific genes have been correlated with a greater likelihood of developing a number of common illnesses like diabetes and a variety of cancers including breast,[320] ovarian, stomach,[321] and colorectal;[322] most are patented. The HGP and HAPMAP projects have

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[318] "Single nucleotide polymorphisms or SNPs (pronounced "snips") are DNA sequence variations that occur when a single nucleotide (ATC or G) in the genome sequence is altered....to be considered a SNP, it must occur in at least 1% of the population. SNPs, which make up about 90% of all human genetic variation, occur every 100 to 300 bases along the 3-billion-base human genome[,]....can occur in both coding and noncoding regions of the genome[,]...[and] [m]any SNPS have no effect on cell function, but scientists believe others could predispose people to disease or influence their response to a drug...This makes SNPs of great value for biomedical research and for developing pharmaceutical products or medical diagnostics. SNPs are also evolutionarily stable --not changing much from generation to generation -- making them easier to follow in population studies." Human Genome Project Information, SNP Fact Sheet, online http://www.ornl.gov/sci/techresources/Human_Genome/faq/snps.shtml#snps.

[319] *Supra* note 309.

[320] For information on the genetic basis of breast cancer, visit http://www.breastdiseases.com/risksfac.htm.

[321] Genetic screening can determine whether an individual carries a gene linked with a rare form which renders him 80% likely to develop the disease. See "Research at Stanford Links Stomach Cancer Deaths to a Single Gene", December 11, 2002, online: <http://mednews.stanford.edu/releases/2002/december/stomachcancer.html>; "Genetic Cause of Stomach Cancer" April 25, 2002, at http://news.bbc.co.uk/1/hi/health/1949530.stm.

facilitated the discovery of disease-related genes which has in turn led to the development of predictive tests to identify genetic predisposition, diagnostic tests for cancer detection in its earliest stage, and therapies targeting abnormalities in cancer cells. Predictive genetic technologies for gene related cancers are an important tool for health outcomes as all cancers arise from genetic alterations and 5-10% are hereditary.[323]

The Genetic Association Information Network (GAIN) launched in 2006, is the latest of research collaborations and is based on a private-public partnership between the Foundation for the National Institutes for Health (FNIH), the National Institutes of Health (NIH), and Pfizer Global Research & Development. Its goal is "to unravel the genetic causes of common diseases over the next three years...The information derived from GAIN will be *publicly available* to researchers world-wide." [324] GAIN signals overdue recognition that genetic data is a public good that should be *pre-competitive* and not subject to intellectual property rights claims, even when research efforts involve private (corporate) actors. In addition,

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[322] Fecenko, *supra* note 249 at 13. See also Andrea D. Brashear, "Evolving Biotechnology Patent Laws In The United States and Europe: Are they Inhibiting Disease Research?" (2001) 12 Ind. Int'; & Comp. L. Rev. 183 at 186-187.

[323] Mikael Rorth, "Cancer Diseases and Heredity", International Health Insurance, http://www.ihi.com/english/individual/27/335.asp. Other gene linked illnesses are HMPCC with colorectal cancer and G6PD with adult onset diabetes. Mikael Rorth, "Cancer Diseases and Heredity", International Health Insurance, http://www.ihi.com/english/individual/27/335.asp. Diagnostic screening for a gene-based chronic disease does not predict that the individual carrier will actually develop the disease but is more statistically likely to. It allows behavioural and environmental changes such as nutritional counseling, diet modification, and sometimes elective surgical procedures (e.g. preventative mastectomy or removal of other organs, such as ovaries or colons). The health gains extend beyond the individual in clinical medicine to potentially whole families who show a clinical history of the illness. For example, eleven family members, the largest ever related group, all descendants of a rare CDH1 gene mutation linked with a 70% increased risk of cancer elected to have their stomachs preemptively removed, "determined to outsmart" this rare form of cancer that only affects 100 families worldwide. Alicia Chang and Malcolm Ritter, "Stomachless Clan Pioneers Prevention of Inherited Cancer" June 19, 2006, Arizona Star, http://www.azstarnet.com/news/134206.

[324] National Human Genome Institute, "Novel Public-Private Partnership Created to Unravel the Genetics Of Common Disease Through Whole Genome Association Studies", February 2006, online http://www.genome.gov/17516722.

> [b]ecause benefiting regions may not coincide with political boundaries[,]...[t]he benefits of public goods provided by one state may spill over into others. As a result provision becomes an international and, with unlimited benefit space, global issue....The more global is the region over which benefits extend, the greater the need for global policy instruments.[325]

Global institutions like the United Nation's World Health Organization (WHO) have emphasized the importance of free access to genetic information for unleashing the full potential of genomics and realizing the promises of biotechnology for all. In a 2002 WHO Report on Genomics, it was observed that

> [t]here are profound concerns that current practices in intellectual property, particularly regarding the granting of patents on fundamental genetic information will place many Member States at a considerable disadvantage in realizing equitably the health care potential of genomics. *WHO should adopt a proactive role as an advocate for health equity in international debates on intellectual property issues.*[326]

WHO's position is consistent with that of public scientists, the HGP, HAPMAP, and Genome Canada in publishing new and emerging genetic data on public websites and databases as soon as possible. This helps ensure that "data are being made swiftly and freely available to public databases,"[327] thereby foreclosing genetic patenting on the basis that 'public domain' information lacks novelty.[328] It also openly subverts the de facto patent policy of patent offices in expanding IPRs through the privatization of genetic information. Before examining the perfidies of patent practice, it is important to have an operational understanding of patent law. That is provided next.

3.3 Canadian Patent Law: A Primer

A patent is an exclusive statutory right within each territorial jurisdiction to use, manufacture, sell, or import an invention for a period of 20 years from the date of

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[325] Kaul *et al.*, *supra* note 191 at xi.
[326] WHO "Genomics and World Health Report 2002" at http://whqlibdoc.who.int/hq/2002/a74580.pdf.
[327] See Genome Canada online: <www.genomecanada.com>; Canadian Program on Genomics and Global Health, online: University of Toronto, < http://www.utoronto.ca/jcb/genomics/index.html>; http://www.utoronto.ca/jcb/genomics/documents/Convergent_Biotechnology.pdf
[328] Researchers are encouraged to access this data through the HapMap Data Coordination Center, the NIH-funded National Center for Biotechnology Information's dbSNP and the JSNP Database in Japan. Visit, www.hapmap.org; http://www.ncbi.nlm.nih.gov/SNP/index.html; and http://snp.ims.u-tokyo.ac.jp/).

filing.[329] The exclusive nature of this right, its transfer, sale, inheritance, and that the patent owner can exclude others from using, making or selling the invention attracts the "property" label despite the poor conceptual fit. Since patents allow the owner to exclude others who have independently invented a similar product or process, the nature of these rights are stronger than those found in other forms of intellectual property and harder to justify on the basis of *fairness* alone.[330] Rather, legal protection is theoretically based on the public *benefits generated* on the incentive rationale with sufficient disclosure to enable one skilled in the art to work or use the patent.

3.3.1 Disclosure & Claims: Two Parts to the Patent

A patent has two parts- the "specification", also referred to as the "description" or the "disclosure", and the "claims." The disclosure essentially functions as a "how-to" guide, providing information so that others are able to make and use the invention. Section 27 of Canada's Patent Act establishes the technical requirements for a patent application. Section 27(3) provides that the specification of an invention must

> (a) correctly and *fully* describe the invention and its *operation* or *use* as contemplated by the inventor;
>
> (b) set out *clearly* the various steps in a process, or the method of constructing, *making*, compounding or using a machine, manufacture or composition of matter, in such a full, clear, concise and *exact* terms as to *enable any person skilled in the art or science in which it pertains or with which it is most closely connected, to make construct, compound or use it;*
>
> (c) in the case of a machine, explain the principle of the machine and *the best mode in which the inventor has contemplated the application of that principle; and*
>
> (d) in the case of a process, explain the *necessary sequence,* if any, of the various steps, *so as to distinguish the invention from other inventions.* (emphasis added).

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[329] The 20 year period under s. 44 of the CPA, *supra* note 82, is now the standard minimum under TRIPS Article 33.

[330] The consideration of justice or fairness is premised on ideas of entitlement: inventors should be compensated for the investment of their time, labour, skill, and knowledge with a return on their investments. In the law of copyright, for example, independent creation is not infringing of a copyrighted work. There, it is easier to argue that fairness requires creators of works of value be paid for the benefits they generate. See Gordon, "Harms and Benefits" *supra* note 26 at 450.

The statute mandates the inclusion of sufficient detail to make the invention disclosed enabling to one skilled in the art to make and use it for its stated purpose.[331] That means that skilled readers should have enough information to allow experimentation with and improvements on the invention during the patent term and for the invention to be practiced with little difficulty under licence or upon expiry. Since this is an integral aspect of the bargain with the crown, "[i]f, at the end of the day, this purpose fails because of genuine doubts about what the disclosure reveals, the whole patent should be invalid."[332] Section 53(1) of the CPA provides, "[a] patent is void if...the specification and drawings contain more or less than is necessary for obtaining the end for which they purport to be made..."

The claims describe the invention to which the exclusive legal rights attach, providing a legal boundary enclosing the patentee's rights. Section 27(4) of the CPA provides that "[t]he specification must end with a claim or claims defining distinctly and in explicit terms the subject- matter of the invention for which an exclusive privilege or property is claimed." The two parts of the patent create a tension fecund for technical and legal debate as well as abuse.[333] On the one hand, the description must be sufficiently detailed to allow the inventor to distinguish the invention from others existing in the prior art[334] (and thereby is narrowly drafted to ensure that the inventor is not

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[331] CPA, *supra* note 82, s. 28.3.

[332] Vaver *IPL, supra* note 34 at 141. For a discussion of how this requirement of the patent system can be used to limit broad biotech patents, see Alison E. Cantor, "Using the Written Description and Enablement Requirements to Limit Biotechnology Patents" (2000) 14.1 Harv. J.L. & Tech 267.

[333] "The game for patentees, especially in highly competitive industries, is to reveal as little and to claim as much as possible. The less disclosed, the more that can be retained as competitive edge. The wider one claims, the tougher it is for imitators. But the specification must stay clear of the known and the obvious. It must demonstrate and claim only something over and above existing technology. Much patent drafting involves trying simultaneously to achieve these aims." Vaver, *ibid.* at 139.

[334] Prior art is a legal term that describes inventions, literature, or other existing documentation that proves that the idea being protected by a patent is not new but has been previously publicly disclosed. The

himself a patent infringer) and still must be specific enough to allow another person skilled in the art to work the patent.[335] This is because claims will be found to be invalid upon challenge if they are broader than the disclosure made.[336] On the other hand, in order to ensure maximum protection of legal interests and to reduce the likelihood and degree of their competition, patentees have good reason to try and disclose the minimum necessary in order to get the claims. Optimal disclosure would be enough to secure a valid patent but not so much as to forfeit market dominance. Consequently, claims are typically very abstractly drafted, narrowing further in scope with each additional claim to help ensure the full spectrum of protection. Upon court challenge, any of the claims may be held invalid without compromising the validity of the remainder. And, of course, "what is not claimed is disclaimed."[337]

The *person having ordinary skill in the art* (PHOSITA) in patent law is very much like *the reasonable person* in tort law[338]- an ever-elusive fictional person creating a nebulous legal standard. Dan Burk and Mark Lemley observe that much of the variance in patent standards is attributable to the use of this legal construct to determine

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problem is that prior art may be difficult to find at the time of the patent application which is why a number of recommendations have been made to create national and international databases of prior art.

[335]Justice Binnie describes PHOSITA as "a hypothetical person possessing the ordinary skill and knowledge of the particular art to which the invention relates, and a mind willing to understand a specification that is addressed to him. This hypothetical person has sometimes been equated with the "reasonable man" standard in negligence law. He is assumed to be a man who is not going to try to achieve success and not one who is looking for difficulties or seeking failure." See *Free World Trust v. Electro Santé Inc.*, [2000] 2 S.C.R. 1024, 2000 SCC 66 at para 44. quoting from H.G. Fox, *The Canadian Law and Practice* Relating to Letters Patent for Inventions (4th ed. 1969) at 184.

[336] *Monsanto Canada Inc. v. Schmeiser,* [2004] 1 S.C.R. 902, 2004 SCC 34 [*Schmeiser SCC*] at para. 124, citing *Amfac Foods Inc v. Irving Pulp & Paper Ltd.* (1984), 80 C.P.R. (2d) 59 (F.C.T.D.) at 80 providing a long list of authority.

[337] Vaver *IPL, supra* note 34 at 139.

[338] For a deconstruction of the reasonable person's identity, see generally Mayo Moran, *Rethinking the Reasonable Person: An Egalitarian Reconstruction of the Objective Standard* (Oxford: Oxford University Press, 2005).

obviousness and enablement, rendering the courts gatekeepers of the privatization of new technology:

> The more skill those in the art have, the less information a patentee has to disclose, but the harder it is to find an invention nonobvious. One reading of the biotechnology and computer software cases is that the Federal Circuit believes computer programmers are extremely skilled, while biotechnology experts know very little about their art. We do not challenge the idea that the *standards in each industry should vary with the level of the skill in that industry*....[T]he use of the PHOSITA provides needed flexibility for patent law, permitting it to adapt to new technologies without losing its essential character....The level of skill in the art affects not just patent validity, but also patent scope.[339]

Even if one were able to locate the PHOSITA, as Vaver notes, the meaning of the patent is ultimately a question of law to be "decided by a judge who usually is not skilled in any art or science, let alone the relevant one."[340] Judges have complained, on more than one occasion, of the linguistic ambiguity in claim drafting.[341] This compounds the existing difficulty in understanding the boundaries to technologically specific and often complex inventions. Yet the complaints seem to have little impact on judicial findings of claim validity, and therefore on the drafting practices they critique. Normally, a challenge to patent validity follows defensively as a counterclaim to a patent infringement suit. To a certain extent, the ambiguity in claims drafting is deliberate in order to benefit from the doctrine of *purposive construction* used by the courts in order to save litigated claims. This doctrine directs judges when reading the patent not to construct a claim too narrowly or literally.[342] If the claim says perpendicular, then a

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[339] See Burk & Lemley, *supra* note 66 at 2-3.
[340] Vaver *IPL, supra* note 34 at 140.
[341] See *Xerox of Canada Ltd. v. I.B.M. Canada Ltd.* (1977), 33 C.P.R. 24 at 88, n. 14, where the judge complained that claims such as the one before the court passed from "riddle to enigma"- the claim to collect used toner from photocopiers was a sentence made of 178 words with little punctuation. See also the 281 word claim also held valid after a nine day trial despite some earlier proclaimed doubts by the judge during interlocutory proceedings. Vaver, *ibid.* at 141. *Risi Stone Ltd. V. Group Permacon In.* (1990), 29 C.P.R. (3d) 243 at 247-248 (Fed. T.D) (interlocutory); (1995), 65 C.P.R. (3d) 2 at 9 (Fed. T.D.) (trial).
[342] See *Catnic Components Ltd. V. Hill & Smith Ltd. (1980),* [1981] F.S.R. 60 at 65-66.

purposive construction, Vaver suggests, would be to interpret it as "more or less perpendicular."[343]

The fence drawing exercise of claim drafting has other problems still. What some call "kitchen sink" patents,[344] others refer to as "reach through claims" for the tendency of the patentee to claim too broadly- to reach through the invention- to privately enclose more than that which is invented.[345] Reach through claims are anti-competitive and reflect the patentee's desire to demarcate as much of the market in a particular field of technology as falling within his or her legal rights. This is a common behaviour in the biotech sector as evidenced by the patenting of DNA sequences of no known or disclosed utility by both the NIH and Celera Genomics. The patentee's spot is 'reserved' for later and broader applications of the disclosed technology (i.e. DNA sequences).

Suppose, for example, that I have "invented" X- which means I have met all legal conditions of patentability. Claim one in my patent would be abstracted to the broadest possible interpretation of what the invention is- the whole of an alphabet comprised of letters, which contains my X. My claim to the alphabet subsuming my invention X, worse yet if granted, gives me a patent lottery because it reaches through to provide me with legal rights more expansive than that for which I invented. If we consider genetic sequences as the alphabet coding for the "book of life", the danger with patenting the alphabet as a whole, or any of its letters, is more readily apparent. Both alphabets are necessary for communicating information and rather than provide network gains, network

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[343] Vaver *IPL supra* note 34 at 142.
[344] See Rivette & Kline, *supra* note 253 at 21 which get their name "because they [the patents] sometimes appear to be asserting ownership of everything under the sun…"
[345] See Keynote Address, Rebecca S. Eisenberg, Dual Controversies of the Double Helix: Challenges of Regulating the Information and Property Aspects of Genetic Technology, *Reaching Through the Human Genome,* Keynote Address. Webcast, online: Centre for Innovation Law and Policy <http://www.innovationlaw.org/tip/pages/genetic_technology.htm>.

losses are created when letter(s) (sequences) or even words (genes) are patented. The genetic alphabet is not culturally constructed, however, but inherited by us from nature. There is no "inventive" quality to this endowment other than through our procreation and self-maintenance, neither of which occurs in the lab nor is legally credited, but can be ascribed to our evolutionary communal "authorship", jointly with nature.[346] The broad claims, if granted, are disingenuous and a breach of the "bargain with the crown" rationale for granting monopoly rights. They are inefficient and upset the proverbial trade-off of short-term monopoly costs for long-term welfare gains. These claims do not serve the public interest because they attract more rights than are merited from the disclosed "invention". If granted, they are anticompetitive in nature and due to the presumption of validity and high cost of litigation, will nevertheless define the scope of legal rights used as the basis for extracting royalties until successfully challenged.

3.3.2 Patentability Requirements

Not all inventions are legally recognized. A patent for Canada must be applied for at the Canadian Patent Office (CPO) and is granted by a patent examiner if it meets the requirements for "invention". Essentially, so long as the invention, which could cover product and process claims, meets the statutory definition, falls into the scope of patentable subject matter i.e. is not expressly excluded in the statute, and is new,[347] useful,[348] non-obvious[349] and fully disclosed,[350] then it *must* be patented without

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[346] Donna MacLean, a disgruntled British waitress and poet picked up on this fact when, in an act of protest on the proliferation of gene patents, she filed a patent application, GB0000180.0 on herself, claiming that she was not new, was useful and was not obvious. See discussion in Amani and Coombe, *supra* note 49.

[347] See CPA, *supra* note 82, s. 28.2(1). Novelty refers to the fact that the invention has not yet been disclosed in public. Before a patent is granted there is a search of the prior art (that is any material already in the public domain) to ensure that the application is in fact a new invention and that as far as is known in good faith, it does not infringe any other patented inventions in that jurisdiction.

[348] Utility, in relation to inventions "means industrial value" elsewhere it may mean industrial application and in any event "must be apparent from the description to one of skill in the art." See Industry Canada,

discretion of the Patent Commissioner.[351] Section 2 of the CPA defines "invention" as "any new and useful art, process, machine, manufacture or composition of matter." Even if it is new and useful, the invention claimed cannot be a development that would be obvious on the claim date to a person skilled in the art or science to which it pertains. The lower the threshold for novelty, utility and non-obviousness, the more inventions will be patentable. TRIPS is essentially silent on the content of these requirements. Restricting or expanding the legal definitions of these preconditions to patentability and raising the bar for the degree of skill of the PHOSITA in biotech applications are TRIPS compliant means of managing desired outcomes of patent policy. Patent applications are published 18 months after they are filed on the website of the relevant patent office before the patent is granted. Since the proceedings and the publications are not *publicized,* however, the ability to challenge a patent generally does not arise until after they have issued and public attention has been drawn to a potential conflict with public interest uses or human rights implications. The threat of a lengthy and costly infringement suit may be required to bring the patent under expert scrutiny, as the next example will show.

3.4 The Perfidy of Patents

The BRCA1, BRCA2 gene patents linked with the propensity to develop breast and ovarian cancers, and the patent for their genetic diagnostic test, are owned by Myriad

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Canadian Intellectual Property Office, *Manual of Patent Office Practice*, March 1998, s. 16.02.01. In short, the invention must have known and described utility but no model prototype displaying such utility/operability is required except for perpetual motion machines.

[349] CPA, *supra* note 82, s.28.3 of the *Patent Act* was added in 1993 as a codification of the requirement of inventiveness that was imported by the case law. Section 28.3 of the *Patent Act* requires that the invention not be obvious and that it not be information publicly available "in Canada or elsewhere".

[350] This is an essential part of the bargain with the crown; it allows the new invention to immediately enter the common stock of knowledge although exclusive control remains with the patentee for the patent term.

[351] CPA, *supra* note 82, s. 27(1).

Genetic Laboratories Technologies Inc. (MGL), an American company based in Utah. Controversy surrounding alleged unauthorized use of these "inventions" forced gene patents into the centre of medico-legal and public health debates in Canada. Ontario's then Premier, Mike Harris, urged the Province to continue to provide women with genetic cancer testing despite MGL's claims that this constituted infringement of their exclusive rights. Ontario had not obtained a licence from MGL or their exclusively authorized licenced Canadian partner, MDS Laboratory Services[352] for the publicly funded test which cost the government $800 a person- a fraction of the cost ($3850) MGL demanded.[353]

The patents-public health relationship finally elicited the public, media, and regulatory attention it deserved.[354] British Columbia complied with cease and desist letters, referring cancer patients to Ontario for two years before resuming testing and demonstrating how corporate proprietary interests can now dictate provincial health policy. Ontario Premier, Mike Harris, refused to back down, saying in a speech to the Ontario Advisory Committee on Predictive Genetic Technology that Canada needs to amend its laws to prevent privatization of human genes and that "[u]nlike new drugs, genes aren't invented- they are discovered. They have always existed." Harris urged that

> [t]he benefits of a world-wide effort such as the human genome project should not be the property of a handful of people or of companies. Our genetic heritage belongs to everyone. We must share

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[352] This example is explored in detail in an earlier publication, see Bita Amani, "Patents and Public Health" (2002) 22:3 Health L. Can. 76 [Amani, "Patents & Public Health"].

[353] See Robert Benzie, "Ontario to defy U.S. patents on Cancer Genes: Province Will pay for $800 test, not $3850 version by Myriad Genetic Laboratories Inc." National Post, 20 September 2001: A15.

[354] See *e.g.* Karen Palmer, Public Health Reporter, "Battle over cancer gene test U.S. company's patenting claim called 'abhorrent'" Organic Consumers Association, 01/09/2003 online www.organicconsumers.org/Patent/010903_patent.cfm; Canadian Cancer Society (CCS) and National Cancer Institute of Canada (NCIC) Position Paper on the Patenting of BRCA1 and 2 genes, March 8, 2002; James Meek, "US firm may double cost of UK cancer checks" The Guardian, January 17, 2000, online http://www.biotech-info.net/US_firm.html; Council for Civil Liberty, "Patenting Breast Cancer.

> its benefits fairly. We must do what we can to make genetic tests and therapies affordable and accessible...if we have the ability to save a life, we have the responsibility to do so.[355]

This was also the position of other international governments who grappled with the cost of Myriad's patent on public health delivery. In France and later Europe, MGL's patents were attacked on the basis that they failed to meet statutory requirements. What was at first a dispute between the Institut Curie and MGL eventually spilled over into all of Europe, involving the French government and European Parliament. The problem of gene patenting was further compounded by the fact that some of MGL's claims were too broad and effectively reached through to limit alternative and possibly more accurate genetic testing by assuming a monopoly on *all* BRCAnalyses. Rather than continue as a potential infringer or subvert health policy, the Institut Curie, the Assistance Publique-Hopitaux de Paris and the Institut Gustave-Roussy filed an opposition notice with the European Patent Office (EPO) which, following public hearings on May 17 and 18, 2004, resulted in the revocation of MGL's patents for BRACAnalysis®; the gene patents were revoked for lack of novelty.[356] The Canadian Cancer society reports that since the

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[355] Benzie, *supra* note 353. In fact, aside from the commodification factor, Craig Venter's view is not too different from that expressed by Harris. In an interview with CNN, Venter concedes that his is "an information company" and that "[w]e consider that we are making discoveries, we're not making inventions, with the primary sequencing. In the U.S., patent law makes no distinction between inventions and discoveries. European law does make that decision -- it has to be an invention, not a discovery. So it is an important difference in different parts of the world and that's why there are different cultures with it." His views very much support a 'common heritage' perspective as evinced from his comments on the shared sequence for some proteins in mice and men: "[I]t's critical because it shows that we're part of this entire genetic repertoire on this planet. We didn't evolve separately from everything else, we evolved through this effort of billions and billions of years working back from single cell organisms to more and more complex organisms. We have the same genes as in the bacteria. The enzymes that correct defects, the genetic code from radiation damage, UV damage in a bacteria, are the same ones that are related to cancer in humans." Stephen Frazier, "Blueprint of the Body", June 3, 1999, online: CNN <http://www.cnn.com/SPECIALS/2000/genome/story/interviews/venter.html>.

[356] See Dr. Mike Adcock, "Myriad Breast Cancer Patent Revoked after Public Hearing" May 24, 2004 online http://www.shef.ac.uk/bioethics-today/archives/files/Patentscomm.html; Amani, "Patents & Public Health" *supra* note 352; Amani and Coombe, *supra* note 49. For historical information over the gene patent, see generally, the CCS, "Background on the Patenting of BRCA1 and 2 Genes" online <http://www.cancer.ca>. MGL also holds the patent over HMPCC linked with colorectal cancer.

EPO "has not yet issued a written discussion that describes the specific reasons it revoked this patent...it is difficult to know what impact this will have, if any, in Canada."[357]

Such after the fact decisions of "revocation" are not the most desirable or efficient response to policy needs. They undermine the securities value of patents by increasing the level of uncertainty amongst patentees and the public as to the validity of the patent. The numerous examples that will follow of the absurd patents granted by the USPTO as "inventions" evince how patents are being rubber-stamped for inventions that are not new and in fact, are obvious even to the layperson unskilled in the art. Some of the reasons affecting quality may be ascribed to the paucity of resources and institutional deficits. However, poor quality patents can also be attributed to lax application of the substantive standards for patentability. This creates a porous system that unfortunately relies on private litigants as a means of maintaining quality assurance. In short, we rely upon industry competitors to subsidize a poor administrative system and to ensure that judges patch up its leakages. And, according to Arti Rai,[358] in the United States, when patents do receive judicial scrutiny, judges are more amenable to intervene (in *favour* of the patentee) where the patent application has initially been *rejected.* [359] Rai observes that:

> [f]irst, the Court of Appeals for the Federal Circuit's (CAFC) reversal of PTO decisions denying patent protection to certain biotechnology and computer program inventions has been a major reason for the proliferation of patents. Second, given the CAFC's frequent exercise of its ability to *reverse* PTO patent denials, PTO reform will, on its own, likely be insufficient. Third, at least for the time being, the most prudent course for addressing patent proliferation may not be a significant change in substantive patent law.[360]

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[357] See "Background on the patenting of BRCA1 and 2 genes" online: http://www.cancer.ca/.
[358] Arti Rai, "Addressing the Patent Gold Rush: The Role of Deference to PTO Denials," (2000) 2 Wash. U. J.L. & Pol'y 199.
[359] Chapter four will demonstrate how patents have been extended to higher life (animal and plant) by judicial fiat using this very method of interpreting and applying patentability requirements and the definition of invention but in an overly inclusive manner.
[360] Rai, *supra* note 358 at 201.

Rai attributes the proliferation of patents in "technologically complex" and "rapidly expanding industries" not to mere changes in substantive law, but also to the immediate impact of institutional actors and the roles that patent offices and courts play. She argues that a re-examination of the relationship between courts and patent offices is needed with greater attention to be directed at the application of administrative law principles:

> With respect to this relationship, considerations of institutional competence—particularly institutional resources and expertise—suggest that the CAFC [Court of Appeal for the Federal Circuit] should be wary of reviewing independently PTO's [Patent and Trademark Office] decision denying patentability. The CAFC's review should be particularly deferential when the denial is based on a determination that the invention is "obvious—that is, not truly new. Deference to patent denials is warranted moreover, even if the PTO continues to have skewed incentives as well as limitations on its own resources and expertise: these limitations will tend systematically to produce errors in patent grants, not patent denials. Indeed, as a consequence, PTO reform will be much more important for ensuring valid PTO patent grants than for ensuring valid PTO patent denials.[361]

Lax application of patent standards and institutional deficits are inter-related phenomena contributing to the creation of secondary incentives towards predatory market behaviour by patent holders. Evidence of "bad" patents (*bad* because they should never have issued if proper attention was given to patentability requirements) in sectors of little comparative importance should serve as a cautionary tale mandating extreme restraint and due diligence in biopatenting. They draw attention to the urgent need for regulatory and institutional reform - especially since the subject matter is of critical importance for a country's socio-economic and technical development, the realization of health and other human rights, and the regulatory discretion needed to meet the cultural and moral values that infuse the public's interest in biotechnology and its privatization.

3.4.1. Quality v. Quantity of Patents: The Rising Price of Presumptive Validity

Until only two decades ago the discussion of patents was an obscure and highly technical one left for the specialized few who were more interested in the underlying

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[361] *Ibid.* at 202.

invention than the broader social, ethical, and welfare issues concomitant with any emerging technology. As a result, stronger protections and their extension to new subject matter occurred with stealth through correspondence with the patent office rather than with public debate about the merits or impact of expanding protection on other policy areas of the regulatory state including public health delivery. The shift from quality patents to quantity patents has been subtle and is reflected in institutional perspectives regarding the desirability and the (false) correlation between patent numbers and innovative activity. The World Bank reports that between 1985 and 1995, the number of applications for US patents by US inventors rose in absolute and percentage terms faster than in any other decade (effectively doubling); by 1995, more than 120,000 patent applications were made in the US.[362] The European Patent Office estimates that 700,000 applications for all fields of inventions are filed annually, with patent protection being sought on average in four countries per invention. The current number of patents in force worldwide today is more than 4 million. Licencing revenues from patented products reached an estimated US$100 billion worldwide by 2000, increasing tenfold since 1990.[363] The OECD reports that "biotech contributed more than average to the overall surge in patenting. Between 1991 and 2001, biotechnology...patents filed at the EPO [European Patent Office] increased 8.3%" compared to the 5.7% for all EPO applications."[364] The World Intellectual Property Organization (WIPO)[365] recently

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[362]The World Bank (Discussion Paper No. 412) *Intellectual Property Rights and Economic Development* (2000).
[363] Cook, *supra* note 251at 6.
[364] Compendium of Patent Statistics (2005), online: http://www.oecd.org/dataoecd/60/24/8208325.pdf.
[365] See footnote 45, *supra*, for a description of this organization. Note, however, the objective of IP within the WIPO definition is to protect the rights of the public including access to protected creations.

celebrated the one millionth patent under the Patent Co-operation Treaty (PCT),[366] applauding this "success" with plans for electronic filing in the near future to facilitate a greater number of applications.[367] WIPO reports that

> PCT applications soared as businesses woke up to the strategic importance of intellectual property *assets*. It took 18 years to reach 250,000 applications but only 4 years to double that figure, and another 4 to double again.[368]

WIPO assumes, as do the EPO, United States Patent and Trademark Office (USPTO), Canadian Patent Office (CPO), OECD, and World Bank, that the world will benefit simply from *more* patents without considering the implication of *overprotection* or the need to ensure that the patents granted are in fact merited. There is consistent growth in patent applications and "patent grants have also risen during this period, but their level is affected by the degree to which Offices can cope with the rising tide of applications." [369]

A paucity of institutional and human resources at most patent offices in the developed world means that the current regime is incapable of providing full and thorough consideration of the growing number of applications before it. Patent offices in North America are so backlogged with applications that they cannot appropriately perform their delegated administrative duties nor function as effective gatekeepers of validly claimed monopolies.[370] While Canadian data is comparatively scant, the

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[366] The PCT provides a unified procedure for applying for a patent in various jurisdictions by allowing a single search and legal opinion even though the actual patent would still have to be granted by each jurisdiction separately. This facilitates the process of obtaining a patent within contracting states but does not grant a single internationally viable patent because such an instrument does not yet exist.
[367] See "PCT 2005 One Million and Counting" *WIPO* Magazine (February 2005) at 2 ["One Million"], online: <ttp://www.wipo.int/freepublications/en/general/121/2005/wipo_pub_121_2005_01-02.pdf>.
[368] *Ibid.* at 4. Yet, there is a fundamental error in assuming that what is correlative is actually causal such that greater innovation is offered as the only cause for the increased number of patents worldwide.
[369] Cornish, *supra* note 63 at 5.
[370] Patent fees, a major source of revenue for financing patent office administration, last changed in 1989 in Canada. They finally increased after more than a decade on January 1, 2004 under the Patent Rules to correspond to CIPO's new capacity as one of ten national offices with status as an International Search and

American statistics are telling. The Director of the USPTO advised in a recent report that while theirs is still the fastest and least expensive of the major patent offices of the world,

> the volume and complexity of patent applications continues to outpace current capacity to examine them. The result is a pending — and growing — application backlog of historic proportions. Patent pendency — the amount of time a patent application is waiting before a patent is issued — now averages more than two years. In more complex art areas, such as data-processing technologies, average pendency stands at more than three years. [371]

On average, only 18 to 36 hours are expended in the USPTO in reviewing an application and conducting the entire examination including searching prior art, interviewing applicants and engaging in correspondence.[372] The USPTO grants approximately 75% of patent applications. Courts invalidate some 46% of litigated patent claims but only a negligible 2% of patents, however, ever get litigated and "less than two-tenths of one percent of all issued patents actually go to court."[373] The costs of a full trial through appeal might approximate $1.5 million dollars for each party according to a study by Mark Lemley.[374] The reported growth in the number of patent applications and grants in the world's largest market reflects broader social trends that demonstrate a ""sharp increase" in the level of patent activity across the world."[375] Presumably the resource problems would be compounded by a shortage of skilled labour in similar offices in

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Preliminary Examination Authority under the Patent Co-operation Treaty. The new fee schedule applies to patents pending and granted patents regardless of when they were filed and marks a 33% increase from existing fees. Patent Co-operation Treaty (PCT) Transmittal fees have also increased, by 50% prompted by the growing complexity of applications, the demands for services and the corresponding inability to meet examination and execution needs. See CIPO online <http://cipo.gc.ca>.

[371] See USPTO, "Fiscal & Accountability Report 2005", online: <http://www.uspto.gov/web/offices/com/annual/2005/02_message_director.html>

[372] Lemley, "Rational", *infra* note 376 at 1508.

[373] John R. Allison and Mark A. Lemley, "Empirical Evidence on the Validity of Litigated Patents" (1998) at 208, online: SSRN < http://papers.ssrn.com/sol3/papers.cfm?abstract_id=118149>.

[374] Lemley, "Rational", *infra* note 376 at 1501-1502.

[375] See the OECD's Compendium of Patent Statistics 2005, http://www.oecd.org/dataoecd/60/24/8208325.pdf. See also "PCT 2005 One Million and Counting" *WIPO* Magazine (February 2005).

developing countries. What can we deduce from these trends regarding quality and validity?[376]

Presumptively valid patents have been granted in the United States for peanut butter and jelly sandwiches (No. 6004596), a method of using the washroom (No. 6329919), a method of swinging, side to side, (No. 6368277), and even a method for drafting patents (No. 6574645).[377] IBM boasts it is the only company to be issued more than 3000 patents in a given year, which it has done for three consecutive years. For the eleventh year in a row, it has ranked as the top recipient of the number of patents issued[378] with a portfolio that includes the obvious method of using a washroom (on airplanes) on a first come first serve basis. Does this mean that IBM is this much more innovative than its competitors or is it simply better at playing the patent game?

The proclivity to patent has been coupled by a trend in stockpiling patents. Microsoft's Bill Gates publicly reported in 2004 that the company planned to file 3000

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[376] Some authors defend the patent system when writing on quality and validity, see *e.g.* Mark Lemley, "Rational Ignorance at the Patent Office" (2001) 95.4 Nw. U.L. Rev. 1495 [Lemley, "Rational"]; while others criticize various components of the system within the context of a specific industry (i.e. biotech, software, or business methods). See *e.g.* Shubha Ghosh and Jay P. Kesan, "What do Patents Purchase? In Search of Optimal Ignorance in the Patent Office" (2004) 40 Hous. L. Rev. 1219 ["Optimal Ignorance]; in biotech, see *e.g.* Rai, *supra* note 358; for business method patents, see *e.g.* R.C. Dreyfuss "Examining State Street Bank: Developments in Business Method Patenting," (2001) Computer und Recht International 1, noting that weak prior art searches generate low quality patents and that the cost/benefit of business patents weighs in favour of their exclusion; R.C. Levin and J. Levin (2002) "Patent Oppositions", *Yale University and Stanford University Working Paper No.* (March) recommending the introduction of an opposition process as a means of generating welfare gains; Bronwyn H. Hall et. Al, "Prospects for Improving U.S. Patent Quality via Post-grant Opposition", Competition Policy Centre Working Paper No. CPC03-38 online: <http://econwpa.wustl.edu:8089/eps/le/papers/0401/0401002.pdf> [Hall, "Opposition"]. See Michael J. Meurer, "Business Method Patents and Patent Floods" (2002) 8 J.L. & Pol'y 309 at 310 and 323. See Bronywn H. Hall, "Business Method Patents, Innovation, and Policy" NBER Working Paper Series, Working Paper 9717, online: National Bureau of Economic Research<http://www.nber.org/papers/w9717>.

[377] See Bita Amani, "Has Patenting Gone too Far?" *Innovate* (Spring 2004) 15 [Amani, "Too Far"]. Patents for (business) methods were another judicially determined expansion of IPRs in the U.S., see *State Street Bank & Trust Co. v. Signature Financial Group Inc.*, 149 F.3d 1368; 47 U.S.P.Q.2D (BNA) 1596. Business method patents have fortunately not garnered the same judicial support in Canada where product and process claims are patentable.

[378] See Martin LaMonica, "IBM retains patent crown" (January 12, 2004), online: CNET News.com

applications that year -up from the approximately 2000 filed the previous year and 1000 filed in years prior- as part of their plan to boost licencing of their IP to other companies.[379] Microsoft's patent portfolio includes a recent patent issued to Robert Burchinal and assigned to Microsoft over a rare apple tree- [380] a case of patenting plant life that wryly comments on the margin for mistake at the patent office. Yet growing concentration of corporate power renders Microsoft's horticultural interests in "apple" plausible as part of the continuous private enclosure of *life* and its building blocks. Such 'bad patents' where the technology is simple allow us to infer deteriorating patent *quality* for all fields and disproportionately where subject matter is more complex and technical, such as with biotechnology where specific examples are less likely to draw public scrutiny.

It is not surprising that through the 1980s the USPTO issued patents on genes that closely corresponded to foreseeable commercial products such as therapeutic proteins or diagnostic tests for recognized genetic diseases. By 1991, the National Institutes of Health (NIH) was undertaking mass patent applications for approximately 2000 genes, some of which were for anonymous gene fragments or raw genomic DNA sequences despite the fact that the functions of these were often unknown. It was not long before Celera Genomics and other private enterprises emulated in kind. Sometimes the utility of the claimed sequence asserted was only their use as genetic probes or expressed sequence tags (ESTs). While most opposition to gene patenting is based on the fact that genes exist in nature (as a product of nature) and are not novel, many believe "the hundreds of

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[379] See Ina Fried, "Gates wants patent power" (July 29, 2004), online: CNET News.com.

[380] There are only approximately 1000 samples of the Burchinal Red Delicious growing in a rural community near Microsoft's home base in Redmond (Patent No. 14757). The assignment appears to be an error for which a certificate of correction is being sought. See David Becker, "Apple patented by Microsoft: Apparently, intellectual property does grow on trees" (May 4, 2004) online: CNET News.com.

thousands of patent applications that have been filed on gene sequences of unknown function should be denied on obviousness grounds."[381]

The USPTO tried to regain control over the number and quality of genomic patent applications by issuing new Utility Guidelines in 2001 that imposed a stricter threshold for applicants. Applicants now have to disclose a "specific, *substantial*, and credible utility." However, while the new guidelines allegedly raise the bar, they also implicitly confirm that applications for patents on gene sequences meeting the higher utility requirements *will* be granted and not defeated *a priori* on the basis of novelty or obviousness. Whether isolated genes should be considered inventions or mere discoveries is not contemplated by the guidelines but has important consequence on public health.[382] There are continued doubts as to whether the doctrinal standards for patentability are being met.[383] In Canada, the utility standard allows for some speculative utility with the doctrine of *sound prediction*:

> Utility is an essential part of the definition of an "invention" (*Patent Act*, s. 2). A policy of patent first and litigate later unfairly puts the onus of proof on the attackers to prove *invalidity*, without the patent owner's ever being put in a position to establish validity. Unless the inventor is in a position to establish utility as of the time the patent is applied for, on the basis of either *demonstration or sound prediction*, the Commissioner "by law" is required to refuse the patent (*Patent Act*, s. 40).[384]

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[381] Rai *supra* note 358 at 216.

[382] The law in some jurisdictions has shifted significantly in favour of biotech patenting from *Genentech Inc. v. Wellcome Found.*, 1989 R.P.C. 147 (Eng. C.A. 1988) which decided that an isolated DNA sequence encoding human t-PA could not be patented to *Biogen Inc. v. Medeva Plc.*, 36 I.P.R. 438 (H.L. 1996) in which an isolated DNA sequence coding for the hepatitis B virus could be patented. See Justine Pila, "Bound Futures: Patent Law and Modern Biotechnology" (2003) 9 B.U.J. Sci. & Tech. L. 326, fn 7.

[383] Nuffield Council on Bioethics Report, *The Ethics of Patenting DNA: A Discussion Paper,* 20 July 2002, online: Nuffield Bioethics Council, <http://www.nuffieldbioethics.org>. [Nuffield Bioethics Report]

[384] *Apotex Inc. v. Wellcome Foundation Ltd.*, [2002] 4 S.C.R. 153, 2002 SCC 77, para. 46. At para. 70, Binnie J. for the Court expounds: "The doctrine of sound prediction has three components. Firstly, as here, there must be a factual basis for the prediction...Secondly, the inventor must have at the date of the patent application an articulable and "sound" line of reasoning from which the desired result can be inferred from the factual basis...Thirdly, there must be proper disclosure. Normally, it is sufficient if the specification provides a full, clear and exact description of the nature of the invention and the manner in which it can be practiced...It is generally not necessary for an inventor to provide a theory of *why* the invention works. Practical readers merely want to know that it does work and how to work it. In this sort of case, however,

Tightening up the requirements by raising the standards for patentability to ensure only quality patents issue is a TRIPS compliant way of directing domestic patent policy to effectively exclude or monitor certain technology and is an easy and effective response to quell the explosion of biotechnology patent application- particularly for biomedical and basic genomic research.[385] The Nuffield Council on Bioethics Discussion Paper, "The Ethics of Patenting Life" made a similar recommendation. This report drew very critical conclusions regarding current patent systems and posited that changes in technology now made sequencing routine; it argued that since DNA claims are no longer "inventive", if they ever were, they should be denied a patent. The Council suggested a re-examination of the requirements for patentability, concluding that gene patents ought to be the exception to a general rule against their issue and DNA sequences as research tools (i.e. ESTs, SNPs) should be completely excluded based on proper application of patentability requirements. Some patents, such as for general methods of genetic diagnostics they argue, should not issue at all because what is being claimed is an *association* that exists between a gene and a disease which is obvious (some allowance is made for particular means of testing). The report also contends that the use of genes in gene therapy is considered an obvious use once the relevant gene is identified. In Canada, section 55.2(6) of the Patent Act deals with exemptions to infringement[386] and preserves common law rights that exempt private, non-commercial acts as well as experiments

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the sound prediction is to some extent the *quid pro quo* the applicant offers in exchange for the patent monopoly." Paras. 41-44 discuss administrative law issues of deference owed to the Patent Commissioner.

[385] Jerome Reichman, "From Free Riders to Fair Followers: Global Competition Under the TRIPS Agreement" (1997) 29, No.1-2 J. of Int'l L. & Pol. 11 at 37 [Reichman, "Fair Followers"].

[386] The section states that the "provisions do not affect any exception to the exclusive property or privilege granted by a patent that exists at law in respect of acts done privately and on a non-commercial scale or for a non-commercial purpose or in respect of any use, manufacture, construction or sale of the patented invention solely for the purpose of experiments that relate to the subject-matter of the patent." s. 55.2 (6).

attempting to improve the patented invention,[387] a good recommendation where the patent is over a gene sequence useful as a research tool for further biomedical scientific research. In the absence of substantive legislated changes in patent law, however, the most obvious ways for patent offices and the courts to contain patents for less than sincere innovations is by tightening up the main requirements for patentability to make the system less porous.[388]

Low patent quality is a short-hand for an additional range of problems such as "... overlapping claims, inappropriately broad claims, slow patent prosecution, and patents on obvious inventions" attaching to current patent practice, according to Meurer. Moreover, Meurer contends, "the problem of overlapping claims is inherent to patent floods because of the likelihood of near simultaneous invention and multiple patent applications covering the same invention. The other problems arise because of the difficulty the PTO has dealing with patent floods. Time pressure, lack of expertise, and lack of prior art yield low patent quality during floods."[389] Poor patent quality further compounds anti-competitive behaviour linked with stockpiling patents by establishing a *false* edifice on which proprietary claims to exclusivity are built:

> reduced patent quality, increased uncertainty about the scope and validity of patents, and increases the frequency of patent litigation. The fragility of the many start-ups in new markets makes them vulnerable to strategic patent litigation. The threat of patent litigation may deter entry or induce exit from the market.[390]

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[387] *Micro Chemicals Ltd.* v. *Smith Kline & French Inter-American Corp.* (1971), [1972] S.C.R. 506.
[388] See *e.g.* J.H. Barton (2001), "Non-Obviousness" (2003) 43 IDEA: The Journal of Law and Technology 475; J.H. Barton, "Reforming the Patent System" (2000) 287 *Science* 1933.
[389] Meurer, *supra* note 376 at 310, 323.
[390] *Ibid.* at 309-10.

"Patent floods", [391] the proliferation of "patent thickets," and patent stacking add to the perfidy of patenting life and all of its subcomponents[392] and threaten to compromise the promises of biotech with overprotection restricting use and access. Patent floods compound institutional resource deficiencies by placing additional demands on an already strained system and thereby lead to continuously lower quality patents which in turn contribute to patent thickets. Patent stacking is particularly a problem in genetics since a single genomic sequence may be patented in several different ways i.e. as cDNA, EST, a gene, a SNP etc., discouraging further R&D in product development because of the royalty costs owed to all the various patent owners of that sequence. [393] These costs would invariably be passed on to consumers. With improved sequencing technology, genomic patents will over-compensate the patentee by rewarding routine discoveries, considered to be "the easiest step in the process", rather than the true innovators who determine downstream application. Overall, these trends "may stultify development of technology because of the costs of securing patent licenses from the large numbers of patent owners."[394] This is far worse than the anti-commons predictions of Heller and Eisenberg for biomedical research since it moves beyond economic arguments against *valid* upstream patents (on the basis that they limit down stream innovation) or that as a matter of policy basic research, products of nature, and discoveries should be

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[391] Defined as "a dramatic jump in the number of patents filed covering a specific class of inventions...A flood of related patents in a new market creates special problems for competition in addition to the usual problems that arise from market power associated with individual patents [by]...strain[ing] the resources of the U.S. Patent and Trademark Office (PTO) and adversely affect[ing] the quality of issued patents." (*Ibid.* at 309-10).

[392] See Carl Shapiro, "Navigating the Patent Thicket: Cross Licences, Patent Pools, and Standard-Setting" (March 2001), online: http://faculty.haas.berkeley.edu/shapiro/thicket.pdf at 2, examining whether our patent system is slowing down the commercialization of new technologies, defines a patent thicket as "a dense web of overlapping intellectual property rights that a company must hack its way through in order to actually commercialize new technology." Patent pools and cross-licences are two common and effective business arrangements for cutting through the ticket, although they have their own transaction costs.

[393] *Ibid.*

[394] Meurer, *supra* note 376 at 309-310.

excluded just as abstract theorems are. The situation is one in which we suspect the upstream patents are of such poor or dubious quality due to *institutional* deficits that we question their validity but refrain from doing so legally because of the cost of litigation! Bad patents constitute a fraud on the public and usurp the public trust mandate inherent in the "bargain theory" of crown granted monopolies; they threaten to challenge our faith in the patent system *in toto*.

3.4.2 A System of Secondary Incentives: The IP/Competition Interface

A patent does not grant the inventor the right to make, use, or sell the invention- only to exclude others from doing so. Moreover, bad patents could be used to extract licencing fees from users and smaller competitors who would want to avoid the cost of litigation, if not liability. [395] The IP "paradox" or the "tradeoff" as it is referred to in the literature, is between the social value of providing incentives to innovate by restraining the free rider with the public costs of the monopoly right which may in fact excessively limit "fair followers."[396] Even where the patents are *good,* Richard Gold claims that the patent regime's current level of incentive for inducing sufficient biomedical research is questionable at best:

> *The argument for greater patent protection should be understood for what it is: an attempt to maximize profit, not to maximize levels of innovation.* Clearly, a company would prefer to have as large a monopoly as possible...But patent law is not about individual profit maximization as it is about maximizing the overall level of innovation in society. *The two do not necessarily go together.*[397]

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[395] Arti Rai, "Addressing the Patent Gold Rush: The Role of Deference to PTO Denials" (2000) 2 *Wash. U. J.L. & Pol'y* 199.

[396] Reichman, "Fair Followers" *supra* note 385. See also Database Protection at the Crossroads: Recent Developments and Their Impact on Science and Technology" (1999) 14.2 Berkeley Tech. L. J. Spring 793-838. See also Suzanne Scotchmer, "Standing on the Shoulder of Giants: Cumulative Research and Patent Law" 5 Journal of Economic Perspectives No. 1Winter (1991) 29-41

[397] Gold, "Biomedical Patents", *supra* note 290 at 423.

To this end, the patent system has created unintended incentives for patentees to claim works of lesser and lesser innovativeness as the basis for garnering maximum protection offered by the statutory monopoly. The shift in using the patent system to protect investment rather than true non-obvious innovation diminishes the welfare improving promises relied upon for generating public acceptance of the new technology. Given that institutional deficits almost ensure that patent quality remains unchecked, investors have realized that the utility of a patent is not exclusively as a *shield* for commercial competition protecting invention related R&D costs from free riders. Rather, presumptively valid patents,[398] coupled with the exorbitantly high cost of litigation reveal their strategic potential as a *sword* for unfair competition using exclusive property rights to extract regular royalty income under the threat of litigation with its attendant costs.[399] Hope Shand contends that patents bar entry for smaller resourced firms:

> The power of exclusive monopoly patents is giving these companies the legal right to determine who gets access to proprietary science and at what price. Participation in industry isn't possible unless a company holds patents or has the money to license them....Pioneer Hi-Bred, the world's largest seed company (now a wholly owned subsidiary of DuPont), claims that one of its new, genetically engineered, insect-resistant corn hybrids requires access to thirty-eight different patents controlled by sixteen separate patent holders....[S]maller enterprises will find it increasingly difficult to compete.[400]

Smaller enterprises often find it simply cheaper to pay the licence fee than be taken to court over infringement, even if convinced that a patent is invalid.[401] Such acquiescence only encourages IP holders to resort to further patent stockpiling and market bullying,

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[398] Section 43(2) of the PA provides the presumption of validity: "After a patent is issued, it shall, in the absence of any evidence to the contrary, be valid and avail the patentee and the legal representatives of the patentee for the term mentioned..."

[399] See "Too Many Patents? U.S. Plans Hearings" 21:29 *Lawyer's Weekly,* November 30, 2001. The main question for these hearings was whether there were too many patents that should never have issued at all, and the results are discussed in text below at page 105.

[400] See also Hope Shand, "Gene Giants", *supra* note 143 at 226.

[401] The strategic uses of patents include rent extraction through licencing of technology or franchising that enable income earnings directly from the IPRs. IBM generates $1 billion and Texas Instruments $800 million in patent royalties per year. See Christopher M. Kalanje, WIPO-WASME Special Program on Practical Intellectual Property Issues, Geneva, October 6-9, 2003.

expending gross amounts of money defending the validity of their claims to discourage similar future attacks. Meanwhile, the firm may seek other ancillary forms of IP protections, like trade-marks or copyright, in attempt to create property rights in perpetuity.[402] Practically speaking, the greatest growing utility in industry is in the potential to use patents to coerce smaller competitors to capitulate to cease and desist letters under threat of infringement and their strategic (barter use) in cross-firm licencing negotiations- particularly in fields, like genomics and biomedicine, where upstream patenting has made licence bundling imperative for scientific research and by patentees seeking to commercialize new technology. These increased transaction costs are lower, however, than the costs of litigation and the risk of liability. Rosemarie Ziendonis argues

> defensive patenting offers firms an alternative to getting "fenced in" by owners of the technologies they use."[403] This is because licencing agreements are "facilitated by having a large patent portfolio of your own, so several firms, large and small, were engaged in defensive drives to increase their patenting rate. This had little to do with encouraging innovation, and in fact looked like a tax on innovative activity.[404]

Such a legal climate reinforces, by reward, bad behaviour. Ziedonis warns:

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[402] The attempt to "evergreen" rights through trade-marks which do not have a specified expiry period has been discussed, see *Canadian Shredded Wheat Co. v. Kellogg Co. of Canada, Ltd.*, [1938] 2 D.L.R. 145, [1938] 1 All E.R. 618; see also, *Interlego AG et al. v. Irwin Toy Ltd. et al.*, (1985) 3 C.P.R. (3d) 476 (F.C.T.D.); *Whirlpool Corp. v. Camco Inc.*, [2000] 2 S.C.R. 1067, 9 C.P.R. (4th) 129, 194 D.L.R. (4th) 193. With respect to copyright protection, Amani and Coombe posit that "if the requirements for obtaining a patent have been substantially relaxed in recent years, the requirements for a grant of copyright may be even more relaxed with respect to originality. The term of protection, moreover, is significantly-- by some seventy years -- longer, explaining the preference for the latter form of monopoly protection....The most recent attempt to use copyright to garner protection has been to encode DNA sequences as MP3s or other such music files and then copyright these "genetic songs" as creative works of authorship. This method of attracting DNA copyright protection through the encoding of the genetic information in technological hardware is itself the subject of a patent application, which if granted, would deny anyone other than the original inventor of such a method, from storing or retrieving genetic data in this way." See Amani and Coombe, *supra* note 49, endnote 2.

[403] Rosemarie Ziedonis, "Don't Fence Me In: Fragmented Markets for Technology and the Patent Acquisition Strategies of Firms" (October 2003) online: http://www.researchoninnovation.org/tiip/archive/2004_3c.html.

[404] See Bronywn H. Hall, *supra* note 376 at 10, referring to the findings of B.H. Hall and R.H. Ziedonis "The Patent Paradox Revisited: An Empirical Study of Patenting in the U.S. Semiconductor Industry, 1979-1995" (2001) 32 Rand Journal of Economics 102.

> From a policy perspective, "mutually assured destruction" games among firms that develop and produce complex technologies exacerbate the problem: to avoid being held-up by others, firms file more patents and, in turn, contribute to the proliferation of patents that others face.[405]

The result is a *secondary system* of *institutional incentives* (secondary to those espoused in industry claims of incentives necessary for R& D that legislation strives to achieve). *Over* patenting compromises the veracity of the biotech narrative when examined in the face of anti-competitive practices and reduces public benefits. It undermines the essence of the IP tradeoff. The glut of patents and their stratified uses are all focused towards accumulation of exclusion-based commodities and the ability to weed out competitors with monopolistic instruments that may chill innovation. They exemplify a mounting anti-competitive predatory ethos spurred on by the system itself.

In 2003, after a series of hearings conducted by the U.S. Federal Trade Commission (FTC) and the Department of Justice (DOJ) on balancing patent and competition policy, the FTC released its report with the goal of better aligning policies for the knowledge based economy. This economy *relies* on free market competition as much as innovative enterprise.[406] The report identifies a number of aspects of US patent law and practice that "exacerbate what already seems to be a zero-sum game",[407] recommending reform be undertaken to reduce the costs of challenging "questionable" patents through the adoption of a post-grant opposition system, improving the rigour of the examination process while relaxing the evidentiary standards required to invalidate a patent and raising the overall quality of patents by raising the bar of non-obviousness. Developing an enhanced post-examination review system might be a good solution for

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[405] Ziedonis, *supra* note 403.
[406] U.S. Federal Trade Commission (2003). To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy, online <http://www.ftc.gov/reports/index.htm>. See also William Blumenthal, "Aligning Competition Policy and Patent Policy: A Perspective From the Federal Trade Commission Staff" June 30, 2006, online http://www.ftc.gov/speeches/20060630FCBABackgroundPaper.pdf.
[407] Ziedonis, *supra* note 403.

checking against low quality or "bad patents"[408] but does not address the embedded or institutionally fostered secondary incentives for anti-competitive behaviour that the patent regime creates. The FTC recommends significant changes in the examination, prosecution and enforcement of patents. Faced with mounting criticism on the existing inefficiencies and flaws of the system, the USPTO has proposed a number of institutional reforms, including increasing human resources, professional training, and other measures geared at producing quality patent products,[409] recognizing that the cost of litigation is high and it is not an optimal way of testing validity, or achieving public interest outcomes. Similarly, while post-grant opposition proceedings and improved human resources are important steps in improving the patent system, they do not substitute for thoughtful policy development and public involvement, ideally through a legislative process, *before* the patent issues. One can infer that the Canadian Patent Office (CPO) generally experiences the same types of institutional deficits, albeit on a smaller scale due to less volume, a smaller market and differences in patent law and policy, and is equally in need of reform.[410] But the CPO has not pursued such full-scale reform measures.

Canadian patent legislation does have a remedial provision for where there has been patent abuse. Three years after the grant of any patent, the Attorney General of Canada or any person interested can apply under s. 65 CPA to the Commissioner and

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[408] Barton recommends re-examination as a way of legally challenging invalid patents and the removal of the presumption of validity, *J.H.* Barton, *"Reforming the Patent System"* (2000) 287 Science 1933.
[409] In 2005, the USPTO hired 978 new examiners, a hundred more than their target goal. For 2006, the USPTO intends to hire 1000 new patent examiners to help overcome current deficiencies. The USPTO has also proposed a number of training initiatives, including a one year academy approach, patent managers and teleworkers, and greater networks, to address the growing need for highly skilled human resources and to restore some faith in the quality of patents that issue. See USPTO Performance and Accountability Report, Fiscal Year 2005, online: < http://www.uspto.gov/web/offices/com/annual/2005/2005annualreport.pdf>.
[410] Mark Lemley has argued that well run patent systems will also suffer from institutional problems and that good patent policy necessitates limits to financial resources and the process for examination. See Lemley, "Rational", *supra* note 376.

request relief including a compulsory license or patent revocation where any of the three statutory conditions deeming abuse have occurred. Historically, domestic (local) manufacturing and "working" of patented inventions was required either by the patentee or its licence holder and the failure to do so constituted an abuse. However, because of Canadian obligations under NAFTA, the local manufacturing requirement was repealed; today, local demand of a patented invention may be met entirely through imports or foreign providers,[411] such as with MGL's BRACAnalysis®. The remaining provision governing abuse continues to be useful. Section 65(2)(c)-(f) of the CPA[412] may be used to prevent anti-competitive behaviour by patent holders and could be amended to deal with situations where patent holders prohibit domestic labs from providing genetic tests or to address anti-competitive practices in licensing, defensive patenting and the array of other current practices using patents as a *sword* for unfair competition. TRIPS expressly allows for domestic regulation to curtail anti-competitive behaviour and abuse of patents.[413]

The use of competition law and other fields should be contemplated by governments in crafting optimal biotech regulation and one which is responsive to societal values including a commitment to a society marked by robust and free competition where abusive behaviours of patent holders will not be tolerated. Canadian competition law provides against abuse of dominance position generally (s. 79) and

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[411] Vaver *IPL*, *supra* note 34 at 169-70.
[412] CPA, *supra* note 82.
[413] TRIPS Article 40.1 acknowledges that "some licensing practices or conditions pertaining to intellectual property rights which restrain competition may have adverse effects on trade and may impede dissemination of technology" and Article 40.2 provides that "Nothing in this Agreement shall prevent Members from specifying in their legislation licensing practices or conditions that may in particular cases constitute an abuse of intellectual property rights having an adverse effect on competition in the relevant market...[A] Member may adopt...appropriate measures to prevent or control such practices...in the light of the relevant laws and regulations of that Member." See also Article 40.3-4.

specifically against abuse of IP (s. 32).[414] The greater use of competition law at the interface of IPRs is being considered by the FTC and DOJ following their report as a means of mediating better industrial policy. In the meantime,

> some firms may continue to form patent pools. Others may reduce R&D spending. Still others may flood the US Patent and Trademark Office for defensive purposes. Polanyi's "drama of innovation" goes on.[415]

3.5 Conclusion

From the foregoing discussion we see that biopatenting has itself become a pandemic in need of an innovative cure. Advances in new technology like semi-conductor chips and biotech only offer a partial explanation of apparent "innovative" activity when measured by patents as an indicator. Institutional deficits, anti-competitive behaviour, strategic business practices, a patent friendly judiciary (the subject of the next chapter) all offer additional, if not alternative, explanations for the proliferation of biotech patents. To quote from the great Professor William Cornish, "[t]he number of patents being granted for inventions ...are threatening to become omnipresent in some [industries]".[416]

Institutional celebration of the exponential growth in patents is based on a false measure of innovativeness and economic productivity and is without due attention to competition and health policy. The result is that incentives created from this regulatory

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[414] Competition Act, Revised Statutes, 1985, c. C-34. See generally, Warren Grover, "The Interface of Biotechnology Patents and Competition Law" (2001), Prepared for the CBAC Project Steering Committee on Intellectual Property and the Patenting of Higher Life, online under publications: Strategis Canada http://strategis.ic.gc.ca Grover outlines consistent ineffectiveness of Canadian competition authorities to appropriately address clear abuses of patent rights, partly due to a lack of understanding of the fundamentals of intellectual property law by the competition lawyers. The Intellectual Property Enforcement Guidelines, published in late 2000, clearly indicate that the competition authorities will not be vigorous investigators of alleged patent abuses. Instead, he recommends the Commissioner of Patents should be granted greater discretionary authority under the legislation to deal with patent misuse he recommends.

[415] *Ibid.*

[416] See Cornish, *supra* note 63 at 5.

system have shifted away from innovation to predatory anti-competitive behaviour based on after-the-fact rewards with current trends threatening to have significant implications for subverting industrial policy, impeding health delivery, and turning the economic rationales for efficiency and welfare maximization on their heads. Such patent perfidies would undermine the human rights promoting promises of biotechnology. In addition to addressing institutional reform, to achieve a more balanced patent law in the absence of legislative amendment, the PTO and courts can adopt stricter standards for novelty, utility, and non-obviousness, require greater disclosure, narrow claims, reset the level of skill for the ordinary person higher, and redefine the art (to include worldwide public knowledge). Courts can reinforce existing legal doctrines and remedies, such as compulsory licences or patent revocation, to respond to users' interest in biopatents. These responses are TRIPS compliant and part of those recommended by Austin and Amani in relation to the grant of gene patents to the Ontario Advisory Committee on Predictive Genetic Technologies in 2001.[417] Patent offices must examine applications "to test their assertions of inventiveness before any grant is made. Otherwise all too often "buccaneers will be armed with dubious rights with which to overpower the vessels of decent traders. Experience shows that they will use them to frighten others into taking expensive but unnecessary licences."[418] Similarly, while post-grant opposition proceedings and improved human resources are important steps in improving the patent system, they do not substitute for policy development ideally through a legislative process involving public debate *before* such patents issue. Certain reforms are underway to improve patent office practice in the United States by increasing institutional resources

[417] Austin & Amani, *supra* note 103.
[418] Cornish, *supra* note 4 at 6.

and improving the application of statutory patent requirements and thereby the administration of the patent regime. These reforms, however, have not been undertaken in Canada even though, as the next chapter will show, Canadian extension of patents to life has very much shadowed developments in American law. In addition to warning against too many IPRs, evidence of patent trends warn against emulating the standards of our American neighbours or converging our laws with other more protective national regimes not only because our social, economic and political context warrant different regulation but also because "inventions" claimed there have proven less than sincere.[419] We can only imagine the kind of dubious inventions claimed in more technical fields that are less accessible to public understanding and therefore scrutiny and where innovativeness may be shrouded by a veil of technical complexity as well as scientific and legal jargon.

For now, the USPTO and CPO continue to issue gene patents based on the ability to isolate and purify genes. In so doing, they reverse, according to Linda Demaine and Aaron Fellmeth, "the traditional principle in patent law of non-patentability of purified natural products and, in some cases, the principle of nonpatentability of natural products in their natural state."[420] Having established a dangerous precedent for the private sector, gene patents continue to be sought and granted by patent offices in all of the developed

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[419] Charles Cella is a former intellectual property attorney who saw great financial opportunity in the failings of the current patent system and its incentive towards abusive and anti-competitive behaviour. Cella started a business, BountyQuest, dedicated to profiting from busting patents of questionable legitimacy. A patent, once issued, can only be overturned when validity is attacked by a challenger based on evidence of "prior art". The idea is that anyone who questions a patent's validity can offer a bounty (starting at $10,000) in order to attract relevant prior art that would help prove that someone else thought of the patented idea first (that the patent lacked novelty and thus failed to meet a critical requirement for patentability). This is a private market solution for patent reform. When Cella was asked why he switched side, he replies: "Because there are a lot of bad patents out there, and there are a lot of valid patents too....What needs fixing is the system of 'prior art'". See Damien Cave "Who ya Gonna Call? Patent Busters" online http://dir.salon.com/tech/view/2000/10/23/cella/index.html.

[420] Linda J. Demaine and Aaron Xavier Fellmeth, "Reinventing the Double Helix: Novel and Nonobvious Reconceptualization of the Biotechnology Patent." (2002) 55 *Stanford Law Review* 304 at 331.

world[421] and with increasing pressure for parity in the law of developing countries. This chapter has argued that granting patents in the field of genomics and proteomics, however, is an inefficient overprotection of private interests, providing a "windfall" due to the initial and often significant prior investment of public sector resources. Moreover, the unfenced region of genetics is better characterized as an information commons not amenable to private rights- in rhetorical recognition that the commons, though not necessarily subject to *private* property regulation, nevertheless embody a claim by a public to its governance (often conceptualized as communal property).[422] Genomic patenting is antithetical to the culture of collaboration and accretion model of science and simply surrenders control and access to private proprietors, emasculating the role of regulatory governments. These monopolies pin themselves to promises framed in human rights vocabularies in order to make the property claims more palatable and to justify the ever intruding encroachment on the public by the private and of the local by the global.[423] The promises of patenting must be weighed by law makers and policy analysts against these costs, the underutilization of biomedical research, and growing unfair competition by patentees. If property does attach to life as new subject matter, then the process of its objectification, its substance, conditions, and limitations necessarily need to be *institutionally* defined to maximize the utility of the monopolies conferred for the

[421] For example, Shiva, *supra* note 90 at 2, provides "Researchers at the National Institute of Health (NIH) in the UK patented a method for gene therapy, which was licensed to Genetic Therapy, who in turn sold it for $395 million to Sandoz, which later merged with Ciba Geigy to form Novartis. Thus one of the world's 'gene' giants has exclusive 'property' rights to a therapy evolved in the public domain."

[422] Here, in contrast to Feintuck's process-derived "public interest," we can assert that "the public interest" in genetic information (especially where it is human and personal information) - and therefore all life as embodiments - has specific substantive content: a common heritage and collective future for the human family and our primal cousins. Feintuck, *supra* note 28.

[423] See Coombe, "Authorial Cartographies", *supra* note 58 at 1364, Coombe states "[t]hose borders which once defined national sovereignty and the spaces of legislative self-determination are now compromised in order to more fully protect and police the new sovereignty of intellectual property owners, who are once again clothed in the more appealing guise of the Romantic author struggling for unalienated survival." Footnotes omitted.

promotion of welfare. Necessary review by policy analysts and lawmakers should occur regularly to ensure continued efficiency. But, that has not occurred despite the patent proliferation trend. The evidence shows a system in dire need of repair. Institutional failures compound existing conceptual problems in extending exclusive proprietary interests in genetic information. Simultaneously, current patent practice undermines the normative force of utilitarian justifications for patents, highlighting the weaknesses of essential premises (i.e. that more patents mean more innovation and greater welfare) by raising doubts about patent validity and quality. Rather than engage in regulatory reform, parliament has all but abdicated its responsibility to safeguard the public's interest to an unelected judiciary that is crippled by the fact that the court's jurisdiction does not extend beyond the facts of a given case to broader public policy. The next chapter will analyze the common law extension of a flawed conceptual and operational system that administratively extends property rights to genetic sequences, to *higher* life, and offers additional recommendations for domestic regulatory reform that would be compliant with now internationally entrenched standards of IP protection under TRIPS.

Chapter Four

Origins of the Patented Species: Of Mice, Men, and the Sincerity of "invention"

4.1 Introduction

Patent offices in the western world have been granting patents on genes, cell lines, proteins, antibodies, hormones, micro-organisms and in some countries even plants and animals (although not in Canada)- this is well established law.[424] The extension of patents to "life" is based on the common law's recognition of biological and organic matter as patentable subject matter.[425] From our review thus far, the normative utilitarian incentive rationale for extending patents seems not to apply to the field of genomics in which significant, now public and private, collaborative efforts continue to be made. GAIN, the latest amongst a series of mapping projects discloses research results immediately in recognition that genetic information should be considered pre-competitive and not patentable. While the institutionalist theory of IPRs and the importance of genetic information as a public good underscore the parliamentary legislative approach required for any expansion of exclusive rights to life, in this case it has occurred through judicial fiat. Nonetheless, states are better positioned to account for broader policy considerations and the appropriate balancing of interests in articulating law and are more properly authorized to do so by the voting public. In fact what seems to be most troubling from media accounts of public protest against biopatenting is the idea that that

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[424] See Nuffield Bioethics Report, *supra* note 383.

[425] See Amani and Coombe, *supra* note 49. See generally Daniel Kevles, "A History of Patenting Life in the United States with Comparative Attention to Europe and Canada", A Report for the European Group on Ethics in Science and New Technologies to the European Commission, (2002), online: The European Group < http://ec.europa.eu/european_group_ethics/publications/docs/study_kevles_en.pdf>.

law has developed by stealth to prioritize property rights without public consultation. A 2002 news article read:

> Surprise! You may not hold full legal title to some of the genes in your body. The Canadian Intellectual Property Office, for some time, has been issuing patents on human genes, without any of the controversy the issue sparked in the United States and elsewhere...[T]here are hundreds of gene patents on the book, including a significant number covering human genes.[426]

Negative, often intuitive, reactions relate to a sense that there has been a breach of public trust in granting gene patents using an 18th century system designed to introduce new imports and new manufacture for something so fundamental to our identities and idea about our place within nature: "patent holders are being allowed to patent a part of nature—a basic constituent of life; this allows one organism to own all or part of another organism."[427]

Once patents on genes, comparatively mundane and obvious were issued by the patent office without significant public or political debate, extension of IPRs to (higher) life was easier to make doctrinally since transgenic life at least contain some modicum, if not a significant degree, of ingenuity and inventiveness, although there are other valid ethical and social reasons why states may want to exclude them from patentability. Canadian courts struggled with this debate for more than ten years as this chapter will show. This chapter considers the judicial history of patenting life forms in domestic law. In Canada, the debate on patenting life has been revitalized with the current Seed Sector Review[428] following on the heels of the MGL breast cancer gene patent controversy and

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[426] Dennis Bueckert, "Patents Quietly Issued on Human Genes" Wed Jan 23 2002 Toronto Star.
[427] *Ibid.*
[428] The Seed Sector Review (SSR) is an industry-led assessment of the seed sector by over 4500 pedigree Canadian Seed Growers and over 200 companies across Canada that belong to the Canadian Seed Trade Association (CSTA), undertaken with the objective of facilitating consultation and consensus building in the Canadian seed and crop sectors and with the goal of creating a "modern regulatory environment for Canada's seed sector." The review extends to the nature of seed protection provided under patent law and plant variety protection: see <http://www.seedsectorreview.com/index-e.html>. It has alarmed NGOs and farmer's groups of potential erosion of farmer's rights to save seeds that may result from recommendations

the recent litigation at, and ostensibly inconsistent findings of, the Supreme Court of Canada on patent protection for plants and animals.[429] Rather than provide clarity and certainty as Supreme Court decisions ought to do, they leave the law in this jurisdiction and the extent of patent rights conferred disturbingly unsettled. Yet, the judiciary *has had* to act even while calling on governments to respond to fill the existing lacunae of law and policy to better address the challenges of biotechnology. When the judiciary has acted, it has typically been responsive to arguments expanding the scope of rights as well as the subject matter to which they attach for a host of reasons including incomplete understanding of the technical science, industrial pressure for greater protections, assumption of rights or utility based rhetoric, or a desire for convergence in standards with more protective jurisdictions and with regard to international trade obligations.

This chapter is divided into six main sections. In section 4.2, a comparative review of the biopatent jurisprudence is undertaken to show the incremental manner in which a flawed system was extended to critical subject matter. This evolution deviates from statutory and prior common law exceptions that protected the public interest in this field and recommendations made by the Canadian Biotech Advisory Committee that parliament assume responsibility for making any changes in patent law. Sections 4.3 and 4.4 locate current patent law on life within an unfortunate paradox created by a differently constituted Supreme Court of Canada in its two most recent decisions relating to non-human higher life. The ensuing analysis of these decisions in Section 4.5 makes

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under this review. See National Farmers Union, "Nine things farmers need to know about the Seed Sector Review" (13 May 2004), online: National Farmers Union <http://www.nfu.ca/seedsector.pdf> and Stephen Leahy, "Monsanto Victory Plants Seed of Privatization" *Inter Press Service* (5 October 2004).

[429] Some commentators exclude DNA from their definition of "life". For those who include it, legally the debate focuses on whether genes are "invented" or merely "discovered". These are primarily economic and doctrinal considerations. Non-human higher life (plants and animals) tends to focus on morality, ethics, and socio-cultural values rather than legal analysis of patentability and higher human life is opposed on constitutionally derived legal terms.

apparent how the most important subject in this field has become the patenting of DNA sequences and lower life, simultaneously emphasizing how judicial interpretation of the scope of patent rights makes grave the dangers warned against in the preceding chapter. This chapter concludes with the first branch of this dissertation's bifurcated response to patenting life by reviewing international prescriptions for domestic patent law and by recommending TRIPS compliant measures for state agency and regulatory reform.

4.2 Review of the Common Law on Life: From Sanctity to Scarcity

Life has not always been patentable. The advances in molecular genetics discussed in Chapter 3 created the impetus to apply for life patents. Molecular genetics created the necessary fragmentation of the body that allowed for its manipulation, commodification, and commercialization, and the ability to ignore the fact that the whole of a living organism is at least the sum of its parts. What is life?

In *Harvard*, the SCC confirmed that

> there is a good deal of debate about what constitutes "life" but some consensus about a few of its characteristics. These include the capacity to grow and develop (including reproduction) i.e., a metabolism, the ability of an organism to draw energy from its environment for this purpose, and the ability to respond to stimuli....Life is no less wondrous at the microscopic level, and to think of "life" primarily in terms of dolphins, chimpanzees and blue whales (examples urged by the appellant Commissioner in the oral hearing) is something of an oversimplification.[430]

Philosophers are also concerned with the inherent difference between life and other patentable technology as one based on the ability of the former to create and change itself (self propagate, self replicate, reproduce and mutate). Biotechnological intervention is *necessarily collaborative* with the nature we dispose over:

> In dealing with dead matter, the producer, confronted with a passive material, is the only one to act. In dealing with organisms, activity is confronted with activity: biotechnology is collaborative with the auto-activity of the active material, the biological system in its natural functioning into

[430] *Harvard SCC, supra* note 185, para. 66.

> which a new determinant has to be incorporated...The mode of the technological act is intervention, not building.[431]

Patenting life has the anomalous effect of granting proprietary rights that recognize the contribution and intervention of others to the exclusion of the contribution (auto-activity) of the living "self". Biotechnological intervention is itself characterized by human conceit because the intervention, according to Hans Jonas, is irreversible in a self-regulated process, and will lead to consequences we cannot control: "To 'produce,' here, means to commit something to the stream of evolution in which the producer himself is carried along."[432] Jürgen Habermas discusses the philosophical writings of Jonas and concludes that the Jonas thesis "resituates genetic engineering in the context of a self- destructive dialectics of enlightenment, according to which the species reverts itself from the domination of nature to servitude of nature,"[433] as today's molecular interventions commit future generations to their consequences. This feature, argues Richard Gold, means that "patent law needs to evolve to recognize that biotechnology is *different* from all other technologies."[434] Nevertheless, life, traditionally thought of as sacred and bountiful, is now a patentable "invention" and therefore scarce and largely privately controlled yet simultaneously exceeding the control of its so-called inventor because of its generative nature.[435]

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[431] Hans Jonas "Lasst uns einen Menschen klonieren," in Jonas, *Technik, Medizin und Eugenik.* Zur Praxis des Prinzips Verantwortung (Frankfurt am Main: Suhrkamp, 1985) p. 165, cited in Jürgen Habermas, *The Future of Human Nature* (Cambridge: Polity Press, 2003) at 47.
[432] Jonas, *ibid.*
[433] Habermas, *supra* note 431 at 48. Habermas provides the critical question Jonas poses: "But whose power is this- and over whom or over what? Obviously the power of those living today over those coming after them, who will be the defenseless objects of prior choices made by the planners of today. The other side of the power of today is the future bondage of the living to the dead."
[434] Emphasis added, as referred to in Stuart Laidlaw, "Reckoning with Technology law in court: Monsanto decision hurts equity, innovation: Expert" *Toronto Star* (21 June 2004) D1 at 1.
[435] See *e.g.* William Y. Brown, "Promise and Peril"(2001) 18:5 The Environmental Forum,30 for the unanticipated ecological effects of GMOs.

4.2.1 Non-Patentable Subject Matter in the USA: Discovery & Products of Nature

The evolution of the patented species finds its origins in the United States. The US patent code was silent on the issue of patenting life. An early precedent was established in 1889 upon the Commissioner of Patents' rejection of an application over a fiber in the needles of a pine tree because, it was found, the ascertainment of the composition of the trees in the forest was not an "invention" "recognized by the statute, any more than to find a new gem or jewel in the earth would entitle the discoverer to patent all gems which should be subsequently found."[436] This precedent created the "product-of-nature" doctrine that, although judicially eroding, theoretically continues to distinguish unpatentable objects of discovery from patentable processes created to extract what is found in nature. The Commissioner found that to allow patents on trees of the forest and the plants of the earth would be "unreasonable and impossible".

The argument that DNA sequences should be considered unpatentable subject-matter is rooted in the idea that these should be treated as discoveries- products of nature- rather than inventions. Patent law does not allow patents to be granted for discoveries. The legal basis for this in Canada lies in the interpretation of s. 27(8) of the CPA, which provides that "No patent shall be granted for any mere scientific principle or abstract theorem." The Federal Court of Appeal has interpreted this provision to indicate a division between "a discovery of a natural phenomenon" and something involving "the application of inventive ingenuity."[437] However, defining an invention as something

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[436] *Ex Parte Latimer,* March 12, 1889, C.D., 46 O.G. 1638, U.S. Patent Office, Decisions of the Commissioner of Patents and of the United States Courts in Patent Cases...1889 (Washington, D.C.: Government Printing Office, 1890) at 123-27 as cited in Kevles, *supra* note 425 at 2. Kevles does a comprehensive historical account of the law and politics surrounding patenting of life forms in the United States.

[437] *Harvard SCC, supra* note 185 at paras. 46-7.

involving ingenuity is not a helpful way to distinguish a discovery from an invention. "It is axiomatic in discussions of patent law that $E=mc^2$ is not patentable because it is a discovery, and yet this clearly involves the application of human ingenuity."[438]

Another way to understand the invention/discovery dichotomy is that outlined by the United States Supreme Court in *Gottschalk* v. *Benson.*[439] In *Gottschalk* the Court reasoned that "[p]henomena of nature, though just discovered, mental processes, and abstract intellectual concepts are not patentable, as they are the *basic tools* of scientific and technological work."[440] That is, if the bargain struck by the *Patent Act* is that incentives for inventions are provided in return for the dissemination of knowledge and useful things, then the policy considerations animating this bargain do not hold in the context of "the basic tools of scientific and technological work". Granting so large a monopoly threatens the very progress that is said to be at the heart of patent law's policy and is an argument for excluding genetics as basic research by analogy to the s. 27(8) exclusions.

Once the DNA structure became known, however, molecular manipulation became possible and legal claims inevitable. This became clear when Ananda Chakrabarty, a biochemist at the General Electric Company, genetically modified a bacterium to break down crude oil spills. In the 1980 decision of the USSC in *Diamond* v. *Chakrabarty,*[441](*Chakrabarty*) a narrowly divided court (5:4 majority) held that a patent could be granted for living micro-organisms as "nonnaturally occurring

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[438] Austin & Amani, *supra* note 103.
[439] 409 U.S. 63. This case is referred to in *Parker* v. *Flook*, 437 U.S. 584. *Flook* in turn was relied upon in *Chakrabarty*, *infra,* which was in turn relied on by the Federal Court of Appeal in the Harvard Mouse case.
[440] *Ibid.* at 67.
[441] *Diamond* v. *Chakrabarty*, 447 U.S. 303 (1980) [Diamond].

manufacture or composition of matter—a product of human ingenuity."[442] The focus of the court was not whether life *per se* was patentable subject matter, as the court found that "anything under the sun made by man" is patentable.[443] Rather, the issue was whether *this* was an "invention" within the statutory definition or a discovery of a product of nature.

In 1985, the scope of patent protection in the United States was extended to higher life forms (man-made plants) that do not occur naturally in *Ex Parte Hibberd*[444] to cover a species of corn that was engineered to produce an abundant amount of the amino acid tryptophan. This was followed by an extension of patent law to cover higher animal life in *Ex Parte Allen.*[445] In this case, the issue was whether an oyster genetically modified for year round consumption could be an "invention". The Patent Board of Appeals recognized that the subject matter was patentable provided the other requirements (novelty, utility, and nonobviousness) of patentability were met. The oysters were bigger and more resilient but were not significantly different from those found in nature and thus were not patentable- despite the level of ingenuity in making the genetically modified organism (GMO). The USPTO in April 1987, just prior to the Board's decision, issued a statement on the subject matter it considered patentable, including "non-naturally occurring non-human multicellular living organisms, including animals". To respond to the concerns regarding financial gain or "ownership" of human beings reminiscent of legally prohibited slavery, the statement specifically excluded

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[442] *Ibid.* at 309-310.
[443] *Ibid.* at 6.
[444] 227 United States Patents Quarterly 443 (Board of Patent Appeals and Interferences 1985).
[445] 2 U.S.P.Q. 2d 1425 (P.T.O. Bd. App. & Int. 1987); (1987), 1077 Official Gazette of the U.S. Patent and Trademark Office announced the new policy.

humans from patentable subject matter for constitutional reasons.[446] Significant public protest and moral outrage ensued nevertheless on the patentability of other higher life[447] but did not prevent Harvard from obtaining the first animal patent in the United States in 1988.[448]

In *Moore v. Regents of the University of California,*[449] the Supreme Court of California extended patenting to human genetic material but denied Mr. Moore a property interest in the commercial sale of his cell line. In the 1970s John Moore suffered from hairy cell leukemia. He had his spleen removed at the University of California, Los Angeles Medical Center during the course of which Dr. Golde discovered that Moore's spleen tissue produced a rare protein that appeared to be of some cancer-fighting utility. Without Moore's consent or knowledge, a cell line, the Mo cell, was made and patented as "invention" (No. 4,438,032) by Dr. Golde. He subsequently sold it to a drug company for $15 million (the reported current value is in excess of $3 billion for the drugs and therapies developed from the patented product). In 1984, upon learning of the facts,

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[446] "The Patent and Trademark Office now considers non-naturally occurring non-human multicellular living organisms, including animals, to be patentable subject matter within the scope of 35 U.S.C. 101. ... A claim directed to or including within its scope a human being will not be considered patentable subject matter under 35 U.S.C. 101. The grant of a limited, but exclusive property right in a human being is prohibited by the Constitution. Accordingly, it is suggested that any claim directed to a non-plant multicellular organism which would include a human being within its scope include the limitation 'non-human' to avoid this ground of rejection." U.S. Patent and Trademark Office, "Notice: Animals--Patentability,'' 1077 Official Gazette U.S. Pat. and Trademark Off. 8 (April 21, 1987).

[447] Jeremy Rifkin, who is the head of the Foundation on Economic Trends (FET), formerly the People's Business Commission (PBC) was very vocal in the protests. Rifkin filed an amicus brief in the Chakrabarty case objecting to the patenting of lower life, objects to the patenting of higher life and continues to challenge the USPTO patent practice by attempting to force a decision on the patentability of a human-animal chimera through filing a patent application over one. See T. Schrecker, C. Elliott, C.B. Hoffmaster, E.W. Keyserlingk, M.A. Somerville, "Ethical Issues Associated with the patenting of Higher Life Forms", May 17, 1997, Westminister Institute for Ethics and Human Values McGill Centre for Medicine, Ethics and Law, online: Strategis.gc.ca http://strategis.ic.gc.ca/epic/internet/inippd-dppi.nsf/en/ip00095e.html.

[448] See in text discussions below under the heading "Comparative Treatment: ...Of Mice".

[449] *Moore v. Regents of the University of California*, 51 Cal. 3d 120, 125; 793 P.2d 479 (Supreme Court Cal.,1990).

Moore sued the university and drug company on eleven causes of action including claims for conversion as 'owner' of the cells, breach of fiduciary duty, and lack of informed consent.

Although the California Supreme Court eventually held in 1990 that the doctors' conduct was tortious and that they had also breached their fiduciary duties by failing to reveal to Moore their research and their financial interest in his cells, it also ruled that there were no grounds for Moore's property claim once the cells were removed from his body for policy reasons- because "research on human cells plays a critical role in medical research... [and granting the patient proprietary rights would threaten to] hinder research by restricting access to the necessary raw materials"[450] Moore's cells were considered to be raw materials in the *public domain* and thus available for the creative and "inventive" activities of others. The irony of the decision in granting property rights to the patentees while denying them to Moore was highlighted in Justice Broussard's dissent:

> ...the majority's analysis cannot rest on the broad proposition that a removed part is not property, but...on the proposition that a *patient* retains no ownership interest in a body part once the body part has been removed.[451]

The majority felt comfortable in granting Dr. Golde a property right in the cells, believing that the patent on the cell-line was substantially different from Moore's own cells. But paradoxically, the majority did not recognize Moore's property right in his own cells, ignoring the auto-collaboration of the living "self" to which Habermas and Jonas refer, as well as Moore's deliberate labour, in the Lockean sense, in maintaining his living cells by eating, sleeping, and generally preserving his health. Commentators have criticized this decision because it denies the source of the valued material (Mr. Moore) a property

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[450] *Ibid.* at para. 96.
[451] *Ibid.* at para. 133-134. For a detailed discussion, see Amani and Coombe, *supra* note 49.

interest in his excised parts but simultaneously recognizes third party interests. The court protects such "an interest using forms of property law such as the law of patents. But does not such an example demonstrate precisely the kind of value which individuals could retain in their excised parts? The properties of the patient's cell are a *sine qua non* of the ultimate invention."[452] The lesson from *Moore* was clear: while possession remains 9/10ths of the law, there is no substitute for legal title. And legal title is, as biocolonialism now and colonialism before it attest, a political enterprise.

4.2.2 Non-Patentable Subject Matter in Canada: The Disclosure Dilemma

In Canada, prior to 1982, living matter was perceived to be a product of nature and was not within the definition of "invention" such that claims encompassing living matter were refused until *Re Application of Abitibi Co.*[453] when, shadowed by developments in American jurisprudence, the Patent Appeal Board found that lower life were patentable. This was for a process and product application over a new mixed fungal yeast culture system that was useful for absorbing foaming spent-sulfite liquor generated in papermaking. The fungi were isolated and subjected to increasing concentrations of foaming sulfites and nutrients in a water medium; those that survived had mutated to consume the foaming effluent thereby clearing the waste stream of the contaminant. Initially, the patent examiner had disallowed the product claims on the basis that microbial culture systems were living matter and thus not a patentable "invention" under

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[452] J.K. Mason and R.A. McCall Smith, *Law and Medical Ethics* (Butterworths, London: 1999) at 492-493. Rosemary Coombe contends that "[j]ust as the authorship and ownership of others was not recognized in the nineteenth century pillage and plunder of their material artifacts..., today the authorship of others in shaping the biological "specimens" that surround them (or the genes within them) is unacknowledged. "They" do not understand their global significance, it would seem, but only their local and parochial meanings. Once again, "our" appreciation enables "our" appropriation on behalf of a global "we" that classifies and maps, not the globe, but the biosphere (or the genome)." See Coombe, "Authorial Cartographies", *supra* note 58 at 1362.

[453] *Abitibi, supra* note 13.

s. 2. The Board considered the similarity of our s. 2 definition of "invention" with the US patent code, and the shared silence on life as patentable subject matter. Having the benefit of the USSC precedent in *Chakrabarty*, the Board noted that the Canadian exclusion of patenting living matter had been based on UK precedents and that "the Chakrabarty decision casts doubt on the correctness of that practice."[454] This marked an early display of preference for judicial convergence with American based standards for more inclusive patentability. The Board found that "[i]f an inventor creates a new and unobvious insect which did not exist before (and thus was not a product of nature) *and can recreate it uniformly and at will,* and it is useful...then it is every bit as much a new tool of man as a micro-organism."[455] Accordingly, the Board suggested that the Commissioner interpret the terms "manufacture" and "composition of matter" to incorporate lower life; accordingly, the Commissioner accepted the Board's recommendation to allow the claims to the micro-organism and issued the patent. As a result of considerations extrinsic to our judicial system, very narrowly decided (the Chakrabarty court was divided 5:4 in its opinion), and without account for social, political, and regulatory differences between the American and Canadian contexts, the *Abitibi* found the yeast culture patentable.[456] The Canadian PO listed these items as now patentable so long as the "invention" claimed could be recreated uniformly on large scale. The Board's requirement of uniformity is an oversimplification that belies differences in organisms, however imperceptible to the decision maker. In any event, now routinely patentable are:

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[454] *Ibid.* at 87.
[455] *Abitibi supra* note 13 at 90.
[456] *Ibid.* at 88, the Court considers German and Japanese law, both which allowed for the patentability of micro-organisims.

> all micro-organisms, yeast, moulds, fungi, bacteria, actinomycetes, unicellular algae, cell lines, viruses or protozoa; in fact...all new life forms which are produced *en masse* as chemical compounds are prepared, and are formed in such large numbers that any measurable quantity will possess uniform properties and characteristics.[457]

The requirement of recreation at will (en masse) and with uniformity[458] is an issue that resurfaces before the Supreme Court of Canada in the Harvard mouse decision discussed below because it is a proposition that defies guarantee. It is *degree,* rather than principle, however, that clearly seemed to matter more to the Patent Board:

> With still higher life it is of course less likely that the inventor will be able to produce it at will and consistently, as more complex life forms tend to vary more from individual to individual. But if it eventually becomes possible to achieve such a result, and all of the requirements of patentability are met, we do not see why it should be treated differently....However a micro-organism, being living matter, will reproduce itself on proper culture medium, so as the inventor can maintain his supply indefinitely. If he places samples of the organism in a culture collection to which others have access, they too will be able to reproduce the organism, and thus have access to his invention, and use it once the patent expires.[459]

Yet as Habermas and Jonas make clear, *all* organisms - "micro" or not - vary; just as human offspring do from their parents even though the degree of genetic variation for the entire human family is only 0.1%.[460] On whether a deposition of the invention in the culture collection is sufficient to satisfy the disclosure requirement, the Board was again influenced by American case law which had found that it was sufficient disclosure for *process* claims since the ordinary skilled person could put the invention into practice.[461] But the Board made a pivotal error in extending the sufficiency of a deposition in a *process* patent application to a *product* patent claim:

> If deposition of a micro-organism in a culture collection is sufficient disclosure of it when an applicant claims a process utilizing that organism, it seems strange indeed to hold it is inadequate when the organism itself is claimed. In both instances the public needs the organism to work the invention, and in both instances it has it...[462]

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[457] *Abitibi, supra* 13 at 82.
[458] See also Fecenko, *supra* note 249 at 84.
[459] *Abitibi, supra* note 13 at 91.
[460] See discussion, *supra* page 112 of this dissertation.
[461] *American Cyanamid Co. (Dann's) Patent,* [1971] R.P.C. 42 cited in *Abitibi supra* note 13 at 91.
[462] *Abitibi, ibid.*

This finding renders moot the important distinction between process and patent claims. Depositions are and should be sufficient for disclosure of process patents because what has been deposited will operate to perform the process function for which it has been patented. However, if the claim being made is to the cultured bacteria itself, then a deposition should not suffice to meet the disclosure requirements for the *product* because of the variability in life, even if the cultured bacteria appear to display the same dominant feature as the deposition from which they are grown.[463] In fact, a significant amount of R&D is currently directed towards mapping projects for various species and the comparative function of DNA sequences (and genes) for the very purpose of determining incredibly minor, often single letter, genetic variation.

The next major decision had no trouble recognizing the disclosure dilemma as it pertained to higher life. *Pioneer Hi-Bred Ltd. v. Canada (Commissioner of Patents),*[464] was the first case to raise the issue of a multicellular organism in Canada. A patent was sought for a new soybean variety developed from artificial crossbreeding and selection but cultivated naturally. The genetic engineering was done through hybridization and selection, without altering the genetic code, using modern variants of old techniques. Again the issue was whether this was an "invention" under the Canadian Patent Act (CPA). While the patentability of plant life was raised as an issue before the court, the SCC was able to uphold the Commissioner's decision denying the application over plants

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[463] There is some evidence that even clones vary since the survival rate is significantly less and the risk of developing health problems statistically more. See L. Paterson, P. DeSousa, W. Ritchie, T. King, and I. Wilmt, "Application of Reproductive Biotechnology in Animals: Implications and Potential Applications of Reproductive Cloning" (2003) 79(3-4) Animal Reproduction Science 137-143; W.M. Rideout, K. Eggan, and R. Jaenisch "Nuclear Cloning Epigenetic Reprogramming of the Genome" (2001) 293 *Science* 1093-1098; and G. Schatten, R. Prather, and I. Wilmut, "Cloning Claim is Science Fiction, Not Science" (2003) 299 *Science* 344. See also "Sorcerer's Apprenticeship", *The Economist*, (15 March 2007).

[464] *Pioneer Hi-Bred Ltd. v. Canada (Commissioner of Patents)* [1989] 1 S.C.R. 1623, [1989] S.C.J. No.72 [*Pioneer*].

and its seed but not on the basis of the subject matter. Rather, the Commissioner's decision was upheld on the basis that *insufficient disclosure* was made by the patentee whose "disclosure" consisted of filing a seed sample. Disclosure requires the inventor to "set forth clearly the various steps required to make the "composition of matter" in such full, clear, concise and exact terms as to enable any person skilled in the art or science to which it pertains, or with which it is most closely connected to make it."[465] The disclosure failed to teach others skilled in the art how to *reproduce* and work the invention. The SCC expressly declined to consider whether new soybean varieties are patentable subject matter under s. 2 "invention", while the Federal Court of Appeal had found that the plant derived from traditional cross-breeding could not be construed as "manufacture" or "composition of matter" in part because plant breeding, an established practice prior to the enactment of the CPA, was not alluded to at all within the definition of "invention" with reference to words such as "strain", "variety" or "hybrid."[466]

Pioneer was the last major case on the patentability of higher life in Canada before two recent SCC decisions and the closest one to recognizing the auto-contribution of living subject matter in its reasoning when recognizing that higher multi-cellular life was not patentable because the so-called "invention" could not be fully disclosed in a manner that would allow the full replication of the invention, one might add, in uniformity and at will. When given proper consideration, the disclosure requirement is not a small one to overcome for life inventions because the self-propagation and mutation of living matter means that inventors do not have full control over all of the characteristics of the resulting product and therefore technically can *never* teach it in their

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[465] See Binnie J's discussion of *Pioneer* in *Harvard SCC, supra* note 185 at para. 27.
[466] Fecencko, *supra* note 249 at 85.

patent application. Patents on life will always be disingenuous as they will technically fail to meet the conditions of the "bargain" with the crown[467] even if a court holds otherwise. Any rights granted to the invention claimed *cannot* be commensurate with the "invention" made as a matter of law or policy. Although a new, useful, and non-obvious cultivation method may be disclosed and patented as *process* claims, granting a claim for a 20 year monopoly in the underlying *product* sanctions a misrepresentation on the public as inventors simply cannot account for the variable contribution associated with life. *Pioneer* was used by the patent office to reject claims for higher animal and plant life on this basis until the case of the Harvard mouse which needs to be followed through three jurisdictions in order to understand its significance to the patenting life debate.

4.3 Comparative Treatment: Of Mice...

The Harvard mouse case focused on the legally distinct issue of whether non-human higher life (plants and animals) were patentable subject matter within the s. 2 statutory definition of "invention". The "oncomouse" epic began in a Harvard lab in the early 1980's with two scientists, Philip Leder and Tim Stewart, successfully engineering a mouse to carry an oncogene (a tumor-causing gene tied to a promoter that activates the gene in the mammary glands of mice) by introducing transgenic material into its DNA. The oncogene increases the probability that the mice carrying it will develop malignant tumors without the traditional degree of exposure to carcinogens, and while it does not

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[467] Pila, *supra* note 382, comments on the insufficiency of written forms of description to ensure "a third party's ability to repeat an invention involving biological material." "It followed" she adds, "from the requirements of enablement and disclosure that if biotech patenting were to be allowed [,] traditional conceptions of reproducibility would need to be revised or an alternative means of description introduced." (at 336). Alternative means were implemented by the 1977 Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure, Apr. 28, 1977, 32 U.S.T. 1241, 1861 U.N.T.S. 361 which allowed for the deposit of microorganisms in lieu of written descriptions. However, as Pila notes, some nations refused to accept these samples as fully meeting disclosure requirement.

ensure it for all, the oncomouse is useful for facilitating carcinogenic studies. After consulting with outside legal counsel, it became apparent for Harvard and its licensee DuPont that the mouse would have to be patented as an invented product in order to ensure maximum protection under the law for its future value as licenced technology to other labs conducting cancer research.[468] Such an application was unprecedented but was anticipated to be an insignificant legal hurdle given that the mouse was new, involved an inventive step (it was not-obvious), had significant research-based utility, and was believed to meet the statutory definition of "invention". The product for which a patent was sought was a genetically modified mouse. Harvard's product claims were excessively broad. Harvard created a transgenic *oncomouse* (a mouse modified to carry a cancer causing gene) but Claim 1 covered a significantly broader "invention" than that invented,[469] reaching through to cover *all* transgenic non-human mammals bearing the specific feature described such as, for example, an *oncomonkey* to which Harvard's claim, if granted, would extend. Harvard thought that there was no legal reason to expect it would be precluded as patentable *subject matter* even though it was animal life.

In the United States, what is patentable is set out in §.101 of Title 35 of the United States Code governing patent grants, which provides:

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[468] Contrary to popular belief, the "work had not been done for the sake of devising a patentable product, but once it was accomplished, Leder recognized that it might have commercial possibilities. In 1983, he brought his mice to the attention of the Office of Technology Licencing and Industry Sponsored Research, the recently established patents arm of the Harvard Medical School" See Kevles, *supra* note 425, discussing the history of patenting life reporting to the European Group on Ethics in Science and New Technologies, at 44 based on the author's interviews with Philip Leder, June 21, 1988 and June 6, 1991. This view was again expressed by Leder in a more recent interview, see IDEAS, CBC Radio One, (June 2003) archived at www.cbc.ca/ideas/calendar/2003/10_October.html, undermining incentive theories.

[469] "A transgenic non-human mammal whose germ cells and somatic cells contain an activated oncogene sequence introduced into said mammal, or an ancestor of said mammal, at an embryonic stage. "Germ cells" are reproductive cells, and "somatic cells are all other cells of the organism other than reproductive cells. It is understood that the transgenic non-human mammals which are sought to be patented will have the oncogene present in all reproductive and somatic cells." *Harvard FCA, supra* note 85 at fn 5.

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore...[470]

In 1984, Leder and Steward's U.S. patent application was assigned to Harvard creating the catalyst for the ensuing controversy over animal patents. To settle the debate, in 1987 the United States Patent and Trademark Office (USPTO) issued a position statement that "nonnaturally occurring nonhuman multi-cellular living organisms, including animals...[would be considered] patentable subject matter...[but a] claim directed to or including...a human being will not be considered patentable subject matter" under patent law.[471] In 1988, the USPTO formally granted the first animal patent for the oncomouse (U.S. Patent 4,736,866) – recognizing higher life as patentable subject matter and establishing the precedent for the range of life patented in the USA since.[472] Harvard succeeded in securing rights to its reach-through claim which meant that Harvard would enjoy an entirely separate revenue stream from licencing any transgenic mammal covered within the claim as well as its mice (which it licences to labs at $1/per) even though disclosure for what was "invented" was only for a mouse.

Once patenting life forms is permitted it becomes acceptable such that restricting the practice becomes more difficult to legally justify, if for no other reason than the principle of *stare decisis*. The search for greater commercial profit means that biotechnology will move beyond R&D in health and food related inquiries and expand into markets where the anarchic whims of consumers will translate into demand for novelty products, like designer pets, which might offer greater potential profit but create

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[470] 35 U.S.C.A. §.101, online: <http://www4.law.cornell.edu/uscode/35/>. This is essentially the language used in the 1793 Thomas Jefferson draft except for the word "process" which replaced the word "art" in a 1952 Congressional reform of patent law.

[471] See D.J. Quigg (Commissioner of the United States Patent and Trademark Office, Policy Statement on Patentability of Animals, 1077 Off. Gaz. Pat. Office 24 (7 April 1987).

[472] Genetically engineered animals include fish, cows, mice and pigs, and there are currently more than 190 of these varieties waiting to be patented. See Shiva, *supra* note 283 at 112.

unforeseeable consequences for future regulation. New ethical questions are raised when transgenic life is created and patented for the exclusive purpose of pet ownership.[473] Glowing mice, fish, and luminescent rabbits[474] have been "invented" and may foreshadow the market for genetically modified ("designer") cats and dogs.

The issues within the patenting life debate are familiar. The ethical concerns include animal welfare,[475] respect for human dignity, the inviolability of the person, and inalienability of the body, informed consent for extracting genetic samples, and loss of control over engineered life with unintended consequences such as cross-fertilization (producing "Super Weeds" and "Super Bugs" resistant to future chemical attack). Many

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[473] See Michael LePage, "They Came, they Glowed...They Could Conquer the Pet Trade" *New Scientist,* December 20, 2003-January 9, 2004, at 24, available on line at www.newscientist.com, LePage reports that California state fish and game commissioner Sam Schuchat told reporters, in response to the new Glofish, "I just don't think it's right to produce a new organism just to be a pet...To me, this seems like an abuse of the power we have over life." The Glofish is a genetically modified zebrafish with a coral gene that makes it fluoresce red. It has been selling well in other states such as Florida according to LePage, and is rivaled only by its darker cousin, Night Pearl- a fish that glows in the dark due to an added jellyfish gene that has been selling in Taiwan since June 2002.

[474] Performance art has also embraced biotechnology as part of its protest. San Francisco artist Marlilyn Donahue commenced a "genome certification program" and prompts members of the public to "become a certified original human. Copyright your DNA." She recommends fixing "authorship" by licking a stamp and posting it on a self-addressed envelope, online <www.mudhaus.com/marilyn/donahue>.

[475] For a comprehensive discussion of the objections against granting patents on transgenic animals, see Rebecca Dresser, "Ethical and Legal Issues in Patenting New Animal Life," *Jurimetrics Journal* (Summer 1988): 399-435. Objections include the survival of the family farm and undesirable distributional consequences; commodification and devaluation of life; increase in animal suffering; interference with the natural world; and the penetration of undesirable commercial imperatives in the organization and priorities of academic research. Additionally, there are concerns over animal and human health and welfare effects of xenotransplants which rely on the commercial production of genetically modified donor animals. See *report of the National Forum on Xenotransplantation: Clinical, Ethical and Regulatory Issues,* Ottawa, November 6-8, 1997 (Ottawa: Health Canada, 1998), online: <http://www.hc-sc.gc.ca/hpb-dgps/therapeut/zfiles/ennglish/btox/reports/frmrptx_e.pdf> discussed in Ted Schrecker and Alex Wellington, "Patenting of Biotechnological Innovations Concerning Animals and Human Beings" Prepared for the Canadian Biotechnology Advisory Committee Project Steering Committee on Intellectual Property and the Patenting of Higher Life Forms, March 31, 1999; see also Sylvia Pagan Westphal "Growing Human Organs on the Farm" *New Science* (December 20, 2003- January 9, 2004) at 4 discussing the creation of human/animal chimeras for harvesting cells genetically identical to a human's. This would allow for damaged organ repair and ultimately transplantation of cultivated human organs in animals. Those opposed are concerned that retroviruses dormant in animal DNA could mutate or activate into infectious forms for humans. A few clinical trials are underway in the United States but the technique is expensive to develop and "then there is the moral issue. Some people oppose the creation of all human-animal chimeras on religious grounds, and many more would join them if there were the slightest chance that sheep with human brain cells might be more than just sheep."

of these concerns are tied to alarmist apprehensions of 'playing god' and public interest unease at privatizing and commoditizing life.[476] Public welfare arguments that support biotech innovation in health and food industries are less compelling with pets as consumable goods. Once patents are granted over higher life forms, debate necessary to determine what qualifications, if any, need to be made around proprietary rights become less imperative. Industry proponents will assert, as they did with gene patenting, that what is already being done hardly begets further debate. Of course, research on creating transgenic animals would not cease without patent protection as scientists are driven by, as Kuhn postulates, an internal desire to solve puzzles.[477] Scientists, such as James Watson, Benjamin Franklin, and others before and after them, are driven by an inconvertible desire to see how far they can push the perceived laws of nature. However, according to the accepted rationales for patenting, granting such IPRs would further the *commercialization* incentive that drives industry to innovate genetically modified higher life, whether the oncomouse or the GFP bunny rabbit which glows in the dark[478] and other novel luxury consumer goods.[479] At the end of the day, it is not clear whether the public in the United States and Canada unequivocally believe that such commercial activity merits further encouragement by our patent system.

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[476] For a discussion of the ethical issues, see Schrecker et. al. "Ethical Issues Associated with the patenting of Higher Life Forms", May 17, 1997, Westminister Institute for Ethics and Human Values McGill Centre for Medicine, Ethics and Law, online: Strategis.gc.ca http://strategis.ic.gc.ca/epic/internet/inippd-dppi.nsf/en/ip00095e.html [Schrecker *et. al.*]. See generally, Fecenko, *supra* note 249.

[477] "[I]n the centuries before copyright and patent laws were established or rigorously enforced, inventive and creative work flourished throughout the world." Vaver *IPL*, *supra* note 34 at 8.

[478] For more information on the green glowing albino bunny named Alba, visit http://www.ekac.org/.

[479] Allowing patents on life forms will likely not change the direction of research. The question, according to Konrad Sechley a patent lawyer with one of Canada's leading IP firms is "whether or not Canada would be able to have some stake in that commercialization or potential business." See David Gambrill, "Court allows patent on Harvard Mouse: Decision paves the way for patenting all life forms except humans" *Law Times*, online at http://www.canadalawbook.ca/headlines/headlines52_arc.html.

American patent policy ignores all issues of morality in its consideration of patentable subject matter. In Europe, national patent law of signatories must conform to the European Patent Convention (EPC)[480] which contains a moral clause. The EPC is a treaty that was created to harmonize the laws of signatory European nations and to create collaboration and convergence regarding patentable subject matter. Administered by the European Patent Office (EPO), the EPC allows inventors to process their application through one office, the EPO to obtain multiple European national patent rights. Neither the EPC nor the laws of its signatories specifically deal with biotechnology patents. Biotechnology patents have been considered under Article 53(a) of the EPC which prohibits patents on inventions *contrary to public ordre or morality;* although these terms, which also appear in Article 27(2) of TRIPS, are undefined in both contexts.

In 1984, Harvard filed its patent application in Europe. It was the first case to invoke Article 53 of the EPC. The application was initially refused in 1989 by the European Patent Office (EPO), not because of *public ordre or morality*, but on the basis that the patent was prohibited by Article 53(b) of the EPC which expressly excludes "plant or animal *varieties* or essentially biological processes for the production of plants or animals".[481] Article 53(b) was drafted in order to prevent interference with the international system for protecting plant breeders' rights under UPOV which was created in 1961.[482] Despite the ongoing public outcry against the patenting of life forms in both

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[480] See European Patent Convention, October 1977 [EPC], online: http://www.european-patent-office.org/legal/epc/e/mal.html.

[481] European Patent Office Press Release No. 10/89, "EPO Refuses Patent Application for Oncogenic Mouse." See generally Kevles, *supra* note 425 at 58.

[482] International Union for the Protection of New Varieties of Plants (UPOV) is an international agreement providing the prevailing model for plant breeders' rights. The 1978 UPOV Act was presumed to permit farmers to re-use proprietary seeds. UPOV 1991 was considered to prevent farmer plant-back. See Crucible II Group, *Seeding Solutions*, *supra* note 2, 40-71. Plant variety protection provides a different form of protection than patents for plants. For a discussion of the latter, see Mark D. Janis, "Sustainable

the United States and Europe, the *ordre public* and *morality* provision was surprisingly not referenced.[483] Instead, the oncomouse was considered the product of natural biological processes- a different breed constituting a new variety- making it ineligible for a patent under the EPC.

Harvard appealed the decision to the EPO's Technical Board of Appeal (TBA) on the basis that this mouse was not a *variety* but a new type of animal "transcending varietal classification, and that [it] was not a natural biological product but—echoing Chakrabarty's claim—a biological entity made by man."[484] The appeal was mired with extensive third party filings[485] from various environmental and animal welfare interest groups on moral grounds opposing the patent grant; the opposition had an impact. Although the TBA reversed the EPO decision in 1990, the application was returned to the original examiners for reconsideration to determine whether the patent would be excluded based on Article 53(a) as contrary to *ordre public* and *morality*[486] with a direction that a balancing test be undertaken to consider three main concerns: the potential suffering of the animal due to cancer; the potential risks posed to the

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Agriculture, Patent Rights, and Plant Innovation" 9.1 Ind. J. of Global Legal Stud. 91-119. Under TRIPS Article 27.3, plant varieties must be subject to some form of protection which can be a combined patent/*sui generis* system. See the discussion later in this chapter on TRIPS, under the heading "The "Wiggle Room and the Will: TRIPS Compliant Regulatory Preferences".

[483] C.M. Ho, "Patent Law and Policy Symposium: Re-engineering Patent Law: The Challenge of New Technologies: Part III: International and Comparative Law Issues: Splicing Morality and Patent Law: Issues Arising from Mixing Mice and Men" (2000) 2 Wash. U. J.L. & Pol'y 247 at 257-258.

[484] Kevles, *supra* note 425 at 58. Chakrabarty is the surname of the inventor of the genetically modified bacterium in the first case to recognize the patentability of life. See the in text discussion of *Diamond*, *supra* note 441 and accompanying text.

[485] Unlike American and Canadian patent systems, the EPC allows interested third parties to file comments opposing or in support of applications pending or on appeal.

[486] This phrase also appears in Article 27(2) of TRIPS and has a deliberately selected meaning: "the negotiators [of TRIPS] rightly replaced the term 'public order or morality' with '*ordre public* or morality.' The reference to public order was inappropriate as a translation of the French concept of '*ordre public*', whose meaning is closer to 'public policy.' See in text discussion at page 169-170.

environment if a GM mouse escaped; and the human benefit of expedited cancer research.[487]

Harvard's reply discharged the burden by asserting that if patented, the oncomouse would be widely available under licence - this would reduce the aggregate number of mice needed for cancer research. In addition, using mice as research subjects has long been an acceptable practice for society due to the benefits of research. Finally, the probability of a mouse escaping and causing environmental disaster was negligible and outside of the contemplation of the patent system, although possibly subject to external regulations. Agencies charged with control over hazardous materials had better jurisdiction over such issues.[488] On October 4, 1991, the Examining Division issued a communication under Rule 51(4) of the EPC that it would grant Harvard its patent. After a period of further opposition pursuant to the EPC, the mouse emerged triumphant under Patent No. EP0169672.[489] The Board took the added rare measure of publishing in the Bulletin its comments on the fundamental patentability issues that were involved in the case.[490] This ruling provoked ten more years of controversy and the "no patents on life" campaign that ensued helped ensure that the Article 27.2 and 27.3 exemptions to patentability, of growing controversy because of the issues raised and the exponential growth of the biotech industry, made it into the final TRIPS text at Uruguay. [491]

Amani and Coombe have observed that in this case, the potential adverse effects of a technology were held sufficient reason to regulate its use in Europe but not to

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[487] EPO, "Decision of the Technical Board of Appeal 3.3.2 of 3 October 1990".
[488] "European Patent Application No. 86 304490.7, President and Fellows of Harvard College, Response to the Official Letter of 11th December, cited in Kevles, *supra* note 425 at 60; Ho, *supra* note 483 at 260.
[489] The patent would take effect later in May once published in the European Patent Bulletin (European Patent Office, Press Release 3/92, "European Patent for Harvard's Mouse).
[490] For a comprehensive timeline, see the Official Journal of the EPO, 10/1992 online: <http://www.european-patent-office.org/news/pressrel/pdf/oj1992_10_p588_593.pdf>.
[491] These articles are set out and discussed below in this chapter.

prevent a patent from issuing in the first instance. Concerns over the need to protect the environment from the unwanted spread of genes and animals from cruelty were considered to be outweighed by the overwhelming consensus in the scientific community that the oncomouse would be instrumental in furthering cancer research. The authors note, "[o]nce again, the Western conception of the scientific research process was reified and valorized over and above all other social considerations while the costs of monopoly rights to the actual practice of research remained unaddressed."[492]

The European Harvard mouse decision signaled the relevance of ethical concerns and the need for the patentee in a European patent application to discharge Article 53(a) requirements. However, it also demonstrated the Division's determination that an animal (mice), being in a higher taxonomic classification than a species, would not be captured by Article 53(b) which means that such subject matter would be patentable if "invention" is demonstrated. In the long term, however, the efficacy of the *ordre public* and *morality* provision to moderate the future of biotechnology animal patents will only be as good as the policy in determining what the substantive standards infusing these terms are. Setting the patentability bar and breathing substantive life- so to speak- into the Article 53 exclusions is a flexible means for addressing policy concerns and for balancing economic interests with policies geared to the protection of human rights. That is because the terms capture important features underlying the need for regulatory diversity. "Morality is a different concept" according to Daniel Gervais, [i]t seems to correspond to the French concept of '*bonnes moeurs*'. It naturally depends to a certain degree on the particular

[492] Amani and Coombe, *supra* note 49.

culture of a country or region. And *ordre public,* translated from French is different from merely "public order."[493] Gervais explains:

> While public order may be defined as the maintenance of public safety, *ordre public* concerns the fundaments from which one cannot derogate without endangering the institutions of a given society. A typical application of this rule in civil law jurisdictions is that while private persons are free to contract in or out of any obligation, that freedom is limited by *ordre public.* Covenant...require approval of the State...where interests of society (represented by the relevant state institutions) are involved.[494]

After 10 years of controversial debate on the patenting of life forms, the EU issued the Biotechnology Directive (EBD) in 1998, now part of European Community law, to try and clarify the role of ethical considerations in EU patent jurisprudence and introduce harmonized standards that assure biotech patentability, but was opposed by a number of EU Member states.[495] The Directive prohibits the patenting of human clones and patenting of innovations that involve industrial use of embryos as well as "parts of the human body.... at various stages of its formation and development, and the simple discovery of one of its elements." Nevertheless, Article 5 provides that "elements isolated from the body, including genes, will be patentable if their [industrial] utility can be established." The delay in implementing these provisions into national legislation in many of the member states, however, suggests that the issue is still a controversial one (although patents continue to issue). The prospects of using the public ordre and morality provisions in Article 53 of the EBD (which mirror those in TRIPS Article 27.2) to limit domestic patents on human genetic materials appear increasingly remote as these are interpreted in the European Patent Office to be restricted to inventions that threaten

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[493] See Daniel Gervais, *The TRIPS Agreement: Drafting History and Analysis* (London: Sweet & Maxwell, 2003) at 222-223. For the drafting of this provision see Philip C. Mendes da Costa, "Patent Harmonization through GATT: TRIP or trap" (1992) 45 *Patent World* 23 at 25.

[494] *Ibid.* at 223.

[495] Members were to implement the Directive into national law by the year 2000 but at least nine Members refused to do so because of strong opposition to the patenting of genetic material of all life forms but for which they can be referred by the European Commission to the European Court of Justice for infringement.

national security or an individual's physical integrity in society. In 1995, *Howard Florey Institute/Relaxin*[496] determined that the "morality" exception applied only "to ensure that patents would not be granted for inventions which would universally be regarded as outrageous", establishing a standard that is arguably impossible to achieve. Moreover, it was held that the invention – human DNA fragments with a particular encoding—did not involve the patenting of human *life*. The capacity of a patent granting body to determine the meaning and boundaries of human life was questionable to many but even on appeal, the Technical Board of Appeal affirmed that "...DNA is not 'life' but a chemical substance which carries genetic information and can be used as an intermediate in the production of proteins..."[497] But DNA engages in the same kind of auto-activity we attribute to life: it replicates, mutates, and creates. Moreover, in Canada, in light of the decisions discussed below, such an artificially narrow interpretation to life would pervert the actual legal consequences given rise to and is simultaneously inconsistent with scientific and popular characterizations of DNA.

Canada's legal definition of "invention" was originally derived from the American statute and is substantially similar. Despite the overall trend in convergence, interpretation by the courts has led to some very significantly different legal results which may relate to the different political and cultural context. For example, in the United States it was judicially decided that methods of medical treatment are patentable but not so in Canada.[498] The Canadian Manual of Patent Office Practice (MOPOP) s. 16.02

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[496] In Re Howard Florey Institute-Relaxin, EPO Opposition Division, [1995] E.P.O. R. 541, as cited in Neil Jenkins, "In Brief: The Impact of the EU Biotechnology Directive on the Patenting of Biotechnology," (2001) *Patent World* 128.

[497] *Howard, ibid* at 541-542.

[498] In *Tennessee Eastmen Co. v. Commissioner of Patents*, [1974] S.C.R. 111, (1974), 8 C.P.R. 92d) 202, it was found that a method of bonding incisions and wounds was not an "art" or "process." It should be noted

confirms that "subject matter related to a process of surgery or therapy on living humans or animals is not considered to be within the scope of "invention" as defined by section 2 of the Patent Act." This is a very important exclusion for a country which prides itself on its public health system.[499] More than eighty countries around the world reportedly have this public policy exclusion.[500] Similarly, while the American Supreme Court has extended patents to previously rejected business methods, these "inventions" are still not patentable within Canadian law and jurisprudence.[501]

The patentability of Harvard's mouse took 17 years to resolve in Canada. During this period, patent protection for transgenic non-human higher life remained uncertain but this did not stifle innovative activity in this field. One reason may be that Canadian inventors derive their incentive to innovate from sources external to the Canadian patent system. The prospect of patenting in more viable and lucrative commercial markets, like those of the United States and Europe, may be a stronger incentive for Canadian inventors than domestic patent law and policy. Harvard's application covered 26 claims and was made on June 21, 1985. It came to rest with the December 5, 2002 judgment of

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that while this common law precedent continues to exist in Canada, the statutory provision on which it was based has since been repealed.

[499] Roy Ramonov, head of the Commission on the Future of Health Care in Canada reports on the judiciary's finding. Commenting on the sanctity of medicare for Canadians and its importance as an integral part of the fabric of our society, our identity, and our culture, he writes: "In my view, there is no better window on the future of our nation than the manner which we collectively deal with medicare. How we handle the issues arising from the recurrent debates on the provision of health provides us with a glimpse of our future together- or not!...Will a particular ideology prevail, despite the preponderance of evidence that its tenets are contrary to Canadians' core values? ... the great social experiment known around the world as Canada? ...Whatever may be the eventual answers to these questions, we are at yet another serious crossroads in both health care and its contribution to nation building, Canadian identity and, not least, health outcomes." Roy Romanow, "Access to care, access to justice: The legal debate over private health insurance in Canada" (from the U of T Bulletin, Sept. 26/05), online: University of Toronto, <http://www.news.utoronto.ca/bin6/thoughts/050926-1665.asp>.

[500] O. Mitnoveski and D. Nicol, "Are patents for methods of medical treatment contrary to the *ordre public* and morality or "generally inconvenient"?" (2004) 30 J. Med. Ethics 470-75, http://jme.bmjjournals.com/cgi/content/full/30/5/470.

[501] See generally Meurer, *supra* note 376.

the Supreme Court of Canada. The application claimed patent protection for both the process of creating transgenic mice, and product claims over an array of related goods including the transgenic material (onco gene sequence), plasmids, oncoeggs, and of course the GM mouse.

The Canadian patent examiner originally rejected 18 of the 24 claims submitted. Upon Harvard's request for review and an amended application for 26 claims, the examiner in 1993 allowed the process claims 13-26 but again rejected the product claims 1-12 as non-statutory subject matter. The Patent Appeal Board heard the appeal from the decision of the Examiner in 1994 which the Patent Commissioner endorsed. Section 40 of the PA gives the Commissioner discretion to refuse a patent which the applicant is not entitled to by law.[502] In so doing, the Commissioner refused to extend "manufacture" or "composition of matter" in the definition of s. 2 "invention" to include non-human higher life forms. Harvard's appeal to the Federal Court Trial Division[503] in 1998 was dismissed by Justice Nadon but was allowed by the Federal Court of Appeal in 2000. Rothstein J.A. for the majority (Linden J.A. concurring, Isaac J.A. dissenting), quashed the decision of the Commissioner and trial judge and remitted the matter to the Patent Commissioner with the direction that the patent be granted cover the product claims 1-12 set out in the application.

Canada's heavy investments in the biotechnology sector and its political support for stronger intellectual property rights[504] led to the assumption by legal and business commentators, confirmed by the Federal Court of Appeal, that Canada's industrial needs

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[502] *President and Fellows of Harvard College v. Canada (Commissioner of Patents)(T.D) [Harvard Trial]*, online: <http://reports.fja.gc.ca/fc/1998/pub/v3/1998fc22348.html> .
[503] *Ibid.*
[504] See Budget Speech, 2000, *supra* note 9.

would take precedence and ensure the patentability of genetically modified life forms. The decision was expected to affect approximately 600 patent applications on genetically-modified animals and plants.[505] The refusal of the Supreme Court of Canada to follow the United States and European precedent that recognized the validity of Harvard's product claims suggested that critical scrutiny of these patents within relevant industrial sectors as well as growing public opposition was finally having some impact.[506] Issues of morality and environmental risk were raised by the numerous intervenors before the Supreme Court. The majority for the Court made sure, however, that they would not be perceived as engaging in judicial patent policy formation; they did so by restricting their reasoning in such a manner as not to obscure the matter of statutory interpretation (with which they were charged) with the issues of morality (for which there was no legislative authority). Justice Bastarache addressed this concern in his decision:

> The sole question in this appeal is whether the words "manufacture" and "composition of matter", in the context of the PA, are sufficiently broad to include higher life forms. If these words are not sufficiently broad to include higher life forms, it is irrelevant whether this Court believes that higher life forms such as the oncomouse ought to be patentable....In my view, whether higher life forms such as the oncomouse ought to be patentable is a matter for Parliament to determine. This Court's view as to the utility or propriety of patenting non-human life forms such as the oncomouse are wholly irrelevant.[507]

Harvard argued for a strict application of the CPA by the Supreme Court in order to preserve the status quo, and strongly advocated that it was not within the jurisdiction of patent law to contemplate moral or policy judgments pertaining to the underlying technology; that statutory interpretation must inherently be amoral; and that the issues raised by the intervenors are better addressed by external regulation which can occur

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[505] Phillip B.C. Jones, "Will the Oncomouse Squeak Through the Supreme Court of Canada?" (July 2002), online: <http://www.isb.vt.edu/articles/jul0206.htm>.
[506] See generally Amani and Coombe and the discussion of the growing NGO movement and protests on patenting life forms, *supra* note 49.
[507] *Harvard SCC*, *supra* note 185 at para. 153.

when and if there is the requisite political will even though granting patents on life is not entirely value free. In fact, neither the concept nor the content of our conception of property rights are morally ambiguous as Mason and McCall Smith find:

> [t]he idea of property is primarily a legal one. It is a construct which allows us to order our society according to a chosen value system, which in turn greatly facilitates the achievement of certain of our social goals- in our case, those of most Western states which encourage commerce and sanction commodification.[508]

Granting intellectual property protection is a policy reflecting a particular set of values in a given society; one which normatively prescribes and reinforces the judicially derived ideology that patents can be granted for "anything under the sun made by man."[509] Meanwhile, the contemplation of morality by our patent law comes in and out of fashion based on domestic economic and political conditions. Justice Binnie's dissent found that the 1993 repeal of the s. 27(3) prohibition against patenting "an invention that has an illicit object in view" made it clear,

> that granting a patent is not an expression of approval or disapproval. At that time, Parliament did not add a provision, present in the European Patent Convention and in many civil law systems and international agreements, that patents will not be granted for inventions whose use of exploitation would be inconsistent with ordre public, public morality, or environmental or health protection. That type of provision would open the door to value judgments in assessing patentability.... Parliament thereby signaled, however passively, that these important aspects of public policy would continue to be dealt with by regulatory regimes outside the Patent Act.[510]

For the SCC, while various references were made to international law, reference to *ordre*, *morality* and patent policy considerations, however, proved unnecessary in the end- but also indicate a judicial reluctance to engage in these determinations better suited to the legislative branch. The majority upheld the Commissioner's decisions

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[508] Mason & McCall Smith, *supra* note 452 at 486. The authors note that "[t]he role of ethics lies not in grounding a property right but in determining whether it is appropriate to commodify something such as the human body which...has a particular moral status."

[509] *Diamond*, *supra* note 441 at 309 (citing S.Rep.No. 1979, 82d Cong., 2d Sess., 5 (1952); H.R.Rep.No.1923, 82d Cong., 2d Sess., 6 (1952)).

[510] *Harvard SCC, supra* note 185 at 12. The provision was CPA, R.S.C. 1985, Cc. P-4, s.27(3), prior to amendment by the North American Free Trade Agreement Implementation Act, S.C. 1993, c.44, s. 192 [*NAFTA I A*]. See also Vaver *IPL*, *supra* note 34 at 120.

distinguishing the patentability between Harvard's product and process claims for the following reasons. First, the decision was grounded in a common sense reading of the statute. The words used in the definition of "invention" are broad. Nevertheless, it is an exhaustive definition that signals on its plain meaning a clear intention of Parliament to include certain subject matter as patentable while excluding others. The oncomouse did not fit within the s. 2 definition of "invention" because it could not accord with common statutory interpretation rules for interpreting the words "manufacture" or "composition of matter." Moreover, the issue of whether something falls within the s. 2 statutory language is, according to the Court, a pure determination of law[511]- supporting a country-specific approach suggested in this thesis.

Second, the SCC deferred to the democratic process and Parliament's role to settle these issues. In so doing, the SCC recognized that before the one size fits all patent is extended to all biotech innovations, it should be decided whether the scientific developments claimed are ones which we would want to otherwise regulate outside of patent legislation.[512] Having found plants and animals to constitute non-human higher

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[511] *Harvard SCC*, *supra* note 185 para. 144-166. On the issue of the level of administrative deference to be afforded the Commissioner's decision, the majority found that "[t]he task is rather to determine whether Parliament intended the definition of invention to be interpreted broadly enough to encompass higher life forms, a question which the courts are as well suited to answer as the Commissioner." (para. 50). Bastarache J, writing for the court concludes that "Parliament did not intend to include higher life forms within the definition of invention found in the Patent Act. In their grammatical and ordinary sense alone, the words "manufacture" and "composition of matter" are somewhat imprecise and ambiguous. However it is my view that the best reading of the words of the Act supports the conclusion that higher life forms are not patentable....I do not believe that a higher life form such as the oncomouse is easily understood as either a "manufacture" or "composition of matter." (para. 155).

[512] For example, imagine that to protect animal welfare, a law is passed making it illegal to create or trade in biotechnologically engineered cats and dogs. It would be inconsistent, inefficient, and generally confusing to have a deterrent criminal law for the same object for which we grant exclusive commercial rights to encourage. Such a legal discrepancy could bring the administration of justice into disrepute and create an undesirable paradox whereby incentives are provided to create something which is criminalized. Considerations of the balance of interests and aggregate social goals should occur *a priori* in the development of industrial policy and its co-ordination with other public policy areas. Would it matter that the engineered dog was not a novel pet but a seeing-eye dog creating a nexus with health? Would such a utility weigh more or less favourably in the argument to have patents issue? For related developments, see

life, the Court relied on the existence the *Plant Breeders' Rights Act*[513] as an indication of legislative intent to exclude higher life from patentability. The absence of similar legislation for animals led to a judicial inference against extending patent protection to them. The majority, for the Court, found that "although Parliament passed 'special legislation' to provide protection for plant breeders, it made no move to amend the Patent Act or to adopt other special legislation to provide for the protection of forms of animal life."[514] Accordingly, Bastarache J. found,

> [g]iven the unique concerns associated with the grant of a monopoly right over higher life forms, it is my view that Parliament would not likely choose the Patent Act as it currently exists as the appropriate vehicle to protect the rights of inventors of this type of subject matter.[515]

Clearly, policy analysts across sectors and legislatures across jurisdictions must work together in consultation with the public to make certain value based decisions on the incentives we want to provide, the rewards we want to give, and the costs we are willing to bear in determining whether life is patentable. How should internal governments co-operate in resolving the arising legal and practical issues? The delivery of health typically falls within provincial jurisdiction over property and civil rights;[516] the

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Paul Marcotte, "The Biotechnology Industry and Animal Experimentation in Canada", Biotechnology Bulletin, Fasken Martineau, (April 2003), online: <http://www.fasken.com. The author reports that "Bill C-10 amending the Criminal Code (cruelty to animals) is currently being examined by the Canadian Parliament's Standing Senate Committee on Legal and Constitutional Affairs and this "has researchers in the biotechnology sector worried." The concern is over animal experimentation for testing new drugs rather than genetically manipulating the animal itself. The provisions against animal cruelty have been removed from Part XI (Willful and Forbidden Acts in Respect of Certain Property) to a new Part V.1 of the *Criminal Code* which may effectively remove access to the specific defences of colour of right and legal justification available under para. 429(2). This amendment would signal a beginning departure from the vestiges of property ownership in animals, reflecting the growing successes of the animal rights movement.

[513] *Plant Breeders' Rights Act,* S.C. 1990, c. 20 [PBRA]. The 1990 act is specifically tailored to providing protection to breeders of plant varieties and while it provides a lower burden for obtaining rights, it offers a correspondingly narrower monopoly than that available under the Patent Act. See discussion in *Harvard SCC, supra* note 185 at para. 188-190.

[514] *Harvard SCC, ibid.* at para. 189. See also PBRA, *ibid.*

[515] *Harvard SCC, ibid.* at para.120.

[516] Section 92(7) grants the provinces authority over hospitals. Under section 92(13), power over health is included in the provincial property and civil rights, and under section 92(16) as a matter of local and private nature. However, health can also fall under the federal power under s. 91(27) for criminal law aspects of

provinces are restrained by federal objectives conditioned on funding transfers (the Canada Health and Social Transfer) as part of the shared-cost programs within each province. This unique relationship makes inter-governmental co-operation and collaboration imperative for the viability of the Canadian health care system and its internal coherence between provinces.[517] Intellectual property regulation, on the other hand, remains within federal jurisdiction[518] making policy co-ordination between two jurisdictions and two separate ministries—provincial health regulation and federal industrial property regulation—all that more difficult. It is not surprising then that the majority of the SCC found that the patenting of life,

> is a policy issue that raises questions of great significance and importance and that would appear to require a dramatic expansion of the traditional patent regime. Absent explicit legislative direction, the Court should not order the Commissioner to grant a patent on a higher life form.[519]

Third, the Court found that the patenting of higher life raised "unique concerns" that do not accord with the scheme of the CPA and are not shared with respect to traditional invention. Here, the Court was referring to the ability of such inventions to self-replicate – what they call reproducibility and Habermas refers to as auto-activity.[520]

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health (criminal regulation of food and drugs) punishing conduct dangerous to health, within the general jurisdiction of the peace, order and good government federal power if the health problem has national dimension (such as the spread of epidemics like water pollution, pestilence, and SARS or the Anthrax scare) and in relation to labour relation standards under the federal jurisdiction. Essentially, the question of jurisdiction depends on "the purpose and effect of the particular health measure in issue." Peter W. Hogg, *Constitutional Law of Canada*, 3d ed. (Toronto: Carswell, 1992) at 476.

[517] See National Forum on Health, *Canada Health Action: Building on the Legacy—Final Report of the National Forum on Health* (Ottawa: Minister of Public Works and Government Services, 1997) at 20; Auditor General of Canada, *Report of the Auditor General of Canada to the House of Commons, 1999* (Ottawa; Minister of Public Works and Government Services Canada, 1999) c. 29 at 19. See Martha Jackman, "Constitutional Jurisdiction Over Health in Canada" (2000) 8 Health L.J. 95, online: University of Alberta <http://www.law.ualberta.ca/centres/hli/pdfs/hlj/v8/jackmanfrm.pdf>.

[518] Patent regulation is expressly granted to federal parliament under s. 91(22) of the *Constitution Act, 1867* (U.K.), 30 & 31 Vict., c. 3, reprinted in R.S.C. 1985, App. II, No. 5.

[519] *Harvard SCC, supra* note 185 para. 155.

[520] *Ibid.* at para. 170. See also Jürgen Habermas, referring to the work of Hans Jonas discusses the inference of "specific self-referentiality and irreversibility of the intervention in a complex, self-regulated process, leading to consequences which we cannot control: 'To 'produce,' here, means to commit something to the stream of evolution in which the producer himself is carried along.'" Habermas, *supra* note 431 at 47.

The Court found the line drawn in *Abitibi* regarding reproducibility en masse of microorganism arbitrary, just as are other legal lines drawn between higher and lower life: "All of them are policy driven and, if they are to be introduced at all, should be introduced by Parliament."[521] As a result, the majority recognizes that life is qualitatively different subject matter for the purpose of determining patentability with a range of prospective issues that should weigh in on patenting of human genetic material. Adopting the view expressed in the June 2002 Canadian Biotechnology Advisory Committee's (CBAC) final report, the Court found:

> Because higher life forms reproduce by themselves, the grant of a patent covers not only the particular plant, seed or animal sold, but also all of its progeny containing the patented invention. In the CBAC's view, this represents a significant increase in the scope of the rights offered to patent holders that is not in line with the scope of patent rights provided in other fields.[522]

Fourth, Harvard's counsel highlighted that lower life (bacteria, yeast and moulds) have long been patentable as a composition of matter and that there was no justifiable or justiciable reason that higher life should be excluded. The Patent Office's distinction between higher and lower life, Harvard argued, was ill-founded and an arbitrary exercise in line drawing. With due respect, all judicial decisions, and legislative ones too, are about line drawing; any critique offered of the majority's decision to discern a difference between higher and lower life is a criticism of the process of judicial decision making in general which necessarily draws lines as was done in *Abitibi* too, – whether between the interests of various parties, between competing interpretation of statutory provisions, between the rights recognized in individuals or corporations and those denied, even in granting access to the court through legal fictions creating "persons" out of corporations. Just as the definition of property could be redefined by a shift in the line that is drawn to

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[521] *Harvard SCC, supra* note 185, para.52.
[522] *Ibid.* at para. 171.

include hitherto excluded positive externalities as part of the bundle of rights enjoyed as "property" (by allowing me to charge you for looking at my well kept lawn for example or the equally absurd idea of charging you to access your own genetic information), the issue of what is or is not patentable is as open and should be based on broader coordinated policy, if not cultural mores.

In Canada, the Harvard decision was derived from a narrow difference of opinion in which the majority recognized that expansion of "invention" under s. 2 of the CPA in such circumstances would be a policy decision best left for Parliament. In the end, the majority approved the line drawn by the Patent Office and courts in the past and adopted three broad justifications for the distinctions between higher and lower life: (1) micro-organisms are produced en masse as are chemical compounds. Any measurable quantity can possess uniform properties and characteristics which cannot be said of plants and animals, both higher life. This argument may become moot once cloning technology becomes effective for en masse higher human life production. The SCC found that the disclosure of the invention would be insufficiently enabling to allow one skilled in the art to duplicate as the capacity to self-propagate and reproduce creates natural variability that cannot be disclosed by the patentee nor duplicated by a person of ordinary skill in the art; (2) there are significant distinctions between higher and lower life which include variations in responses to stimuli; and that (3) the *Agreement on Trade Related Aspects of Intellectual Property Rights* (TRIPS), and the *North American Free Trade Agreement* (NAFTA), each contain an article whereby members can "exclude from patentability"' specifically provided for subject matter which, while including plant and animal life, does not extend to micro organisms. In its final reason, the Court implicitly comments on the

desirability of reducing friction with international obligations by noting that the decision of the majority would not compromise Canada's position nor bring it in conflict with international trade obligations. The substantive line drawn by the Patent Office was defensible and to be respected overall, according to Justice Bastarache:

> [I] am of the opinion that the unique concerns and issues raised by the patentability of plants and animals necessitate a parliamentary response. Only Parliament has the institutional competence to extend patent rights or another form of intellectual property protection to *plants and animals* and to attach appropriate conditions to the right that is granted. In the interim, I see no reason to alter the line drawn by the Patent Office. The distinction between lower and higher life forms, though not explicit in the Act, is nonetheless defensible on the basis of common sense differences between the two. Perhaps more importantly, there appears to be consensus that human life is not patentable; yet this distinction is also not explicit in the Act. If the line between lower and higher life forms is defensible and arbitrary, so too is the line between human beings and other higher life forms.[523]

4.4 ...And Men: Schmeiser & the Definition of "use"

4.4.1 The Case and Its Challenges

The problem with line drawing is that the line can always be redrawn. The SCC in *Harvard* conferred the responsibility on Parliament, declaring that it is *only parliament* that *has the institutional competence to extend patent rights...to plants and animals.* Yet, with the changing bench, the SCC reclaimed jurisdiction to determine the patentability of higher life- this time in relation to plants. The *Harvard* Court was cognizant of the leave to appeal from the Federal Court of Appeal decision in *Monsanto Canada Inc. v. Schmeiser*[524] (*Schmeiser*) upholding a genetically modified plant patent as valid and infringed. As the case before the SCC in *Harvard* was only about animals, presumably that Court's consistent reference to plants and animals, and the specific finding in *obiter* that existing plant breeder legislation suggested that plants were not patentable, was an effort by the majority in *Harvard* to prescribe a legal standard for treating the issue of

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[523] *Harvard SCC, supra* note 185 para. 199.
[524] *Monsanto Canada Inc. v. Schmeiser* (2001), 12 C.P.R. (4th) 204 (F.C.T.S.), aff'd. [2003] F.C. 165 (F.C.A.) [*Schmeiser FCA*]

patents on higher life forms as a class inclusive of plants *and* animals with the pending *Schmeiser* appeal in mind. However, *Harvard's* majority became *Schmeiser's* minority opinion and the deference to Parliament to legislate the patentability of higher life was quickly usurped by a reconstituted Supreme Court in 2004. When the mouse decision was released in December 2002, it was humorously speculated amongst IP academics that the 5:4 split majority was due to the Catholic vote. Amongst industry participants, there was separate speculation as to whether the restructuring of the Bench would dictate a different outcome for Monsanto's appeal. Reasonable people (just as reasonable nations) will reasonably differ on matters as legally ambiguous, socially contentious, economically significant and morally charged as the patenting of life form. When the decision is close, with a 5:4 split, a change in the Court's composition can create a precedent with long lasting effects until Parliament finally intervenes. Politicians may avoid such charged issues motivated by self-interest leaving it to the courts to determine by the majority of its opinion rather than that of the public's. The result is a very closely divided Supreme Court of Canada in these two cases- the conjecture transpired with the new Bench.[525]

In *Schmeiser,* Monsanto had obtained a Canadian Patent, No. 1,313,830 for an invention relating to glyphosate resistant plants.[526] The patent covered claims to a

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[525] In Harvard the 5:4 majority decision against patentability of higher life (animals) was delivered by Bastarache J, with justices L'Heureux-Dubé, Gonthier, Iacobucci, and Lebel concurring. The dissent was written by Binnie J. with McLachlin, Major, and Arbour concurring. In Schmeiser, the 5:4 majority opinion effectively supporting patent protection for higher life (plants) was delivered by Chief Justice McLachlin and Fish J., with Major, Binnie and Deschamps concurring. The dissent was delivered by Arbour J (dissenting in part) with reasons of Iacobucci, Bastarache, Arbour, and LeBel.

[526] Claim 1: A chimeric plant gene which comprises:

a promoter sequence which functions in plant cells;

a coding sequence which causes the production of RNA, encoding a chloroplast transit peptide/5-enolpyruvylshikimate-3-phosphate synthase (EPSPS0 fusion polypeptide, which chloroplast transit peptide permits the fusion polypeptide to be imported into a chloroplast of a plant cell; and

a 3' non-translated region which encodes a polyadenylation signal which functions in plant cells to cause the addition to polyadenylate nucleotides to the 3' end of the RNA; the promoter being heterologous

chimeric plant gene that encoded for an enzyme which conferred resistance to glyphosate herbicide such as Roundup that Monsanto produces. The claims extended to plant cells that contained the chimeric gene. Monsanto Canada licenses Canadian commercial seed growers to grow their Roundup Ready Canola (RRC) that expresses the gene and is resistant to Monsanto's herbicide, Roundup, which kills all other plants, making it easier to control weeds. Licensees sign an undertaking not to save seed from one year's crop for future replanting or inventory and not to share (sell or give) the seed to third parties.[527]

Mr. Schmeiser, a farmer of 50 years, never purchased the canola, never obtained a licence, and claims not to have taken advantage of the patented feature of the canola plants. Yet, after an anonymous tip sent investigators to his Saskatchewan farm in 1997, it was discovered that 95-98% of his 1,000 acres of canola crop was made from Roundup Ready plants although the origin of the plants remained speculative.[528] In his defence, Mr. Schmeiser argued that "the subject matter claimed in the patent is unpatentable. While acknowledging that Monsanto claims protection only over a gene and a cell, Schmeiser contends that the result of extending such protection is to restrict use of a plant and a seed." Both Mr. Schmeiser and the Court agreed that seeds, plants, and animals are

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with respect to the coding sequence and adapted to cause sufficient expression of the fusion polypeptide to enhance the glyphosate resistance of a plant cell transformed with the gene.

[527] Michael Blakeney reveals, however, that the "conspicuous success of RoundUp Ready® seed is explained because the increase in seed price to cover the price of genetically engineered herbicide tolerance is offset by profits from enhanced yields. On the other hand, increased yields might result in glutted markets, with a commensurate decline in profits." See Blakeney, *supra* note 282 at 10. That is the inherent problem with the promise of eugenic genetics.

[528] During trial, Schmeiser claimed that the canola plants were the result of cross-field breeding by wind or insects, making him an accidental infringer if at all. Trial Judge W. Andrew Mackay was not persuaded that the innocent bystander claims put forward could explain the high degree of concentration of RRC "'of a commercial quality' ultimately present in Schmeiser's crop." See *Monsanto Canada Inc. v. Schmeiser* (2001), 202 F.T.R. 78 at para. 118 [*Schmeiser Trial*].

not patentable in Canada pursuant to the *Harvard* decision.[529] But the SCC did not agree with the defendant that the patentability of plants or seeds was the issue before the court in *Schmeiser*:

> This case is different from *Harvard Mouse*, where the patent refused was for a mammal....The Patent Commissioner had allowed other claims, which were not at issue before the Court in that case, notably a plasmid and a somatic cell culture. The claims at issue in this case, for a gene and a cell, are somewhat analogous, suggesting that to find a gene and a cell to be patentable is in fact consistent with both the majority and the minority holdings in *Harvard Mouse*.[530]

Moreover, the majority in *Schmeiser* found that whether the scope of patent protection extends from gene and cell claims to provide rights to activities in relation to a plant was not relevant for the determination of validity but infringement.[531] On the issue of patentable subject matter, the majority did not focus on the issue of patent protection over plants but the narrower issues of the validity of the patent over genes and cells. They referred to *Kirin Amgen Inc v. Hoechst Marion Roussel Ltd.*:

> That case dealt with a protein useful in the diagnosis and treatment of blood disorders. The English court construed the claims to exclude the naturally occurring form of the DNA sequence in a human cell. However, this was done to accord with the provisions of a regulatory scheme that has no parallel in Canada: Article 5 of the European Parliament's Directive 98/44/EC, which regulates the patentability of biotechnological inventions. It states that the discovery of elements of the human body, including genes, is not patentable, although such elements are patentable when isolated or otherwise produced through technical means. The legislature has not enacted a comparable statutory scheme in Canada to narrow the scope of patent construction. Thus *Kirin Amgen* is not applicable to the case before the Court.[532]

Consequently, Monsanto's gene and cell product claims were held to be valid.

4.4.2 The Trouble with "use"

The Federal Court of Appeal affirmed the trial judge's finding of patent validity and Schmeiser's infringing "use". This encouraged the Canadian Intellectual Property Bar to advise their clients to pursue claims to cells, sequence listings and so forth because the appellate decision broadly interpreted patent rights through the definition of "use" and

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[529] *Schmeiser SCC, supra* note 336, para. 21.
[530] *Ibid.* at para. 22.
[531] *Ibid.* at para. 24.
[532] E.W.J. No. 3792 (QL), [2002] EWCA Civ. 1096 (C.A.), in *Schmeiser* SCC, *supra* note 336, para. 89.

effectively established backdoor protection for higher (plant) life through exclusive rights claimed over the genetic and cellular material.[533] When the case reached the SCC, the majority for the Court stated that "it is uncontested that Monsanto's patented claim is only for the gene and cell that it developed....The more difficult question—and the nub of this case—is whether, by cultivating plants *containing the cell and gene*, the appellants *used* the patented components of those plants."[534]

In a decision delivered in May 2004, the majority affirmed that while Schmeiser did not infringe Monsanto's exclusive rights under s. 42 of the CPA by *making* or *constructing* the invention, the collection, saving, and planting of seeds containing Monsanto's patented gene and cell constituted an infringing "use" of the invention, and contravened the patentee's guarantee of exclusive rights.[535] The error in the majority's reasoning to support this interpretation of "use" is apparent from the following passage which starts with a quote from a leading academic but leads to an inappropriate analogy and consequently the wrong conclusion by the majority:

> As Professor Vaver states, *supra,* at p. 152:
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> '"Use" applies both to patented products and processes, and also to their output. A patent that covers a Zipper-making machine or method extends to zippers made by the machine or method. Each zipper sold without authority infringes the patent, even if the zippers themselves are unpatented. This expansive doctrine applies, however, only if the patent plays an important part in production.'
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> By analogy, then, the law holds that a defendant infringes a patent when the defendant manufactures, seeks to use, or uses a patented part that is contained within something that is not patented, provided the patented part is significant or important. In the case at bar, the patented genes and cells are not merely a "part" of the plant; rather, the patented genes are present throughout the genetically modified plant and the patented cells compose its entire physical structure. In that sense, the cells are somewhat analogous to Lego blocks: if an infringement use were alleged in building a structure with patented Lego blocks, it would be no bar to a finding of

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[533] See Torys Newsletter, No. 2002-29T, December 6, 2002, online: Torys, <www.torys.com>.

[534] Emphasis added. See Schmeiser SCC *supra* note 336 at paras. 77-80; the court found that "provided the patented invention is a significant aspect of the defendant's activity, the defendant will be held to have "used the invention and violated the patent....Infringement does not require use of the gene or cell in isolation."

[535] For a summary of the majorities propositions, see *Schmeiser SCC, ibid.* at para. 58.

> infringement that only the blocs were patented and not the entire structure. If anything, the fact that the Lego structure could not exist independently of the patented blocks would strengthen the claim, underlining the significance of the patented invention to the whole product, object or process.
>
> Infringement through use is thus possible even where the patented invention is part of, or composes, a broader unpatented structure or process.[536]

With due respect to the Court, the majority makes the common error of collapsing the essential distinction in patent law that weighed heavily in *Harvard,* between *product* versus *process* claims just as the Board did in *Abitibi.* Harvard wanted a patent product claim over the oncomouse and was not satisfied with the CPO's grant of claims extending to genetic and cellular material (products) as well as the process used to make such material and a transgenic organism. This was a legitimate pursuit since if a rogue mouse escaped, was stolen or was created by some other processes not within Harvard's patent and went to create more mice with the patented oncogene through natural breeding, there would be no infringement. That a run-away, stolen or otherwise manufactured mouse prominently featured the patented qualities of the oncogene would be insufficient to extend Harvard rights to the mouse. Otherwise the effort to secure a product claim over the mouse would effectively be redundant with claims granted over the transgenic matter. Vaver's "zipper" analogy is correct but improperly applied by the Court. It is only if the zipper is itself patentable that a zipper made by some other process and not made 'by that machine' or "by that method" would constitute an infringement of the patentee's rights. Similarly, if a plant or animal carries a patented genetic or cellular matter, but does so because it is the result of an unpatentable (natural) process, such as independent mating or cross-pollination, then arguably the resulting progeny or plant should not constitute an infringement unless these plants or animals are themselves patented products. If liability

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[536] *Ibid.* at paras. 41-43.

were to be imposed, then it would have to be based on some fault-based principle, not in the CPA, that would render the acts of the defendant culpable for dirty hands- *i.e.* that a mouse was stolen and procreated through *breeding* rather than independent mating.

GM contamination in nature is not uncommon.[537] The SCC concedes that this may occur and Monsanto asserted that it would not bother with litigating such cases. Mr. Schmeiser made 'innocent by-stander' arguments contending that any occurrence of the GM crop occurred through wind-blown contamination of his fields, over which he had no control (an alternate process).[538] But whether the RRC appeared innocently on Schmeiser's farm through airborne transgenic contamination was also held to be irrelevant to the determination of infringement which, the court affirmed, is based not on intent but on whether the defendant has *made*, *used*, or *sold* the patented invention.[539] Nevertheless, here "use" was strictly determined. From the reasoning of the majority, it appears as though despite dicta to the contrary, intention consequently *did* play a role in this decision. Chief Justice McLachlin and Justice Fish, writing for the majority, identify the "salient facts" to include that Schmeiser did not purchase the GM crop nor obtain a licence to plant it,

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[537] For a discussion on transgene contamination in Mexico, see the NGO, Action Group on Erosion, technology and concentration (ETC Group), report "Maize Rage in Mexico: GM maize contamination in Mexico- 2 years later", October 10, 2003 which describes how no less than 4 governmental studies have been taken in a two year period to determine whether or not transgenes are present in the native maize of Mexico. Maize is one of the world's most important food crops with origins in Mexico where government officials and the scientific community have now acknowledged that traditional maize crop is contaminated with DNA from GM maize despite the government ban on the planting of GM seeds in Mexico. "Of 2000 maize plants tested, samples from 33 communities in nine Mexican states tested positive for contamination. In some cases as many as four GM traits, all patented by multinational Gene Giants, were found in a single plant." Traces of insecticidal toxin (Cry9c), an engineered trait found in StarLink maize formerly sold by Aventis CropScience, were also detected causing alarm because the US government had never approved StarLink for human consumption due to possibilities of increased allergic reaction." The ETC report provides that a massive recall of tainted food products in the US lead Aventis to withdraw StarLink from the US market. The global problem of traveling transgene contamination has reportedly affected cotton in Greece, canola (rapeseed) in Canada, soy in Italy, and papaya in Hawaii. See www.etcgroup.

[538] *Schmeiser SCC, supra* note 336, para. 6.

[539] *Ibid.* at para. 49.

> [y]et, in 1998, tests revealed that 95 to 98 percent of his 1,000 acres of canola crop was made up of Roundup Ready plants. The origin of the plants is unclear...The trial judge found that "none of the suggested sources [proposed by Schmeiser] could reasonably explain the concentration or extent of Roundup Ready canola of a commercial quality" ultimately present in Schmeiser's crop ((2001), 202 F.T.R. 78, at para. 118).[540]

Schmeiser was shortsighted in its implications but indicates that the majority was influenced by the specific facts of the case and two factors in particular. First, the Court could not get around facts which, they seem to imply, suggest that there may have been some bad faith on the part of the appellants supported by suspicious findings that most of Mr. Schmeiser's corn was RRC and that he actively cultivated and harvested RRC seeds. Although his fields of canola were not sprayed with Roundup Ready®, so he derived no technical use, he did end up with 1030 acres of RRC which would have cost him $15,000.[541] This led the majority to conclude that "[i]n these circumstances, the presumption of use flowing from possession stands unrebutted."[542] Second, the Court was compelled by the "stand-by or insurance utility" of the properties of the patented genes and cells. Regardless of whether a farmer actually sprays the Roundup herbicide on the RRC, "[t]he farmer benefits from that advantage from the outset: if there is reason to spray in the future, the farmer may proceed to do so."[543] To conclude that cross-contamination with the patented crop invariably is a benefit to its owner is to reveal the normative value placed on the patent regardless of the nuisance and harm that such unintended GM contamination may cause in diminishing the integrity of his crop

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[540] *Ibid.* at 6.
[541] *Ibid.* paras 60-70, and para. 87. Incidentally, there are current efforts underway for devising a "synthetic" gene coding for glyphosate resistance in plants that would achieve the same result as Monsanto's patented product but without infringement. See *e.g.* Todd Funke et. al., "Molecular Basis for the Herbicide Resistance of Round Up Ready Crops" (Aug. 2006) 103.35 PNAS 13010-13015, online: < http://www.pnas.org/cgi/content/abstract/103/35/13010?ck=nck>.
[542] *Ibid.* at para. 87.
[543] *Ibid.* at para. 84. The court also found that "cultivating RRC also presents future revenue opportunities to "brown-bag" the product to other farmers unwilling to pay the licence fee, thus depriving Monsanto of the full enjoyment of their monopoly." (At para. 85).

(important in an age where consumer niche markets are developing around "organic" and "GM free" labels). The potential liability of such companies in trespass to real property and nuisance law may have been given due consideration had the facts not given rise to the uncertainty regarding the cause of contamination of Mr. Schmeiser's fields.

David Morrow, who represented Harvard at the SCC, and acted as co-counsel for the intervener, the Canadian Seed Trade Association in *Schmeiser,* summarizes the impact of the *Schmeiser* decision as follows:

> The result of this decision provides a fairly strong confirmation that the making, using or selling of a "macrobiological article such as a plant or seed, even when made by a macrobiological method such as planting seeds, infringes a claim for a microbiological article such as a gene or cell that is included within the macrobiological article. In other words, even though there was no patent on the "Roundup Ready" canola plant, the plaintiff Monsanto was able to get remedies for infringement as though there had been a patent on the actual plant. As a result, this decision may provide means for patentees of microbiological articles to have effective protection for plants even in the absence of a claim to the patent.[544]

The majority of the Supreme Court allowed Mr. Schmeiser's appeal in part, finding that on the facts the appellants had made no actual profits as a result of his use of the patented invention (that is, he made no additional profits beyond that which he would have made in any event through the sale of his corn). The award for account of profits was set aside but in all other respects the trial Judge's decision was confirmed.[545] Like the SCC in *Harvard*, the Court in *Schmeiser* also invited a legislative response to the patenting of life issue.[546]

The dissent casts the issue very differently, noting that the lower courts' decisions in *Schmeiser* were without the benefit of the SCC *Harvard* decision: "The heart of the

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[544] See A. David Morrow and Sandee Smordin, "Examination of Biotech Patent Issues: The Harvard Mouse Case" An International Conference on Intellectual Property, University of British Columbia September 19, 2003 at 18 discussing the F.C.A. decision which was upheld by the majority of the SCC.
[545] *Schmeiser SCC, supra* note 336 at para. 106.
[546] *Ibid* at para. 94: "Where Parliament has not seen fit to distinguish between inventions concerning plants and other inventions, neither should the courts"; para. 95: "Again, if Parliament wishes to respond legislatively to biotechnology inventions concerning plants, it is free to do so. Thus far it has not chosen to do so."

issue is whether the Federal Court of Appeal's decision can stand in light of our decision in that case [*Harvard*]...that higher life forms, including plants are not patentable."[547] The majority's decision conflicts with the Patent Office's long standing policy not to grant exclusive rights to higher life forms (defined as plants and animals) although patents over lower life and processes for engineering transgenic higher life are permissible.[548] Finally, the majority's emphasis on the commercial value of the exclusive rights to the patentee as the primary consideration for extracting the "essential elements" of the patent claims ignores three other considerations that the dissent considered relevant to a purposive construction of the claims: namely (1) fairness and predictability[549]; (2) what is not claimed is disclaimed[550]; (3) the person skilled in the art.[551]

Using the same three principles of statutory interpretation that the majority applied, the minority reached a very different conclusion on infringing "use" as one linked to the invention and therefore limited by the subject matter and the construction of claims. As a result, the dissenting opinion concludes that use of the chimeric gene in its

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[547] *Schmeiser SCC, supra* note 336 paras. 107-111. The court quotes from E.R. Gold and W.A. Adams, "The Monsanto decision: The edge or the wedge" (2001), 19 *Nat. Biotechnol.* 587, asserting that both lower court decisions "allo[w] Monsanto to do indirectly what Canadian patent law has not allowed them to do directly: namely, to acquire patent protection over whole plants." at 108.

[548] See Patent Office, *Manual of Patent Office Practice* (1998) at para. 16.05 which states: "Higher life forms are not patentable subject matter. However, a process for producing a higher life form may be patentable provided the process requires significant technical intervention by man and is not essentially a natural biological process which occurs according to the laws of nature."

[549] Where predictability is achieved by tying the patentee to its claims and fairness is achieved by interpreting the claims in an informed and purposive manner. See *Schmeiser SCC, supra* note 336 at para. 122 fn omitted.

[550] This is the "classic rule" that an inventor may not get exclusive rights to an invention that was not part of the public disclosure and feeds into the predictability that the public must derive from what is claimed in order to decide whether their activities will infringe on the exclusive rights granted. If the patentee has limited the claims (as Monsanto did by explicitly disclaiming rights over the RRC plant), then the public is entitled to rely on that limitation. *Ibid.* at para. 124.

[551] While patent claims must be interpreted from the view of a hypothetical worker skilled in the art, a reasonable person skilled in the art must also be taken to know the state of the law as it relates to the subject matter of his invention. See paras. 125-126, *Schmeiser SCC, supra* note 336. At para. 126, the dissent finds "a person skilled in the art, upon filing of Monsanto's patent, could not reasonably have expected that the exclusive rights for gene, cell, vector, and method claims extended exclusive rights over unpatentable plants and their offspring."

isolated form to create an expression or cloning vector or a transformation vector which is used to create a transgenic plant cell, or the use of the cell to regenerate a "founder plant" but not its offspring, would all be infringing uses. That would mean that other herbicide producers could not use the transgenic material or processes disclosed in the patent to create a different herbicide resistant plant but Mr. Schmeiser's use would be permitted. This is, Arbour J. states, consistent with TRIPS Article 27.1, which obligates Canada to make patents available without discrimination to the field of technology, and Article 27.3 which specifically allows the exclusion from patentability of plant and animal life (although if not a patent, an effective *sui generis* system is required for the protection of plant varieties which Canada has satisfied with its plant breeders' legislation).

4.5 Reflections on the SCC Decisions

The two SCC decisions on the patentability of higher life allow us to draw certain conclusions. First, the issue of patenting life remains highly contentious and more important today than it was before these two decisions. Its significance can be evinced by the number of interveners who sought and were granted leave to participate in the proceedings; in *Harvard,* no less than twelve[552] and in *Schmeiser* eleven including the Attorney General of Ontario.[553] Second, the highest court has adopted what Mason and McCall call a "schizoid" approach to protecting proprietary interests in the subject matter

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[552] Canadian Council of Churches, Evangelical Fellowship of Canada, Canadian Environmental Law Association, Greenpeace Canada, Canadian Association of Physicians for the Environment, Action Group on Erosion, Technology, and Concentration, Canadian Institute for Environmental Law and Policy, Sierra Club of Canada, Animal Alliance of Canada, International Fund for Animal Welfare Inc. and Zoocheck Canada Inc.

[553] Attorney General of Ontario, Canadian Canola Growers Association (CCGA), Ag-West Biotech Inc., BIOTECanada, Canadian Seed Trade Association, Council of Canadians, Action Group on Erosion, Technology and Concentration, Sierra Club of Canada, National Farmers Union, Research Foundation for Science, Technology and Ecology, and International Centre for Technology Assessment.

and a demonstrated ambivalence to what the law should be.[554] While both Courts left unchallenged the CPO practice of issuing patents on genes, cells, hormones, etc., *Harvard* was decided by a 5:4 split against the patentability of higher life where an animal was at issue and *Schmeiser* was decided by a 5:4 division effectively favouring an interpretation that extends patent rights to unpatentable higher (plant) life through the definition of "use".

The status of the patentability of life is murkier today than it was prior to these decisions. Rather than clarifying the law, these decisions in tandem have obfuscated existing patent law as well as Patent Office practice. Third, both decisions invite parliamentary response through legislative reform, which has a number of apparent advantages over judicial fiat. Most notably, courts can only decide the issues presented in the case before them, are limited to the collation of facts given, and may be swayed by extrinsic emotional factors such as the desire to correct against piracy and bad faith as well as political influences such as a desire for convergence with patent law in other jurisdictions perceived to be in compliance with international obligations. But, the precedents established extend beyond the narrow facts of a given case to all fields of technology and areas of patent practice, often conflicting with other areas of public policy. Consequently, patent law develops incrementally without any consideration of a centralized underlying policy (or the need for coordinated policies with other sectors of vital importance such as health and food). It becomes internally incoherent with

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[554] "It seems that whether we are dealing with living or dead human tissue, whether we are looking at humanity at the structured or the molecular level, or whether we are considering domestic or international regulation, we are faced with a *schizoid* approach to property in human material. On the one hand, there is antipathy to the concept; on the other, we accept the inexorable march of "science" knowing that, if something is there to be discovered, someone will discover it- and with little concern for the consequences." Mason & McCall Smith, *supra* note 452 at 497, emphasis added.

exemptions, in Canada, for abstract theorems and methods of medical treatment but not for basic research (DNA) and diagnostic methods of testing even though they do not seem fundamentally different from both a policy and doctrinal perspective. Finally, it is clear that neither Supreme Court decisions affect the practice or legality of patenting of genes. Human, plant, animal genetic sequences and micro-organisms continue to be patentable and patented which means that we are on the horns of an interesting legal dilemma. On the one hand, the SCC in *Harvard* has found that higher life is not a patentable product. On the other hand, the SCC in *Schmeiser* has found that a use of an unpatentable product (e.g. plants, animals, and humans) which contains a patentable component (e.g. a microorganism, virus, vector, DNA sequence, gene, cell, or plasmid) may be an infringing "use" of the patent holder's exclusive monopoly rights in the subsumed patented invention.

Inequitable results will follow. Imagine that Myriad manufactures a mouse with its patented BRCA1/2 gene using a process that does not encroach on Harvard's transgenic process claims. The BRCA1 mouse is useful for facilitating breast cancer research. Myriad would effectively enjoy a patent right extending to the whole mouse as a product due to the *Schmeiser* definition of "use" despite the finding in *Harvard* that higher life (transgenic mice) are not patentable.[555] In fact, Myriad's rights would extend to the whole mouse or any other higher life that carried its patented gene(s), even if it did not manufacture or invent such a mouse or higher life with a disproportionately harmful

[555] A patent does not give you a right to the actual tangible embodiment of the invention- only the idea of it. The product patent was so important to Harvard because it would have protected against potential rogue mice and would have allowed Harvard to enjoin others from using such an oncomouse whether they independently created, reverse engineered, or came across it innocently. As discussed in text, *supra* at p. 187, a product patent would have made its unlicenced manufacture, use or sale an infringement of Harvard's rights in all contexts. The *Schmeiser* definition of "use" has corrected for this and would in fact extend protection to the animal as product based on the fact that the mouse contains patented material (such as the plasmids).

impact on the future of gene therapy.[556] Considering the statistics discussed in the last chapter on the significant portion of the human genome patented, the implications of the SCC *Schmeiser* decision may be so dire that they simply cannot be overestimated.

The merging of mice and men, as poetic as it may be, is being contemplated by North American scientists considering the implantation of human embryonic stem cells into a mouse embryo as the next chimera proposal. The experiment is to test whether human embryonic stem cells - on which research is controversial because a human embryo is destroyed during their harvest - have the capacity to grow into every tissue type in the body. The mixing of the species is not entirely new as

> [s]cientists have for years successfully inserted human genes into mouse DNA to study certain diseases. They have also fused mouse cells with human cells. But they have never created a mouse carrying human cells, each of which contains a full complement of human genes, said Ronald Worton, head of Canada's Stem Cell Network and the Ottawa Hospital Research Institute...The Canadian Institutes of Health Research, which distributes federal funds for medical research...president Dr. Alan Bernstein noted...that no Canadian scientist receiving CIHR funds would be permitted to conduct such an experiment. 'We don't even really know what happens when you mix two different species like this,' he said, 'Are you going to have a mouse walking around with human sperm- what would be the public reaction to that?[557]

In addition to raising the ethical and philosophical question of what is the essence of "human" and the degree of genetic hybridization that any given society is willing to accept within its definition of "human", this example raises an interesting implication in

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[556] Gene therapy is a means of correcting defective (faulty) genes responsible for disease development and entails one of several approaches to accomplish this including inserting a normal gene "into a nonspecific location within the genome to replace a nonfunctional gene...An abnormal gene could be swapped for a normal gene through homologous recombination[,] the abnormal gene could be repaired through selective reverse mutation, which returns the gene to its normal function[,] the regulation (the degree to which a gene is turned on or off) of a particular gene could be altered." Human Genome Project Information http://www.ornl.gov/sci/techresources/Human_Genome/medicine/genetherapy.shtml.

[557] See Carolyn Abraham, "Scientists look at Creating a Human-Mouse Embryo", Globe and Mail, online: <http://rtnews.globetechnology.com/servlet/ARticleNews/tech/RTGAM/20021128/wxmous11>. This report highlights three very important points. First, it highlights the ethical and socially contentious nature of such research. Second, it reaffirms that in the absence of public consultation and regulation, certainly there is no further *need* to use the carrot of property rights vis-à-vis the patent grant to create *incentives* for this research. In fact, the administrative decision to grant a patent or not should be stayed on such inventions until further public consultation is made. Finally, it creates an interesting quandary in light of the SCC decisions.

light of the SCC's definition of "use" which would effectively extend patent protection to the chimera product if it contained a patented component despite the fact that the Court in *Harvard* found that neither mice nor men are patentable.[558] Regrettably, what we can expect then, in addition to the growing patenting trend, is a shift in the type of biotech patents sought, away from macrobiological products (such as plants, animals, humans) the legal status for which is uncertain, to permitted microbiological products such as viruses, bacteria, fungi, and also genetic sequences of these, that will effectively provide protection to higher, possibly human, life. This means that private mapping projects will also shift to mapping the genome of lower life, microorganisms, bacteria, and viruses for which patents can be obtained -on them as a whole or simply their genetic information- and thereby secure broader rights to macro-organisms.[559]

In the Harvard mouse case in Canada, a key issue was the distinction between higher and lower life which the Court found has been a line established long ago by the Canadian Patent Office. Since 1982, patents have routinely issued by the Commissioner in Canada on lower life forms as within the s. 2 definition of "invention" as *composition of matter* and *manufacture*. The Respondent Harvard argued that there was no legal or evidentiary basis for the distinction the Patent Office drew between "lower life such as bacteria, yeast and moulds, and higher life forms such as plants and animals."[560] Yet

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[558] Justice Binnie's dissent at the SCC emphasized that granting Harvard its patent is not equivalent with crediting it with inventing life. What Harvard did was to "modify every cell of a living creature in a new and useful way, and to the extent that modification is a valuable addition to the advancement of learning..." at para. 69. The majority, however, found that since the progeny of the mice were created through natural reproduction, to grant Harvard a patent in the mouse as product would be to over compensate Harvard for more than the scope of its invention, creating a windfall since the products of biotechnology "...can contain important characteristics that have nothing to do with the invention." See para. 168.

[559] "Craig Venter: Beyond BioBabble", Business Week, 2 June 2003, online: <http://www.businessweek.com/magazine/content/03_22/b3835715.htm>.

[560] *Harvard SCC*, *supra* note 185 at para. 198.

Justice Bastarache maintained the importance of the distinction for the Court's determination of patentability when he wrote for the majority in *Harvard*:

> The patentability of lower life forms is not at issue before this Court, and was in fact never litigated...[but] it is now accepted in Canada that lower life forms are patentable. Nonetheless, I agree with the appellant that this does not necessarily lead to the conclusion that higher life forms are patentable, at least for the reason that it is easier to conceptualize a lower life form as a "composition of matter" or a "manufacture" than it is to conceptualize a higher life form in these terms.[561]

Despite this finding, the majority's definition of "use" in *Schmeiser* also renders this line drawing exercise moot since it is no longer necessary to obtain a patent for higher life when the patent to lower life and genes will effectively garner protection in essentially *anything* containing it including higher life. Such an outcome does not anticipate the likely future of complex genetic manipulation of plants as biopharmaceuticals or nutriceuticals containing multiple patented subcomponents held by different patentees. Imagine, for example, a patent for genetic information responsible for producing beta-carotene for vitamin A nutritionally enriched Golden Rice *and* a separate gene coding resistance to herbicides such as the RRC, both expressions of which appear in a plant. Since TRIPS also makes a distinction between higher and lower life in the Article 27.3 exception, this means that the permissive language in TRIPS for excluding higher life from patentability is now also moot, at least in Canada, since lower life patents provide higher life protections. Former standard patent practice of patenting genes and lower life now provide additional 'windfall' in increasing the scope of the patent holder's rights to unexpected licence generating streams and have consequences unanticipated by all parties including the issuing office when the grant was made. All of

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[561] *Ibid.* at 198 and 201. Although the issue of whether lower life has ever been litigated remains contested by Justice Binnie in his dissent at para. 36. Binnie J. adopts an organic definition of life and states "certain enzyme products (which are living matter) were held to be patentable by this Court 60 years ago in Continental Soya Co. v. J.R. Short Milling Co. [1942] S.C.R. 187, as were engineered micro-organisms used as an antibiotic in Laboratoire Pentagone Ltée v. Parke Davis & Co/. [1968] S.C.R. 307." For reasons unknown, the majority of the Supreme Court, in its wisdom, omitted reference to these two decisions.

this by the court's extension of rights well beyond that which has been invented to that which *contains* the invention even though the disclosure of the invention in the patent application will have no reference to this. This is an unnecessary ex post reward for already patented inventions. Finally, how meaningful is the highest Court's finding that the Constitution protects against the patentability of human life when human genes continue to be patentable and the same Court has liberally defined "use" to effectively extend patent protection to all living matter that contain a patented invention, through trespassory rights broadened in scope to allow findings of infringement not only for matter not demarked by the patentee's claim, but actually *disclaimed* in the patent application?[562]

4.6 Sincerity of 'Invention': The Need for State Agency

This review of the jurisprudence warns of the consequences of an incremental expansion of patents to life by the courts without consideration of a coherent overarching patent policy and how, though marked by controversy, this has nonetheless occurred without *political* debate. Industry influences these so often closely split judgments urging for convergence in Canadian patent law with legal outcomes in the United States where a more powerful corporate lobby exerts economic and political pressure despite differences in the regulatory climate, public, cultural, and social values, and national commitments to social and economic rights under international instruments.[563] There are

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[562] See *supra* footnote 526 for Harvard's claims which disclaims human embodiments of the activated oncogene by reference to "non-human" in claim 1.

[563] Unlike Canada, the United States has not ratified the International Covenant on Economic, Social and Cultural Rights under which health rights are located. The irony is, however, that the United States, after leading the world down a path towards greater propertization and its extension to life and genomics as patentable subject matter, is on the brink of considering a new proposal to ban patents on all nucleotides (and possibly polynucleotide) and their functions. On February 9, 2007, California Congressman Xavier Becerra and Mr. Weldon proposed a new bill to ban human nucleotide patents (U.S., Bill H.R. 977, *Genomic Research and Accessibility Act*, 110th Cong., 2007 to Amend Title 35, United States Code),

growing pressures at patent offices and the courts to harmonize laws towards greater protection for patent holders. Proliferating bilateral agreements and commitment to what was perceived as strengthened IPRs in the multilateral trade regime with *TRIPS* was an important issue for the minority in *Harvard* and majority in *Schmeiser.* These instruments are used to argue that the IP protections contained therein establish optimal standards and should be adopted as the norm towards which judgments and patent office practice should converge. The judiciary often responds to these industry-led pressures, influenced by the compelling force of economic arguments founded on private property rights, with the view that to deviate would be to discourage foreign direct investors in biotech. Currently, there is no provision for proper scrutiny of the merits of the invention claimed,[564] moral consideration for its privatization, or policy considerations outside of those raised within litigation. In this context, the role of the court as the conscience of society and the keeper of the public's interest which is to be accounted for in patent law becomes critical. The SCC decisions in these two cases remind us of the power of the judiciary and the manner in which statutory provisions can be used to provide variant outcomes that either extend or curtail patent scope and application on a piecemeal basis.

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online: <http://thomas.loc.gov/home/gpoxmlc110/h977_ih.xml>. In his introductory speech before Congress in February 2007, Becerra implored: "I rise today with the hope of fixing what I believe to be a regulatory mistake-a mistake that at first glance may seem minor in scope, but upon further examination has dramatic, costly and harmful implications for every American. I speak of the practice of gene patenting, where private corporations, universities and even the Federal Government are granted a monopoly by the United States Patent and Trademark Office on significant sections of the human genome.... It is my belief that this practice is wrong, ill-conceived and stunts scientific advancement....My legislation, the Genomic Research and Accessibility Act, is straightforward: it ends the practice of gene patenting. It gives guidance to the United States Patent and Trademark Office (PTO) on what is not patentable-in this case, genetic material, naturally-occurring or modified. It is not retroactive-it does not rescind the patents already issued... We have overstepped our bounds. We have made a regulatory mistake. We have allowed the patenting of a product of nature. Fortunately, we have the power to end the practice expeditiously and for the benefit of all." See discussion, *infra* footnote 626 and accompanying text. ." See (U.S., *Cong. Rec.,* daily ed., at E315 (9 February 2007) (Rep. Becerra)), online: Library of Congress, < http://thomas.loc.gov/cgi-bin/query/D?r110:60:./temp/~r110KYJQHb::>.

[564] Jay P. Kesan, (2002) "Carrots and Sticks to Create a Better Patent System. 17.2 *Berkeley Technology Law Journal,* 763-797.

In this process, great reliance is placed on the argument that strong IPRs are necessary to ensure industrial Canada remains on an equal footing with its competitors by offering equal protections to inventions patented here. But Canada would do well to position itself as the beneficiary of stronger IP protection in basic research in the US market, in which most patent holders are interested, without committing to providing these in our laws. Free market competition in upstream basic research in Canada would reduce transaction cost for applied research with the likely impact of attracting foreign firm investments to Canada for applied R&D where the true innovation can be said to exist; our patent policy need not be the same as our neighbours, for its own sake, given the significant difference in cultural values and social programs.

Scholars generally support state intervention in order to develop sound patent policy to restore the equilibrium between the need to provide incentives for genuine innovation and the monopoly rights awarded for contributions of minimal ingenuity. If markets protect consumer and public interest, then statutorily created monopolies, antithetical to the benefits of competition in their creation of artificial scarcity, are only in the public interest if they operate according to design. If a system is conceptually flawed (as discussed in Chapter 2) and fails operationally and institutionally (as outlined in Chapter 3), the need to critically re-examine its normative rationales and judicial extension becomes paramount. At the same time, any expansion of private rights should be held to strict doctrinal scrutiny. It seems that with the patenting of life and its genetic subcomponent, traditional doctrinal distinctions between discovery and products of nature, process and product patents, and the requirements for disclosure have surrendered to normative values that project the desirability of establishing *strong* IPRs protections.

These, in turn, infuse and are internalized in the institutional structure of patent protection in both national and international context. According to Vandana Shiva:

> Due to the inherent conflict between private and public interest, patent laws that are strong for protecting the private interest are thus weak for protecting the public interest. However there is no 'strong' or 'weak' patent law in an absolute sense. Strength and weakness are basically relative to the interest being protected. The one-sided reference to 'strong systems' in the debate on IPRs in GATT has an underlying, tacit assumption that only corporate rights count.[565]

The relationship is dialectic and more complex than that. In fact, strong IPR systems *can complement* the public interest so long as the integrity of the system is retained, the bar for patentability remains high, and safeguards are in place to curtail anti-competitive behaviour. Incorporating these three suggestions would strengthen any IPR system according to merit and unite patent theory with practice. Furthermore, patent policy needs to situate patent practice in the broader context of total gains and losses for society, which requires ongoing review and monitoring of its institution. The Federal Court of Appeal's helpful reminder of the utilitarian function of patented inventions is silent on the distribution of these benefits as between the inventor and the public. Benefit to the public cannot be measured purely on the basis of the greater *number* of patented inventions disclosed or that Canadian patent law is congruent with American jurisprudence. Rather, the public must be educated and encouraged to participate in a uniquely Canadian dialogue on patent policy and its implications for public health delivery in order to ensure that the monopolies issued are legitimately created, enjoyed, and tolerated. With the seemingly inconsistent findings of the SCC on the patentability of higher life, the law remains uncertain until further litigation creates precedents to fill the legal lacunae - a costly, unpredictable, and cumbersome enterprise for determining patent legality in a technical field where patents are routinely granted. In genomics,

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[565] Shiva, *supra* note 283 at 6.

given the numerous existing patents granted over DNA sequences of various species, relying on challenges to patent validity through litigation is a poor form of quality control and policy development; it is an additional incident of taxation without representation for the Canadian public.[566]

4.7 The "Wiggle Room" and the Will: TRIPS Compliant Regulatory Preferences

Jerome Reichman has examined the potential use of TRIPS to support the positive adoption of desired domestic policies where the Agreement is ambiguous and has popularized the argument made early on by Jayashree Watal, and a number of authors since her, that TRIPS provides ample "wiggle room" for Members to exercise discretion to formulate domestic regulatory preferences.[567] The extent to which Canada and other countries can adopt domestically diverse measures to respond to the need for balanced regulation in relation to biotech patents is the focus of this last section and constitutes the

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[566] See Rebecca S. Eisenberg & Robert P. Merges, "Opinion Letter as to the Patentability of Certain Inventions Associated with the Identification of Partial cDNA Sequences, 23 AIPLA Q.J. 1 (1995), see also Amani and Coombe, *supra* note 49. Compare with Melanie J. Howlett and Andrew Christie, "An Analysis of the Approach of the European, Japanese and United States Patent Offices to Patenting Partial DNA Sequences (ESTs)" University of Melbourne Legal Studies Research Paper No. 82.

[567] See Jayashree Watal, "Trips and the 1999 WTO Millennium Round: Some Reflections on Future Issues Related to IPRs in the WTO and the Way Forward for Developing Countries" (2000) 3 J. World Intell. Prop. 3, 7-24. See generally, Reichman "Fair Followers", *supra* note 385 at 27-51, fn 51 and 72 and accompanying text. For a discussion of the pressure and demands for higher levels of protection by IP owners pressing for a strict interpretation of existing norms and the ambiguity of the "wiggle room" areas, see J.H. Reichman, "The TRIPS Agreement Comes of Age: Conflict or Cooperation with the Developing Countries" (Summer 2000) 32.3 Case W. Res. J. Int'l L. at 454-470 [Reichman, "Conflict or Cooperation"]. For a discussion of diplomatic ways to encourage co-operation with TRIPS standards through strategic initiatives that rely on the built-in capabilities for implementing obligatory minimum standards, see J. H. Reichman and David Lange, "Bargaining Around the TRIPS Agreement: The Case for Ongoing Public-Private Initiatives to Facilitate Worldwide Intellectual Property Transactions" (Fall 1998) 9:1 Duke J. of Comp. & Int'l L 11 [Reichman & Lange] where the authors suggests that government representatives, local entrepreneurs, and foreign rights holders who negotiate within a cooperative framework characterized by goodwill, can achieve better success in resolving conflicts arising from TRIPS standards through agreement on a transactional basis than is otherwise possible using the conflict based system of dispute resolution that the Agreement provides. Reichman adds that the presence of government officials, in their economic capacity, at the bargaining table would "...ensure that any deals struck between foreign rights holders and local firms would also redound to the public interest, without, however, compromising the larger political organs ability to maintain official positions on intellectual property law and policy in the relevant international forums." See Reichman, "Conflict or Cooperation" *ibid.* at 467.

first branch of the prescribed bifurcated approach for state agency central to this dissertation. A TRIPS overview is provided to demonstrate readily available options.

4.7.1 Trade Dimensions of IP Regulation: TRIPS Overview

The TRIPS agreement attempts to harmonize IPRs by introducing universal minimum standards for their protection. Under the auspices of the WTO, it provides for a formalized multilateral dispute settlement process, incorporates some of the main pre-existing obligations from the Paris Convention for the Protection of Industrial Property (Paris) [568] into the WTO agreement (Article 2), adds the Most Favoured Nation principle (MFN) not present in Paris (Article 4),[569] and reiterates the National Treatment Principle (NTP) germane to the GATT, Paris, and almost all other international agreements (Article 3).[570]

By adopting key substantive Paris provisions, TRIPS indicates a preference by the negotiators to update and adapt existing rules rather than create a new system of IP

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[568] Established in 1883 with the agreement of 14 countries and now with 169 signatories Of March 20, 1883 last revised at Stockholm on July 14, 1967. Of these 169 contracting parties (countries only), by development status breakdown statistically as follows: countries in transition, 16%, developing countries 44%, industrialized countries 19%, least developed countries 21%. See WIPO, Treaties Statistics, http://www.wipo.int/treaties/en/statistics. Paris was the primary instrument governing the protection of patents (industrial property) prior to the high level of universal minimum standards introduced under TRIPS. It was an elegant and refined instrument in terms of its substantive standards which provided for complaints to be made to the International Court of Justice. In theory, a State could even retaliate for another's violation but practically speaking that rarely, if ever, happened because such decisions lacked coercive enforcement since states would voluntarily submit to the jurisdiction of the ICJ; all that really was germane about Paris was national treatment and priority rights.

[569] The MFN essentially provides that with respect to IPR, any advantage, favour, privilege or immunity granted by a Member to the nationals of any other country shall be accorded immediately and unconditionally to the nationals of all other Members (no playing favourites) with limited exceptions.

[570] The NTP requires that "[e]ach Member shall accord to the nationals of other Members treatment *no less favourable* than that it accords to its own nationals with regard to the protection of intellectual property." This is in contrast to Paris which only required the "same" treatment, the *same protection,* and *same legal remedy* for nationals of other contracting states in the Union (Article 2(1)). Effectively, foreigners can be treated *better* with more protection, which is defined in TRIPS: "[f]or the Purposes of Articles 3 and 4 of this Agreement, Protection shall include matters affecting the availability, acquisitions, scope, maintenance and enforcement of intellectual property rights as well as those matters affecting the use of intellectual property rights specifically addressed in this Agreement." TRIPS Agreement, in Paul Goldstein, *International Legal Materials on Intellectual Property* (New York: Foundation Press, 2000).

protections calibrated to different needs and stages of development of Members and the challenges of new technology.[571] These include the right of priority in the case of patents (and where they exist, utility models) giving the applicant 12 months priority over other applications filed by competitors in other countries during the same period over the same invention.[572] Common rules for contracting states include that patents granted for the same invention in different states are independent of each other and do not oblige other contracting states to grant the patent (maintaining the sovereignty of nations in their IP laws); nor can a patent be refused, annulled or terminated in one state on the basis that it has been so in another contracting state (Paris Article 4bis) such that Canada could not, for example, revoke MGL's BRCA1/2 patents merely because France has done so. By recognizing the independence of patents obtained over the same invention in different countries, Paris conceptually supports the proposition that one country's piracy is another country's transfer of knowledge and technology. Article 2 of TRIPS incorporates these specific Paris provisions.

Paris also provides that regulatory restrictions on the sale of a patented product or a product derived from patented processes may not be used to invalidate a patent (Article 4quater). However, it is important to note that other regulatory mechanisms can be used to monitor or regulate market *accessibility* and the *commercialization* of a patented invention. For example, Human embryonic stem (hES) cell research is critical for future preventative and therapeutic medicine but the private monopoly right belongs to the University of Wisconsin's Alumni Research Foundation (WARF) which has patented

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[571] See Gervais, *supra* note 493 at 68-70, "The Logic of TRIPS". See also Reichman, "Fair Followers" *supra* note 385 at 27-28 discussing how this "backward looking" feature of TRIPS its virtue and curse.
[572] This is based on a regular first application filed in one of the contracting states. Applicants can then consider which countries they want to patent in assessing their varied requirements for due diligence, administrative compliance, application processes, processing and legal fees.

hES.[573] While regulation alone could not invalidate the patent per se, parliament, if it saw fit, could impose restrictions or requirements as precondition to the commercialization of that patent (i.e. an ethics review approval as suggested by the Nuffield Council on Bioethics or a regulatory oversight similar to the Patented Medicine Prices Review Board suggested by Austin and Amani).[574] Paris (Article 5) also provides for conditional use of compulsory licenses to eschew patent abuses and forfeiture after all else, including the compulsory licence, fail to avert the ongoing abuse by a patentee. TRIPS Articles 31 and 40 also expressly address the provision of compulsory licences and abuse of patents respectively in national IPR regimes.[575]

Part II, Section 5 (Article 27-34) of TRIPS sets out minimum national standards for patent protection within the member states. Patentable subject matter is set out in Article 27 and has proven very contentious:

> ...patents *shall* be available for any invention, whether products or processes, in all fields of technology, provided that they are *new, involve an inventive step and are capable of industrial application*...[and] shall be available and patent rights enjoyable *without discrimination* as to the place of invention, the *field of technology* and whether products are imported or locally produced.[576]

Canada meets this obligation in that it provides patent protection for any invention (product or process) in all fields of technology so long as the novelty, utility, and non-obviousness requirements are satisfied. TRIPS does not establish any substantive ceilings or floors for the content of the domestic patentability requirements, which is why

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[573] See Carl Gulbrandsen "Stem Cell Patent Holder's View of the California Challenge" Wisconsin 11/16/04, http://wistechnology.com/article.php?id=1352. See also "Foundation's stem cell patents impede search, scientists say", San Diego Union Tribune, July 30, 2006.

[574] The Nuffield Council on Bioethics Report, *supra* note 383, recommends patent offices to engage in ethical reviews. Austin and Amani, *supra* note 103.

[575] The potential use of Article 31 is discussed in detail in the next chapter as part of the events leading up to a TRIPS amendment.

[576] Emphasis added. See Article 28 TRIPS for the patent rights conferred; generally the exclusive right to prevent third parties without consent from making, using, offering for sale, selling or importing for these purposes that product.

I have argued for a tightening of the application of these requirements administratively before the patent issues at the CPO but also on validity reviews and infringement determination by the courts. Article 27, while prohibiting discrimination on the availability of a patent or rights enjoyed based on the *field* of technology, does not foreclose raising the entire requirement bar, the degree of knowledge attributed to the person of ordinary skill in the art, and then calibrating the standards of patentability in accordance with the technology just as the standard for the PHOSITA are permissibly variable. That is, a state cannot through legislation refuse to confer patent rights to all biotech inventions as a class but this may nonetheless result from regulatory reform that focuses on more stringent standards for novelty, utility, non-obviousness, and disclosure and creates additional criteria (i.e. ethics review). TRIPS standards are only universal *minimums,*[577] after all.

A number of safeguards to protect the public's interest are also incorporated directly into the language of Article 27. Article 27.2 states:

> Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or *morality*, including to *protect human, animal or plant life or health or to avoid serious prejudice to the environment*, provided that such exclusion is not made merely because the exploitation is prohibited by domestic law.[578]

The wording demonstrates the intent to locate patent rights amidst a hierarchy of pressing domestic regulatory objectives for Members, allowing for a general exclusion from patentability *ex ante* inventions to protect human health amongst other things. However, the measure must be justifiable by objective standards and not merely as a

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[577] Article 27 merely states that a patent "shall be available"- it does not state that a patent which meets the established criteria cannot be refused (based on additional criteria) or that a patent "shall be *granted*". The 20 year minimum period for patent protection was based on western standards of IP (*e.g.* s. 44 of the CPA) now entrenched under TRIPS Article 33.

[578] See also NAFTA 1709(2) for the parallel provision with almost identical wording.

result of domestic prohibitive laws. What that means is, as with Paris, governments may make regulatory restrictions on commercialization, by requiring for example labelling of all GM products,[579] or regulatory approval similar to that required for drugs, or prohibit exploitation of an invention but such restrictions cannot alone render the invention *unpatentable.* Daniel Gervais explains: "any exclusion under the Article would need to be justified as indicated above, and the fact that the exploitation of the invention is prohibited under national law is, at best, one of the arguments necessary to meet the condition prescribed."[580] In addition, this exemption may in fact be narrowed through future judicial interpretation, especially of the words *"necessary to protect"* which may be construed conservatively to mean *least restrictive means* as in prior GATT XX decisions.[581]

If legislative reform appears too daunting politically, nothing prevents our government from issuing its own Biotech Directive which, although not binding, would reaffirm the intention to incorporate more expressly the Article 27.2 exclusion in patent *practice* (with changes reflected in the CPO's Manual of Patent Office Practice).[582] This would be instructive to patentees, patent examiners, and courts on the normative regulatory position of our government. The Directive could include a provision for *morality* or *ordre public,* express a position on gene patents, and establish the threshold for the requirements of patentability. Article 27.2 is not useful to rely on *ex post facto* as

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[579] See *e.g.* Commission of the European Communities, "Proposal for a Regulation of the European Parliament and of the Council concerning traceability and labeling of genetically modified organisms and traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC, online: http://ec.europa.eu/food/fs/biotech/biotech09_en.pdf.

[580] Gervais, *supra* note 493 at 223.

[581] GATT Article XX and the interpretation of "necessary" in reference to Article XX(b) which uses the same language are discussed in detail in chapter six. Essentially, it means that the domestic measures must be justifiable by objective standards and not constitute a means of arbitrary discrimination or disguised restriction on trade. Full GATT 1947 online: http://www.wto.org/english/docs_e/legal_e/gatt47_01_e.htm.

[582] Online: CIPO, <http://strategis.ic.gc.ca/sc_mrksv/cipo/patents/mopop/chap16-e.html>.

the limited exclusions are from granting patents over inventions that would otherwise meet the patentability criteria and not as an independent ground to *defend* the infringement of patent rights, such as those alleged against the Canadian government for unauthorized use of MGL's BRCA1/2 patents. This is even if the infringement, as in the Canadian context, is to meet the same policy objectives (human health) set out in the Article.[583]

Finally, TRIPS Article 27.3 allows a specific content based exclusions for domestic protection over life forms. Members may exclude patents

> ...for diagnostic, therapeutic and surgical methods for the treatment of humans or animals" and "...for plants and animals other than microorganisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes.

This section is broad and vague but has significant potential benefit in supporting deferential treatment for domestic regulatory measures where human health is concerned. It is at the core of debates on the patentability of life as well as the patentability of inventions that have a direct effect on health policy. Genetic tests can be excluded from patentability if they are characterized as "diagnostic" or "therapeutic" under Article 27.3(a). Canada is in the position that if it were to amend its laws to exclude the patentability of diagnostic methods, it would remain TRIPS compliant under Article 27.3(a) even though on the wording of the provision it cannot be relied on to justify any violation of an existing valid patent (like Myriad's BRCA1/2 gene patents); that is not to say, however, that existing gene patents such as Myriad's cannot be revoked. In fact, TRIPS confirms that they can and only requires that "[a]n opportunity for judicial review of any decision to revoke or forfeit a patent shall be available."[584] Furthermore, it is not

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[583] See chapter six for a detailed account of how this provision should be interpreted and "adjudicated" by the WTO panel or Appellate Body in the case of a TRIPS dispute.
[584] Article 32, TRIPS, *supra* note 8.

clear whether predictive genetic testing is in fact *diagnostic* as it only correlates with the *propensity* to develop a medical condition and not the diagnosis of one per se.[585]

Members can exclude plants or animals, other than non-biological microbiological processes, as patentable subject matter under Article 27.3(b). The only requirement is that if patent protection is not granted to plants, that some form of plant protection (not necessary for animals) be provided, if not under a patent, then by an effective *sui generis* system. Canada is already in compliance with this requirement. The SCC in *Harvard* established that animals and plants are not legally patentable and Canada already provides *sui generis* protection for plants as it is required to do under plant breeders' legislation. Microorganisms, non-biological processes and microbiological processes must be afforded patent protection, however, under Article 27.3(b) of TRIPS. There are a several problems that become apparent here. First, some critics have noted, genetically modified organisms and DNA sequences may potentially be patented as microorganisms or microbiological processes. None of these terms are defined in TRIPS and the method by which a gene sequence may be introduced into its host is often by way of a "vector" or similar microbiological means recapturing it within the scope of the universal minimum standard for patentability. A firm then could obtain de facto patent rights to a GMO life form by patenting the vector and the process of its introduction even if the life form itself was not patentable. The legislative branch of government is often much slower to act than the judicial branch and within the latter inconsistencies arise as evinced by the two recent SCC decisions. After *Schmeiser*, this is unfortunately not merely conjecture since patent protection would extend to products in

[585] The discovery of the BRCA1 gene in chromosome 17 means that certain women can be tested to determine 85% *likelihood* that they will develop breast or ovarian cancer sometime in the future.

which the patented invention, be it a gene, vector, or some other microorganism was embedded, despite the same Court's finding that the Harvard mouse was not patentable as life and that plants would also be excluded from patentability. This back door windfall protection has dire consequences for the practical operability of the TRIPS exclusion and the sovereign discretion that TRIPS strives to maintain on this very controversial, culturally contested, and morally charged arena of commodification and trade. Worse still, it may undermine the realization of universal human rights that Canada has committed to (discussed in the next chapter) based on judicial misapprehension of international obligations coupled with political and industrial pressures from which judges are not immune.

To summarize, regulatory governments have a number of available responses to their concern whether life and its genetic building blocks should be patentable within their jurisdiction and these responses would help ensure the necessary balance with user's and 3rd party interests in patented inventions. In addition to tightening the patentability standards, the CPA may be amended to exclude patentability of all life or specific objects (such as DNA sequences, or human/animal chimera), redefine the statutory definition of "invention", specifically exclude products of nature and impose an ethics review, labeling (for GM food products), or other regulatory requirements before commercialization is allowed. It is worth mentioning that the courts can create common law exemptions, for diagnostic testing for example, as they have done in the past in Canada with the exclusion of methods of medical treatment from patentability. Amendments or judicial review could also provide specific exemptions to infringement or recognize relevant defences. If as a matter of industrial policy it is decided that Canada does want to continue to allow

patents on genes for example, legislated special provisions, like those governing the Patented Medicines Prices Review Board,[586] could be drafted to respond to the concern over prohibitive prices that biotech patents create for the delivery of health by providing that patented genetic tests and health products receive similar treatment as patented medicines subjected to price review mechanisms. The Article 27.2 and Article 27.3 exclusions of TRIPS help ease any concerns regarding the adoption of health friendly patent policies. Some additional regulatory discretion over cultural diversity in the biopatenting debate may be found in the broader exclusions in Article 27.2 which relate to morality and public policy. Perhaps the greatest deference to state sovereignty, however, comes in the provisions of general application.

Article 7 established the general objective of a strengthened trade-related IPR regime and Article 8 establishes the principles that are to guide members in the formulation of their domestic IPR regimes. Article 8.1 and 8.2 provides further grounds for co-coordinating patent and health policy:

> 1. Members may . . . adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technical development, provided that such measures are consistent with the provisions of this Agreement.
> 2. Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.

Article 8.1 expressly acknowledges the need to safeguard health and food concerns while Article 8.2 provides ample leverage in custom designing domestic measures by defining what constitutes "abuse" and "unreasonably" broadly. This wiggle room is supported by the general objective for the protection and enforcement of IPRs. According to Article 7, the objective is to promote technological innovation, transfer and dissemination "to the

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[586] See s. 83-85 of the CPA, *supra* note 82.

mutual advantage of producers and *users* of technological knowledge and in a manner conducive to *social and economic welfare, and to the balance of rights and obligations.*[587] It is important to note that Article 7 adopts the utilitarian function of patents for the "promotion" of innovation but it is a false correlative to assume that in the absence of patent rights, R&D in biotech (potentially offensive nonetheless to morality and *ordre public*) would *not* occur- the argument advanced in this dissertation thus far is that scientific progress and technological advancement will continue in the absence of patent protection and particularly with other appropriate regulatory oversights in place (such as public education, prizes and procurement). The balance of these policies is necessarily inward looking by a nation state. Any true objection to the underlying technology requires a patent policy response to be coupled with regulation external to the patent regime. As the US Supreme Court in *Chakrabarty* observed,

> The grant or denial of patents on microorganisms is not likely to put an end to genetic research or its attendant risks. The large amount of research that has already occurred when no researcher had sure knowledge that patent protection would be available suggests that legislative or judicial fiat as to patentability will not deter the scientific mind from probing into the unknown any more than Canute could command the tides. Whether respondent's claims are patentable may determine whether research efforts are accelerated by the hope of reward or slowed by want of incentives, but that is all.[588]

The degree and nature of the incentives offered remains within a sovereign's jurisdiction. TRIPS Article 1.1 states expressly that "Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice." The statutory basis for the creation and scope of patent rights, their historical origins and their public policy objectives all lead to the conclusion that these are functional tools of public policy institutionally justified on the basis that the state sanctioned interference ultimately serves the public interest by regulating in a

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[587] TRIPS, *supra* note 8. Emphasis added.
[588] *Diamond, supra* note 441.

balanced way the various stakeholders' interests in knowledge - a public good. If there are problems in the patent system, they are due to conceptual misunderstandings of intellectual objects, the role of the state and institutional actors in regulating access to these objects, a patent friendly and not technically trained judiciary and resulting failures of design and operation. The public, in whose name IPRs are heralded, more often than not has been neglected in industrial policy development and patent office practice as the law in relation to patenting life has developed primarily through jurisprudence. But, this is *not* due to regulatory limitations imposed under TRIPS as is commonly perceived in misgivings about the Agreement. Recital 4 of the TRIPS preamble recognizes the "underlying public policy objectives of national systems for the protection of intellectual property, including developmental and technological objectives [.]"

To protect the public policy objectives from being trumped by the private interests protected by domestic patent law that provides more property rights than internationally required under TRIPS, citizens should demand state appropriate action by their regulatory governments. Parliament has created IP rights but fails to regulate the application of this system to sensitive biological and hereditary material. The common law, through judicial and administrative complicity, has been integral to the process to fence basic science and research while expanding IPRs to formerly precluded- and properly excluded by doctrinal standards- subject matter. The hegemony of property within a Western ideological discourse has led to the assumption that "more is better" and "what's mine is not yours."[589] These are not amoral choices, though they are apparently void of ethics:

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[589] David Vaver, "What's mine is not yours: Commercial appropriation of personality under the Privacy Acts of British Columbia, Manitoba and Saskatchewan" (1981) 15 U.B.C.L. Rev. 241.

> Inevitably...the law is drawn into the debate, and this is especially so when there is a conflict of individual interest...It is pointless to attempt to disengage the moral from the legal dispute- when we talk about legal rules, we are inevitably drawn into a discussion of moral rules.[590]

While the courts' jurisdiction and impact is always remedial, governments are forward looking and, suggests Jillian Clare Cohen, a University of Toronto Professor specializing in pharmaceutical policy and international health, can anticipate situations and write laws to meet them- although it may take constant pressure to get governments to act because "[p]olitical decision makers do not want to have to make tough decisions, so they pass the buck to the court system."[591] There is a danger to this inactivity, as these de facto domestic interpretations may one day infuse the interpretation of contested measures under the hard bargained for Article 27.2 and Article 27.3 exemptions under TRIPS, just as the pressure for convergence towards more protection has reciprocally resulted in gradual extension of patents to DNA and life. It would be prudent for parliament to legislate the definition of life for the purpose of the Canadian Patent Act to include DNA and genes in light of the implications of the SCC's *Schmeiser* decision and to amend the Canadian laws to expressly *exclude* life, however defined, as patentable subject matter. In Canada, with a publicly funded health care system in dire need of reform, efficient allocation of scarce resources is critical to the preservation of our public health program. We need not adopt an IP policy crafted by our American cousins, nor one that effectively allows IP protection to impede the future of research and compromises the delivery of health with the risks and exigencies of litigation.[592]

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[590] Mason & McCall Smith, *supra* note 452 at 4.
[591] Quoted in Laidlaw, *supra* note 434.
[592] Amani and Coombe, *supra* note 49.

4.8 Conclusion

"DNA, you know, is Midas' gold. Everybody who touches it goes mad."[593]

The judiciary has all but vacated the possibility of optimizing available "wiggle room" under the TRIPS. Incrementally, patents have extended by common law and administrative discretion to various components of life, marking in a perverse sense the legal, rather than scientific, evolution of life from bacterium to now higher life with the possibility of mixed human/animal chimeras not too far on the horizon- as though all species were *invented.* Not only is the concept of property inherent to patents (as IPRs) conceptually flawed as discussed in Chapter 2, but its stealthy application to life and its genetic building blocks creates inconsistencies between patent doctrine and its rationales.

This chapter has addressed judicial agency as a historically significant factor in the current law on patenting life and a critical part of any appropriate future state response to trade obligations that compete with other domestic regulatory policy preferences and the intersecting human rights obligations (to be discussed in chapter 5) that may underlie them. Without further legislative activity, the common law has arguably graver consequences for national regulatory responses than does TRIPS and must be adequately addressed by our government. Since legislative interpretation by the courts is always limited to the context in which it is raised, the evolution of the patentability of life lacks a coherent and coordinated policy. Current biotech patent law in Canada is, accordingly, in a state of disequilibrium- unnecessarily complicating patent jurisprudence in such a way that, unless legislated, will require many years of further litigation to resolve with potentially serious costs, public interest considerations, and human rights consequences.

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[593]Maurice Wilkins. Wilkins shared the Nobel prize in 1962 with Watson and Crick for discovering the structure of deoxyribonucleic acid., cited in Judson, *Eighth Day, supra* note 284 at 51.

One danger is that due to the costs and lengthy nature of litigation, the dissonance created in patent law may take too long to correct if left to the common law system. Moreover, jurisprudential changes to the domestic patent law of lead Western negotiators cause serious concern as these laws are then used for harmonizing international standards in multilateral and bilateral agreements towards stronger protection when transplanted and sutured into international legal fora; they may additionally come to inform TRIPS interpretations at the dispute settlement stage while they continue to fence off basic science and knowledge which belongs to the commons.[594] But patent policy need not take priority over health policy as our review of relevant TRIPS provisions has revealed.

Patent proliferation trends call for a practical and institutional examination of patent law and practice. Judicial agency has more than compensated for the state's failure to act in regulating domestic industrial policy in light of biotechnologies' formidable challenges. Rather than a political balancing of stakeholder interests in a policy optimizing manner, our courts for the most part have engaged in an exercise, as the SCC in *Harvard* found, of arbitrary line drawing. From our review in this chapter, the line on occasion seems to have been drawn based on an injudicious understanding of the underlying technology and the nature of life. The Supreme Court of Canada decisions emphasize the need in Canada for a legislative response in this field, reaffirming the recommendation of the Canadian Biotech Advisory Committee. Given the impact of the decisions, that need is now more immediate not only because of its importance for policy coordination but also because patent law's current turmoil is

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[594] Abbott, Cottier & Gurry, *supra* note 196 at 130. David asks: "Will the mode of scientific inquiry that was responsible in great measure for the technological foundations of the modern information revolution thus receive a collective "knock on the head" – through the agency of their own technical creations?..." David, "Commons", *supra* note 221at 4.

dangerous to the public's interest. The problem, however, is in the lack of political will in properly engaging TRIPS flexibilities for optimal policy outcomes where Western standards have *not* been incorporated in the international texts, such as with the debate on whether life is patentable subject matter. This exclusion from TRIPS was the result of strong advocacy and fierce resistance by developing and least developed countries during contentious and politicized negotiations. As the next chapter will reveal, these gains were hard bargained for by matching trade-offs and compromises, sometimes in IP and other areas of trade negotiation.[595] Such hard fought sovereignty should be retained to ensure that the rights-promises of biotechnology are not betrayed by greater protection than TRIPS requires.

In 1959, Fritz Machlup famously concluded that he had just enough confidence in the patent system that he could not recommend it be abandoned to the US Senate; however, had it not existed he would not recommend adopting such a system.[596] Having a system, and its universal minimum requirements, are now prescribed for all WTO Members through TRIPS. These trade obligations have created standards that prevent *absolute* discretion in tailoring patent law to domestic needs and yet retain sufficient flexibility to allow the human rights- with which they intersect- to be domestically prioritized by Member states. In relation to health and social welfare, despite potential misgivings by legislators and the courts, TRIPS is a significantly more facilitative instrument than it is given credit for and significantly allows diverse regulatory measures in relation to patenting life. Any concern by courts or parliament over compliance with international obligations should factor in *all* obligations and not just those arising under

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[595] See Gervais, *supra* note 493 on the drafting history. See also Trebilcock & Howse, *supra* note 237.
[596] F. Machlup, *An Economic Review of the Patent System* (1958) Study No. 15, US Senate Committee on the Judiciary, Sub-Committee on Patents, Trademarks, and Copyrights

TRIPS. The next chapter is dedicated to reviewing the nexus of trade-related IPRs with human rights and their complementary historical objectives. I will discuss some of the specific human rights obligations that need to be accounted for in domestic law and policy development and the sovereign right of states to self-determination for doing so.

Chapter Five

TRIP'ing Over Human Rights? A Legitimacy Crisis at the WTO

> [I]ntellectual property rights are rule-governed privileges that regulate the ownership and exploitation of abstract objects in many field of human activity...[I]ntellectual property rights are *liberty-intruding* privileges of a special kind...[T]hey promote factionalism and a dangerous level of private power. From the viewpoint of distributive justice, their scope should be limited.[597]

5.1 Introduction

In Greek legend, Damocles, a servile courtier to King Dionysius I of Syracuse, is enchanted by the apparent power, prosperity, and happiness of his king who quickly tires of his flattery. The king invites Damocles to a banquet and offers Damocles to sit in his chair. It is only after feasting on food and wine that Damocles raises his head to witness a sword precariously suspended above him by a horsehair. The moral of the story: kingship (governance) brings with it uncertainties and responsibilities that accompany a position of power. This myth teaches us about the vulnerability of our existence and our global governance institutions' that, according to Mendes and Mehmet, like us display hubris as their 'tragic flaw'.[598] Despite perceived impenetrability and strength, the metaphor portends the contingent nature of the institutional survival of the WTO and its authority in an age of 'global restructuring of capital'[599] coupled with a noticeable absence of a "global political ethics."[600]

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[597] Drahos, *A Philosophy, supra* note 164 at 5.

[598] Errol Mendes & Ozay Mehmet, *Global Governance, Economy and Law: Waiting for Justice,* (New York: Routledge, 2003) at 1, explain "the aspirations of humankind to eradicate the conditions that led to the Second World War and the evils that occurred during the war were soon overwhelmed by the tragic flaw within the nature of humankind. This tragic flaw...is the urge in human nature, which is then reflected in the institutions of global governance, to seek the supremacy of territorial integrity over human integrity and dignity in the pursuit of perceived collective power and self-interest."

[599] Rosemary Coombe refers to this as an "opaque phrase that attempts to encompass a multiplicity of phenomena—the emergence of a global interconnected economy, the dispersion of manufacturing production to ever-shifting sites around the globe—largely from so-called First World to so-called Third World areas, the proliferation of export processing zones in indebted areas facing World Bank and IMF pressure, the growth of international finance markets, the increasing feminization of the global manufacturing labour force, new migration patterns and the development of a global network of factories,

Nicolaidis and Howse envision a politic of ethics as a cure for the WTO legitimacy crisis, which is reminiscent of Rawlsian prescriptions for a realistic utopia:

> [O]ne might not be able to have democracy at the global level, but one can certainly have democrats, people who operate, advocate and decide, informed by a political ethics inspired by democratic ideals. Such a political ethics- defined by values such as inclusion, participation, transparency, attentiveness to distributive effects, *tolerance of diversity* and of their levels of legitimate governance- may already be implicit in the utopian projection of the European elites; even if their natural instincts as elites often cause them to act at odds with that utopian projection. If this is the case, it may be easier to describe this utopia in a mirror as it were, as the image that could inspire the rest of the world.[601]

The existence and efficacy of the WTO- its power in governance- is tied to its increasingly contested legitimacy amongst member states[602] and equally, in turn, to the legitimacy of state action in committing to *technocratically* determined trade policy- so characterized by Howse[603] - without broader consideration of the interests and preferences of civilian constituent populations or the moral force of their human rights

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service outlets, and capital investments." See R.J. Coombe, "The Cultural Life of Things: Anthropological Approaches to Law and Society in Conditions of Globalization" 10 Am. U.J. Int'l & Pol'y 791 [Coombe, "Anthropological Approaches"] at 797-798.

[600] Kalypso Nicolaidis and Robert Howse, "'This is my EUtopia...': Narrative as Power" (2002) 40.4 JCMS 767 at 775-776, citation omitted ["EUtopia"].

[601] *Ibid.*

[602] Many scholars suggest that changes in the past fifty years in world politics, sources and centres of power, emerging technology, decolonization, globalization, and the changing dynamics of international organizations (IOs) may have created a "legitimacy deficit." See essays in Jean-Marc Coicaud & Veijo Heiskanen, eds., *The Legitimacy of International Organizations* (New York: United Nations University Press, 2001) [*Legitimacy of IOs*]; Daniel C. Esty, "The World Trade Organization's Legitimacy Crisis" (2002) 1 World Trade Review 7; Robert Howse, "The Legitimacy of the World Trade Organization" in *Legitimacy of IOs* at 355. Ross P. Buckley contends that "the WTO faces a particular challenge in the Doha Round in redressing this sense of broken promises and unfinished business." See R. P. Buckley, "The Changing Face of World Trade and the Greatest Challenge Facing the WTO and the World Today" at 2 in Ross P. Buckley (ed.) *The WTO and the Doha Round: The Changing Face of World Trade,* Global Trade and Finance Series, (New York: Kluwer Law International, 2004) [*Changing Face*].

[603] Robert Howse, "From Politics to Technocracy- and Back Again: The Fate of the Multilateral Trading Regime" (Symposium: the Boundaries of the WTO) (2002) 96 AJIL 94, [Howse, "Technocracy"], online: <http://www.asil.org/ajil/wto6.pdf> discusses the development of the multilateral trade regime by technocrats and trade specialists; Nicolaidis and Howse in "EUtopia" *supra* note *ibid.* at 776 write: "Yet, the sensibility that informed these exercises of regime management was technocratic and economistic, not political or even juridical...trade issues were largely left, domestically, to a single part of the government, and to trade specialists- the trade policy elite.", the sensibility of whom "was fundamentally that of the Anglo-Saxon petit bourgeois...[and] a mentality that, generally speaking, likes to respond to pressure for change by readjusting bargains rather than building or rebuilding institutions, that likes rules for their regularity but resists their transformation into a normative system that constrains the messy methods of 'ad hoc' and 'muddling through'. Public policies are viewed as sets of alternative means to fixed, single objectives or ends, not as expressions of social and cultural norms."

claims. Jeffrey Dunoff articulates the problem well: "The world trade system is in turmoil, in part over the issue of public participation...a story about litigation, frustration, agitation, and legitimation."[604] And others have noted,

> [T]he WTO currently face[s] crucial challenges - dare we say crises? - of legitimacy. One speaks in both cases of the 'democratic deficit' and the need for legitimate governance; ... political elites are accused of letting the social fabric fall victim to the forces of markets and globalization."[605]

Civil society is bound by and subject to this palpably democratically deficient international legalization of trade rules[606]- and with IPRs, property rights- that represent a creeping encroachment on all facets of civilian day-to- day lives by compromising the state's ability to respond to demands for social justice, cultural diversity, human rights, and the participation of various publics in devising both policy development and regulatory outcomes at the national and international level.[607] Burgeoning scholarly literature and entire inter-disciplinary conferences have proliferated on the interstices of intellectual property and the public interest (be it from the perspective of human rights, development, or more generally the management of the intellectual and informational commons).[608] Rosemary Coombe had well anticipated these problems; her observations of a decade past are even more accurate in today's acutely fragmented legal climate:

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[604] Jeffrey Dunoff, "Public Participation in the Trade Regime: Of Litigation, Frustration, Agitation, and Legitimation" (2004) 56 Rutgers L. Rev. 961 (Symposium edition: Citizen Participation in the Global Trading System).

[605] Nicolaidis & Howse, *supra* note 600 at 769.

[606] This is not unique to the WTO. Other international organizations, including the IMF, may suffer the same criticism. The growing NGO lobby, civil protest, and anti-globalization sentiments vocalized against the WTO should signal warnings to the institution that reform of the WTO instruments and operations are not only matters of social good but also self-preservation and self-interest. See e.g. Charles Sampford et. al. "Living up to the Promises of Global Trade" and Bradly Condon, "The Twin Security Challenges of AIDS and Terrorism: Implications for Flows of Trade, Capital, People, and Knowledge" in *Changing Face supra* note 602, 9-37 and 251-284. Nicolaidis & Howse see civilian power as part of a broader narrative of imperializing liberalism, *supra* note 600 at 767-769.

[607] Some scholars consider internationalization "as evidence of the ultimate powerlessness of progressive legal politics." See Denise Reaume, "The Politics of Globalization" *Ultra Vires* 13-14, March 2001.

[608] See *e.g.* Florida Symposium Edition on Intellectual Property and Human Rights (2001-2002) 14 Fla. J. Int'l L.; Duke IPG, *supra* note 244.

> The global restructuring of capital and the intensified flows of capital, goods, imagery, people, and ideas has shaken the authority of nation states, cast cultural differences into sharp relief, and undermined the capacity of governments to deal with social welfare concerns. This raises new questions about the loci of power, the nature of accountability, and the authority of traditional communities and leaders, and creates crises of legitimacy and representation of unprecedented scope. In such circumstances, we might ask whether and to what extent any singular legal regime is "constitutive"....If diverse laws govern worlds of their own creation, people may occupy a number of juridically mediated worlds simultaneously.[609]

Stratified publics share in common their global identity as subjects of multiple governance norms and institutions with multiple sources of law, some seemingly in conflict if not competition with each other and potentially affecting the realization of their (cultural and political) demands as *consumers* of governance- in neo-liberal terms- and subjects of a representative government within their respective communities. The reality remains that there is only one tangible and accessible 'King' in the absence of a supra-national global sovereign: the government of the nation state within which the individual resides (it is what makes citizenship so critical in an age of mobility).[610] Bound by multiple governance norms, the publics are only able to formally participate in the formation of these norms at the national level but the degree of participation is circumscribed by international obligations committed to by the executive or legislative branches of government.[611] In this legally fragmented world, it becomes more difficult to hold any external source accountable to obligations and responsibilities that arise in

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[609] Coombe, "Anthropological Approaches", *supra* note 599 at 798.

[610] I acknowledge the literature on the growing contestability of citizenship. See *e.g.* B.S. Chimni, "International Institutions Today: An Imperial Global State in the Making" 15.1 (2004) EJIL 1-37 discussing the growing network of international institutions (economic, social and political) which create a nascent global state whose current task is to realize the interests of an emerging transnational capitalist class in the international system (to the disadvantage of subaltern classes in third and first worlds). It should be noted that Rawls also distances himself from the idea of a single world government. He writes: "I follow Kant's lead in *Perpetual Peace* (1795) in thinking that a world government-by which I mean a unified political regime with the legal powers normally exercised by central governments-would either be a global despotism or else would rule over a fragile empire torn by frequent civil strife" *Supra* note 18 at 36.

[611] Informal international participation is, however, critical as NGOs and various interest groups mobilize to play a significant role in international law making. For a discussion of their impact see *e.g.* Amani and Coombe, *supra* note 49. See Susan K. Sell, "Industry Strategies for Intellectual Property and Trade: The Quest for TRIPS, and Post-TRIPS Strategies" (1992) 10 Cardozo J. Int'l & Comp. L. 79, 101-102 [Sell, "Industry Strategies"] for a discussion on how IP owners may use lobbying to block new extension of IPRs.

relation to industry led intellectual property rights forged upon a failing "Club Model" of trade policy-making,[612] in the absence of a proper balancing of stakeholder interests, and immune from the rigours of a democratic process.

The last chapter considered domestic solutions for affecting change in patent doctrine in a TRIPS compliant manner in order to remedy the questionable extension of patent rights to DNA and life and to allow for better policy co-ordination amongst domestic health and industrial ministries. These recommendations would overcome the perfidies that threaten to undermine the human rights and welfare promoting promises of biotechnology by improving the quality of patents and are additionally appropriate ways for a state to avoid conflict with international trade law while mediating competing interests under human rights instruments.

Unlike human rights instruments, since the multilateral trading system is founded conceptually on a barter process of negotiation and contracting, those States with more limited resources and fewer "trade elites" are disparately affected by the process and therefore its outcomes.[613] Consequently, legitimacy becomes a paramount concern not

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[612] Dunoff, *supra* note 604 at 969-970, defines the club model as "a relatively small number of economists and diplomats from like-minded states worked quietly to make trade policy without much public input or oversight...it was successful in the sense that it oversaw dramatic decreases in tariffs and other trade barriers, and a corresponding increase in global trade and prosperity...Paradoxically, however, the advantages of the Club Model of trade policy-making contained the seeds of their own destruction... First, increasing trade liberalization caused citizens to be more sensitive to further liberalization ...complicat[ing] future efforts at liberalization. In addition, the Club Model was not sustainable in a context where developing states began to demand a greater role in trade negotiations and policy-making. Developing states distrusted a club that excluded them from a seat at the table, and generated rules that seemed to help rich states more than poorer states...[It] no longer represents a politically viable management structure for the international economic system" footnotes omitted. See also Robert O. Keohane & Joseph S. Nye, Jr., "The Club Model of Multilateral Cooperation and Problems of Democratic Legitimacy," in Roger B. Porter, et. al, eds. *Efficiency, Equity ,and Legitimacy: The Multilateral Trading System at the Millennium,* (Washington D.C.: Brookings Institution Press, 2001) at 264.

[613] Scholars writing on the negotiating history of TRIPS draw attention to the inequality of bargaining power and coercion that coloured the process. For a thorough and insightful discussion, See Susan K. Sell, *Private Power, Public Law: The Globalizing of Intellectual Property Rights* (Cambridge, Cambridge University Press, 2003) pp 108-120 describing bargaining strategies [Sell, *Private Power*]; see also Peter Drahos, "Developing Countries and International Intellectual Property Standard Settings", 5 J. World Intell.

only amongst Members but citizens adversely affected by state agency as measured by the paucity of their government resources, technocratic "know-how", and ultimately their experience with the regime's architecture.[614] The history of TRIPS is a testament to this, shaping perceptions of fairness, justice, and equity in form (the processes through which the individual has legal recourse for complaint) and substance (the content of what Cutler calls the *juridification* process affecting people in their daily lives).[615] The juridification of power relations is at the heart of current criticism over the politics of trade policy and

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Prop 765 critiquing the "trade-off" theory of TRIPS as part of a larger package of concessions. For empirical analysis of global IPRs and the differential impact of TRIPS mandated rights on national jurisdictions, see Keith Maskus, *Intellectual Property Rights in the Global Economy* (USA: Institute for International Economics, 2000); David M. Gould and William C. Gruben "The Role of Intellectual Property Rights in Economic Growth" in Keith Maskus, (ed). *The WTO, Intellectual Property Rights and the Knowledge Economy* (USA: Edward Elgar Publishing Limited, 2004) at 594-623.

[614] Lack of capital informational resources in the negotiation process for developing countries resulted in initiatives for a joint capacity building project on IP and development launched by the UN Conference on Trade and Development (UNCTAD) and the International Centre for Trade and Sustainable Development (ICTSD) in 2001, see UNCTAD-ICTSD *Capacity Building Project on Intellectual Property Rights*, http://www.iprsonline.org/unctadictsd/description.htm. The Projects resource book on TRIPS and development is intended to assist with WTO and other IP negotiations for officials from developing countries. See *Resource Book on TRIPS and Development: An Authoritative and Practical Guide to the TRIPS Agreement* at http://www.iprsonline.org/unctadictsd/ResourceBookIndex.htm.

[615] A. Claire Cutler, *Private Power and Global Authority: Transnational Merchant Law in the Global Political Economy* (Cambridge: Cambridge University Press, 2003) [*Transnational Merchant*], discussing juridification, pluralization, and privatization of authority relations. Others have defined the term as "an ambiguous concept... In descriptive terms some see juridification as the 'proliferation of law' or as 'the tendency toward an increase in formal (or positive, written) law;' others as 'the monopolization of the legal field by legal professions,' the 'construction of judicial power,' 'the expansion of judicial power' and some quite generally link juridification to the spread of rule guided action or the expectation of lawful conduct, in any setting, private or public... In normative terms juridification is sometimes seen as the hallmark of constitutional democracy, the triumph of the rule of law over despotism; at other times as undermining not only efficiency, but also democracy and civil society, for example in the form of 'legal domination,' and eventually the rule of law itself." Lars Chr. Blicher & Anders Molander, "What is Juridification?" online: http://www.arena.uio.no/events/documents/PAPER_002.pdf at 3-4 [footnotes omitted]. See also James Bohman, "Constitution Making and Democratic Innovation: The European Union and Transnational Governance" (2004) 3 Eur. J. Pol. Theory 315-337, wherein the author argues that the problem the constitution has to solve is one of *juridification* , "or the possibility of legal domination in the face of institutions that cannot organize a singular and unified popular sovereignty. Such legal domination is not simply tyranny, but rather the imposition of a cooperative scheme upon others who cannot influence or revise its terms." See also Daniel H. Joyner, "Bridging the Gap between International Law and Foreign Policymaking" (2003) 31.3 Denv. J. Int'l L. & Pol'y 437.

the inclusion of TRIPS in the multilateral system and as this chapter reveals, threatens to undermine WTO legitimacy for lack of attention to social justice.[616]

The historical analysis undertaken in this chapter is to demonstrate how the emergence of separate systems for facilitating trade and preserving human rights, both arguably to promote welfare, the public interest, dignity and development, has led to a divisibility of the world's governance institutions, and therefore our dually legally constructed identities, as though these identities are mutually exclusive despite the indivisibility of their goals. At any given moment, a state is perceived to be acting as agent for either "merchants" or "missionaries", never both at the same time, creating a moral divide with regrettable results that potentially undermine the synergistic gains of a reconciled "identity". This dualism is based on a false dichotomy that pits the liberal self empowered with an individual human right against state authorized traders operating on a capitalist imperative, also strategically framed as a "right" (IPRs). But the dichotomy is illusory for reasons accounted for in this chapter. To maintain any coherence in our international institutions for governance, I argue, we must reconcile human rights with trade obligations and eliminate binary interpretations of the instruments arising from the twin institutions (UN and WTO) for global governance. The interplay of the two bodies of international law is evident from their post-war historical emergence, stated goals, and

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[616] "Trade liberalization is good for rich countries with strong and established economies but very damaging for emerging economies. Furthermore, and most importantly, they [skeptics] maintain that developed countries use their greater bargaining power and knowledge capital to extract very favourable terms for themselves out of trade negotiations." Sampford *et al.*, *supra* note 606 in *Changing Face, supra* note 602 at 9. But see Peter H. Lindert & Jeffery G. Williamson, "Does Globalization Make the World More Unequal?" National Bureau of Economic Research, Working Paper 8228, April 2001, online: <http://www/nber.org/papers/w8228> and Michael Trebilcock, "Post Seattle Reflections: A Qualified Defense of the WTO and an Unqualified Defense of the International Rule of Law" Paper presented in Session 6, Corporate Power, National Sovereignty, and the Rule of Law in a Global Economy, NY University School of Law, 2000, 319-329, [Trebilcock, "A Qualified Defense"], online: <http://www.loc.gov/bicentennial/abstracts_trebilcock.html>. That some emerging economies have benefited is evinced in the examples of the Asian Tigers, India, and China such that any assertion of damaging consequences related to trade would have to be contextualized and qualified.

various textual references. Trade and human rights must be read in a complementary and coherent manner, as a dialogue with each state about how to devise a better world where respect for *dignity* and *human development* is made paramount in a self-determined way. This thesis argues that such an approach to international obligations is both desirable and congruent with the domestic and international prescriptions offered. While the "publics" constituted by domestic governance and defined by increasingly imagined territorial boundaries are not juridical parties before the WTO,[617] it is in their 'interest' that the WTO has been constituted with promises to improve social welfare by lowering consumption costs facilitated by reduced trade barriers. TRIPS, however, reveals that trade liberalization in this area is not motivated by concern over people (consumers in market terms) but corporate greed linked to the push for minimal substantive IP standards based on economic motivations that transcend state boundaries for articulation while relying on state agency for enforcement.

This chapter is divided into 4 sections. Section 5.2 familiarizes the reader with the multilateral trade system, the underlying theory of trade, and provides an overview of the negotiation rounds leading up to the formation and function of the World Trade Organization (WTO) after Uruguay. Section 5.3 looks at TRIPS' emergence out of that context and politicizes it as resulting from an industry driven corporate imperative for convergence in establishing stronger IPRs and enforcement mechanisms. I argue the role of the corporate 'person' cannot be ignored any longer as its power, authority and rights now threaten to usurp the rights of real persons. Section 5.4 introduces the United

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[617] Only states can be parties to WTO disputes and no provision in the WTO DSU expressly allows civil society participation in the dispute resolution process. See Understanding on Rules and Procedures Governing the Settlement of Disputes [DSU], Apr. 15, 1994, WTO Agreement, Annex 2, art. II, Legal Instruments- Results of the Uruguay Round (1994) vol. 31, 33 I.L.M 1226 (1994) online http://www.wto.org/english/docs_e/legal-e/28-dsu.pdf.

Nations human rights system as a complementary institution for global governance, providing an historical account and overview for understanding various dimensions of human rights and why states that have ratified social and economic rights are charged with the realization of those rights over any obligations that may be owed to (corporate) patent holders. Trade-related human rights affected by stronger mandated IPRs are discussed to draw attention to the social dimensions of IPRs as more than "trade-related". Whether IPRs should be considered competing human rights is also considered in order to establish the nature of the potential conflict that is to be resolved by my prescribed framework. Are IPRs human rights which, when held by corporations, are to be pit against the IP-intersecting human rights affecting individuals? If there is a human right to IP, how ought that right be understood given our conceptual analysis of institutional IPRs and our new-found appreciation for genetic information as part of the "commons"? Having argued that states have an obligation to act on behalf of their constituent "publics", section 5.5 provides the argument that doing so is well within the sovereign right of states to self-determination and the duties owed to its citizens. The ability to formulate diverse and responsive regulatory mechanisms or measures is essential for a meaningful right to self-determination and for mediating the tensions that threaten to undermine the legitimacy of the WTO and therefore its welfare-promoting potential.

5.2 The Multilateral Trading System

5.2.1 Trade Theory's Contradiction: Institutionalizing IPRs

Seventeenth and eighteenth century mercantilism was a dominant form of trade favouring government regulation restricting imports but liberal export policies promoting a strong domestic manufacturing industry and was successfully displaced by moral

philosopher Adam Smith's seminal treatise, *The Wealth of Nations.*[618] Smith's Theory of Absolute Advantage, revered by economists as classic trade theory, argued that states would benefit from realizable gains from even unilateral liberal trade where there was specialization and division of labour. Critics, however, questioned whether liberal trade and economic integration would remain a desirable policy for countries naturally poorly endowed (in all respects) when compared to trading partners. David Ricardo's Theory of Comparative Advantage[619] continues to enjoy a pre-eminent status amongst trade proponents because it recognizes that even if a country is less efficient in *all* sectors of domestic production (with no absolute advantage), it could still realize gains from trade if specializing in production for export in the area in which its *comparative advantage* is *most* and disadvantage is least. Accordingly, all states were encouraged to trade- an important objective since "history tells us clearly that isolationism and policies aimed at economic self-sufficiency are in fact a prescription for poverty."[620]

Western diplomats and transnational corporations (TNCs) rely on the theory of trade to support globalization, despite the growing criticisms,[621] to assert that trade liberalization, by changing market structure and encouraging competition, is a panacea

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[618] *Supra*, note 33.

[619] See David Ricardo, *The Principles of Political Economy (1817)*, cited in Trebilcock & Howse, *supra* note 237 at 3-6, with additional discussion of modifications of this theory.

[620] See Buckley, *Changing Face, supra* note 602 at 4 and accompanying footnote 9 providing examples. See also Sampford *et al.*, in Buckley, *ibid.* at 10-11 and United Nations Conference on Trade and Development, "Linking International Trade with Poverty Reduction" Least Developed Countries Report 2004, United Nations, online: UNCTAD, <http://www.unctad.org/en/docs/ldc2004_en.pdf>. See also Akira Iriye, *The Cambridge History of American Foreign Relations, Volume III: The Globalizing of America, 1912-1945* (U.K.: Cambridge University Press: 1993) at 139-48.

[621] See generally Joseph E. Stiglitz, *Globalization and Its Discontents* (N.Y.: W.W. Norton & Company, 2002) and the insightful book review offered by Kevin Kennedy, (2003) 35 The Geo. Wash. Int'l Rev. 2551-263. Compare to Martin Wolf, *Why Globalization Works* (USA: Yale University Press, 2004); Jagdish N. Bhagwati, *In Defense of Globalization* (USA: Oxford University Press, 2004); "Globalization and its Critics: A Survey of Globalization" *The Economist* (29 September 2001) 3 ["Survey of Globalization]"; Edward Graham, "Fighting the Wrong Enemy: Anti-Global Activists and Multinational Enterprises" Institute for International Economics, December 1 2000; Trebilcock, "A Qualified Defense", *supra* note 616.

for poverty, stimulates development by increasing domestic production for export which in turn increases capital flows and personal income. This then empowers the poor to participate in growth and by extension improves the conditions for health, education, and innovation by increasing living standards and life expectancy and, as a corollary, political stability and personal security, all of which feedback into the social loop that contribute to further better health, education, and dignity for the citizens of the state as well as more innovation and economic development. Strong IPRs to protect new innovations have been found to correlate with domestic economic growth when linked with liberal trade policies according to Keith Maskus who reports on the findings of a 1996 Gould and Gruben study:

> They found no strong direct effects of patents on growth, but there was a significantly positive effect when patents interacted with a measure of openness to trade. That is, stronger patents in open economies raised growth rates by 0.66 percent on average, suggesting that market liberalization in combination with stronger IPRs tends to increase growth.[622]

Sampford *et al.* contend the question is not one of fact as to *whether* the "deal" will make everyone better off but rather on *how* to ensure that the promises of trade theory translate into experienced realities especially for developing and least developed countries.[623] Yet, the disparities in social and material conditions resulting from and

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[622] Keith Maskus, *Intellectual Property Rights in the Global Economy*, (Washington D.C.: Institute for International Economics, 2000) at 168; Lee G. Branstetter, "Do Stronger Patents Induce More Local Innovation" 7(2) J. Int'l Econ. L., 359-370 (2004) and his review of several empirical studies by economists that fail to find evidence of a positive correlation.

[623] But see Ralph E. Gomory and William J. Baumol, *Global Trade and Conflicting National Interests* (USA: MIT Press, 2000) who argue that classic trade models proposing beneficial outcomes for *all* who participate in free trade critically depend on assumptions which may no longer be true in today's society (at 13). When classicists wrote, the agricultural industry dominated production supporting the economic principle of *diminishing returns to scale*. Today's world is marked with significant *economies of scale* which has ushered in the age of large multinational corporations that challenges the classicists' conclusion of only a single stable positive outcome ("equilibrium") driven by the invisible hand of the free market. The various equilibria from a world output perspective undermine efficiency claims of the comparative advantage model because if a particular equilibria is sustained by the market, it may serve to perpetuate distributional inequalities based on pre-existing factors (for example, fortuitous or disastrous conditions- such as famines and wars- migration patterns, political orientations of prior governments etc.) that influence market forces determining which equilibrium is selected. A country that is producing more than

contributing to knowledge asymmetries mean disparate outcomes from trade negotiations; asymmetries which existed at the dawn of the international system and continue to operate today to distinguish the haves and have-nots.

The institutionalization of the trade-intellectual property linkage under the WTO exemplifies asymmetric benefits garnered by developed countries of the "North" and agency capture by industry lobbyists within their boundaries. TRIPs illustrates how international (trade) law can translate the ideology of the powerful within powerful nations into a social construction that strives through politics, economics, and foreign and domestic policy to perpetuate itself as paradigmatically normative despite its market bias. Domestic regulatory diversity, and the sovereign discretion to respond to international human rights obligations, must be held as a defendable position against trade violation claims because it will allow the 'public' a necessary means of contributing to an alternative narrative; one more concerned with justice and individual rights. TRIPs scholars criticize its coercive nature as contradicting proponents' claims that the universally adopted strong standards for IP protection prescribed[624] will benefit all

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its population's share of world commodities has, they argue, more to trade, more to consume, and is better able to compete. The particular equilibria of the market may help retain this advantage and perpetuate a state's advanced position while freezing out other countries from most industries leaving them unable to enter the market: "[W]hich country makes what product is generally uniquely determined in the classical economic model of trade. And the outcome always serves the economic interests of the general public in all the countries involved because a country can be the prime supplier in an industry only if it is the lower-cost supplier of the item at a fixed quality level, or alternatively, that at a given cost, it is the higher – quality supplier....But today's world of industry contrasts sharply....[I]n many of today's industries, with large-scale operations required with difficulties of entry, and with acquired advantages rather than natural ones playing a more decisive role, the situation is basically different...there *is no single clear cut and natural outcome*." At 5-6. At the 2001 G8 summit in Genoa, Italy, the leading trading nations admitted that the poorest countries of the world had yet to benefit from the multilateral trade regime and that greater effort to increase access to markets of the developed world for developing countries' exports were needed.

[624] See Ruth L. Gana [now Okediji], "Has Creativity Died in the Third World? Some Implications of the Internationalization of Intellectual Property," (1995) 24 Denv. J. Int'L. & Pol'y 109, at 112 examining the affects of TRIPS "as a form of passive coercion"; Marci A. Hamilton, (1996) "The TRIPS Agreement: Imperialistic, Outdated, and Overprotective," 29.3 Vand. J. Transnat'l L. 613 at 614 intimating that TRIPS may become "one of the most effective vehicles of Western imperialism in history"; J.H. Reichman, "intellectual Property in International Trade: Opportunities and Risks of a GATT Connection," (1989) 22

Member economies and therefore their respective publics. Such an assertion, TRIPS opponents argue, ignores distributional realities tied to the fact that some Members "differ in terms of their levels of wealth, economic structures, technological capabilities, political systems, and cultural traditions. They have different needs and aspirations and require different intellectual property systems."[625] Any additional monopolistic rights provided above the base amount necessary for innovation in any given state is *inefficient;* based on the review of patent law and practice in North America in our discussions thus far, there is good reason to believe that the current system is failing to achieve the necessary equilibrium even in the western world from which it is derived. TRIPS' "one size fits all" regime, as it turns out, currently seems ill fit for *any.*[626] According to David Vaver, law professor and Director of the Oxford Intellectual Property Research Center, TRIPS was a step in the wrong direction:

> [l]egal standardization may be beneficial in general but is not so for intellectual property in either the developed or developing world. The law in developed countries is currently incoherent and itself requires major reconsideration. The imposition of such a defective law on the developing world is helpful to neither side. [627]

Its impact is greater than that which is textually provided, however, due to the scope *imputed* to the obligations as both more restrictive than the language providing for

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Vand. J. Transnat'l L. 747 at 813 contending that "Imposition of foreign legal standards on unwilling states in the name of 'harmonization' remains today what [Steven] Ladas deemed it in 1975, namely a polite form of economic imperialism" (footnote omitted); see more generally, Lloyd Geering, "The World to Come: From Christian Past to Global Future" online, http://www.religion-online.org/showchapter.asp?title=2735&C=2467: "*What is universalism to the West is imperialism to the rest* . . . The West is, for instance, attempting to integrate the economies of the non-Western societies into a global economic system which it dominates." (At 184, emphasis added).

[625] Peter K. Yu, "Four Common Misconceptions About Copyright Piracy" (2003) 26.1 Loy. L.A. Int'l & Comp. L.J. 127 at 135.

[626] This is evinced by the recent introduction of a Bill to prohibit further gene patenting in the USA discussed *supra,* footnote 563. Scholars have also been successful in pointing out there is little theoretical and empirical evidence supporting the contention that a stronger IPR system will spur greater innovation. See *e.g.* Lee G. Branstetter, "Do Stronger Patents Induce More Local Innovation" (2004) 7(2) J. Int'l Econ. L. 359-370 and his review of several empirical studies by economists that fail to find evidence of a positive correlation. Similarly, the literature increasingly calls into question the international claim that a developing country will stimulate foreign direct investment by raising its IP protection.

[627] Vaver, "Uniformity" *supra* note 63 at 5.

them (furthering the optics of a repressive regime) and, at the same time, more emancipating (the claim that IPRs are necessarily good for development) than practice will support. Paul J. Heald recommends that the developing world remain skeptical of Western claims that stronger IPRs will necessarily lead to economic prosperity and development as, he suggests, in the world of IP each country needs to consider its own economic situation and infrastructure to craft TRIPS compliant IP policy.[628]

> [s]trong intellectual property protection tends to serve economies that are advanced enough to be developing intellectual property- not countries in which the need for proper nutrition, hygiene, housing, and education- the fundamental necessities of life- remain outstanding for the majority of the population.[629]

The lack of basic institutions relates to comparative advantage differences. Trebilcock and Howse write:

> [i]n terms of neoclassical trade theory, whether a particular country will want stronger or weaker intellectual property protection will depend on whether its comparative advantage lies more in innovation or in the imitation and adaptation of others' innovations. This is simply an extension of the argument concerning the allocation of resources domestically between imitation and innovation. More precisely still, a rational country would have different levels of protection for different industries, representing different trade-offs between innovation and imitation in each industry depending upon where its comparative advantage lies.[630]

Some DCs enjoy a comparative advantage in *imitation* due to cheap labour and low regulatory compliance costs rather than in *innovation*. Innovation capacity is stronger in industrialized and industrializing economies with liberal democracies and supporting public institutions and infrastructure in health and education. Lacking comparable domestic contexts that facilitate knowledge production, DCs have begun more vocally to object, as evidenced by the troubled Doha Round of negotiations, to the

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[628] See Paul J. Heald, "Mowing the Playing Field: Addressing Information Distortion and Asymmetry in the TRIPS Game" (2002) *Vanderbilt Law and Economics Research Paper No. 02-21: Vanderbilt Public Law Research Paper 02-15* http://papers.ssrn.com/sol13/papers.cfm?abstract_id=319301.

[629] Similarly, DCs and LDCS complain that the General Agreement on Trade in Services (GATS) does not equally benefit them. They are hardly in a position to export services. TRIPS and GATS became significant developing country issues in the Doha Round of negotiations.

[630] Trebilcock & Howse, *supra* note 237 at 400. For a discussion distinguishing the technology neutral theory of patent law from the technology specific application of the rules given by the courts to the biotechnology and computer software industries, see Burk & Lemley, *supra* note 66.

diminishing value of their comparative advantage. The gains to be realized by cheap labour, a lack of regulatory oversight, and the capacity to reverse engineer inventions patented elsewhere, is now circumscribed to a great extent by the shift in focus to substantive domestic regulatory IP regimes as non-tariff barriers to trade under TRIPS- but *not* in relation to life forms (for reasons explained in chapters four through six).

Nevertheless, the inclusion of TRIPS contradicts the very tenets central to trade theory on two counts. First, it *requires* that Members of the WTO *create* market monopolies by necessitating domestic IPRs legislation and enforcement mechanisms. Free trade agreements generally try to reduce monopolies by increasing access to markets and opening them up for competition.[631] Adam Smith, who argued for free trade as a means of increasing the wealth of nations, spoke against the evil of monopolies.[632] The gains to be garnered by states and ultimately consumers, with increased global competition, by reducing government interference with markets and eliminating state barriers to trade, cannot be fully realized if replaced with substantive standards justifying anti-competitive (monopolistic) behaviour of private corporate actors.

The international protection of IP monopolies under threat of sanctions has led to the conclusion by many critics of TRIPS, including developing countries, that its

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[631] "Liberalization has a positive effect on market structure and prices. Barriers to entry foster conditions where domestic companies become monopolies. This environment interferes with the workings of market mechanisms and leads to an inefficient use of resources. The opening of domestic markets weakens the possibility of monopolistic power." Sampford et. al., *supra* note 606 at 11. Traders private economic activities are facilitated by the increased contract opportunities and reduced transaction costs that free international trade enables and "hence the mutual gains realizable from exchange as parties with different endowments of specialized resource or skills are able to reap the gains from their differential advantages and disadvantages through trade." Trebilcock & Howse, *supra* note 237 at 4.

[632] Smith "gave much attention to issues that can fairly be characterized as concerning the interaction between trade and competition policy. He denounced the monopoly power of the British East India Company, which he argued hurt both India and the UK, thus presciently drawing attention to the significance of *international anti-competitive* behaviour for trade and development and to the symbiotic role of private and public actors with regard to such practices." See Robert D. Anderson & Peter Holmes, "Competition Policy and the Future of the Multilateral Trading System" (2002) 5.2 J. Int'l Econ. L. 531 at 535, emphasis added.

requirements are unjustifiable incursions on public goods and individual rights, rendering the welfare promoting function of trade (and domestic regulatory mechanisms for industrial policy) disingenuous.[633] For the provision of public goods, there is always, at least conceptually, a trade-off between equity and efficiency: "If no country is to be made worse off as a result of cooperation, equity considerations have to be borne in mind."[634] The nature of global public goods, or their opposite, "public bads", is that their respective benefits or costs cut across borders.[635] UN Secretary General, Kofi A. Annan, urges that global public goods be recognized as an important aspect of multilateralism:

> Whether we are talking about *preserving biodiversity*, preventing climate change, *fighting the spread of communicable diseases*, establishing rules for trade and aviation, or *setting global standards of human rights*, it is impossible for any single state to secure such goods on its own. Quite the contrary, *global public goods can only be attained if countries work together, and globalization has only increased this fundamental interdependence.*[636]

TRIPS, however, requires states provide private *individual* property rights which is why they are considered so objectionable by free market proponents as well as social justice seekers; their inclusion in the free market-promoting trade regime creates barriers for state provision of public goods and is inimical to trade and competition policy:[637]

> there is wide acknowledgement that competition policy and trade liberalization share common objectives relating to the promotion of economic efficiency, consumer welfare, and that a lack of effective competition policies can impede the realization of the gains from liberalization.

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[633] Such claims are supported by evidence of predatory behaviour and the rise of "bad patents" discussed in chapter three.

[634] Inge Kaul *et. al.,* "How to Improve the Provision of Global Public Goods" in Kaul *et al.*, supra note 191, 21 at 25.

[635] Inge Kaul *et al.*, "Why Do Global Public Goods Matter Today?" in Kaul *et al.*, *supra* note 191 at 2.

[636] "Endorsements" in Kaul *et al.*, *supra* note 191 at ii, emphasis added. See also *WTO Agreements & Public Health: A joint study by the WHO and the WTO Secretariat,* Geneva (August, 2002), online: World Trade Organization <http://www.wto.org/english/res_e/booksp_e/who_wto_e.pdf>.

[637] The United States' original proposal for an International Trade Organization (the defunct version of today's WTO) carried provisions addressing restrictions that private combines and cartels' imposed on the principle that goods affected would not be able to flow freely across borders so long as private agreement divided the markets of the world amongst cartel members. Such anti-competitive behaviour was detrimental to trade liberalization. The proposals were incorporated into the 1948 Havana Charter (Chapter V), ultimately opposed by the US Congress over concerns for potential constraints on domestic sovereignty and was consequently never adopted. Anderson & Holmes, *supra* note 618 at 535 and accompanying footnote citations referring to US Proposals, Department of State Pub. No. 2311, at 4 (1945), also quoted in John H. Jackson, *World Trade and the Law of GATT* (Indianapolis: Bobbs-Merrill, 1969) at p. 522.

> Furthermore, there is a growing recognition that anti-competitive practices impact directly on the welfare and prospects of developing countries, and hence are no longer (if they ever were) a concern exclusively for the developed world.[638]

TRIPS-required market intervention through prescribed rules for patent monopolies and their domestic enforcement (with its imposition of 20 years for *all* technology) is inconsistent with the historical territoriality of patents institutionally and is antithetical to trade values. Second, derogating from first principles in trade theory with the TRIPS instrument not only renders that deviation suspect but also undermines the legitimacy of trade policy. Member States that do not enjoy an absolute advantage in any area of trade, cannot exploit the area in which they *do* have a comparative competitive advantage in production because the international rules were abruptly *changed* at the last moment of a heavily invested and very exhausting Uruguay Round to include never before established uniform standards for IPRs.[639] TRIPS neutralizes any comparative advantage in imitation and has rendered developing (DCs) and least developed countries (LDCs) less willing to make concessions in traditional areas of trade negotiation during the most recent Doha Round which was to conclude December 2006. Sylvia Ostry, a former Canadian trade negotiator observes that

> [t]he degree of intrusiveness into domestic sovereignty bears little resemblance to the shallow integration of the GATT with its focus on border barriers...The WTO has shifted from the GATT

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[638] As a result, some are calling for WTO rules on competition policy. See Anderson & Holmes, *ibid.* at 532 and n. 4 reference to World Trade Organization, "Special Study on Trade and Competition Policy," in *Annual Report for 1997* (Geneva: 1997), chapter IV; UNCTAD, *World Investment Report: Transnational Corporations, Market Structure and Competition Policy* (Geneva: 1997) and the OECD, *Trade and Competition Policies- Options for a Greater Coherence* (Paris: 2001). Still, as the authors note in their review of the literature, the competition-trade discussions continue. Some commentators argue against the WTO's extensive involvement in the area of competition policy based on compatibility concerns over operational modalities, the implications of an overly rigid codification of the principles of competition policy, and in applying the WTO Dispute Settlement Understanding (DSU) to competition law and policy. See discussion at 532-33 and accompanying footnotes. See also Trebilcock & Howse, *supra* note 237 at 588-611 on trade and competition policy and Figure 18.1 at 465 showing that welfare effects of monopoly "include undesirable consequences such as lower quantity, higher price, 'dead-weight-loss' and 'populist concerns that large concentrations of economic power carry the potential for undue political influence."

[639] See Gervais, supra note 493 at 3-26.

> model of negative regulation – what governments must not do–to positive regulations, or what governments *must* do.[640]

Third, heuristic utilitarian economic rationales, such as the principle of pareto-efficiency, would be inapt in justifying the imposition of higher intellectual property protection through trade obligations because strengthened protection while improving welfare in some countries would reduce it in others making it Pareto-inferior. Instead, the dissonance of stronger trade-related protections with neo-classical trade theory is often justified in trade literature as part of the *bargaining* process that created "fair" trade-offs between disparate ("competing or conflicting economic") interests of states during trade negotiations.[641] But the diminution of the *comparative advantage* in imitation over the artificial inflation of that in innovation should be attributed, at least in part, to the system's normative ascription of a comparative advantage in *process dominators* and *realpolitik.*[642] Differences in negotiated outcomes arise from a disparity in resources, inequality of bargaining power, and power politics at the WTO[643] which undermine

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[640] Sylvia Ostry, "The WTO: Institutional Design for Better Governance" (paper presented at the Conference on Efficiency, Equity, and Legitimacy: The Multilateral Trading System at the Millennium, Kennedy School of Government, Harvard University, Cambridge, Mass., 1-2 June 2000) 6 as cited in Claude E. Barfield, *Free Trade, Sovereignty, Democracy: The Future of the World Trade Organization* (Washington, D.C.,: The AEI Press, 2001) at 5-6.

[641] See *e.g.* Trebilcock & Howse, *supra* note 237 at 401.

[642] "The most widely held theory of international politics is realpolitik, which refers to a policy based on realistic calculations of state power....By comparison...idealpolitik [is] the formulation of policy choices based on an idealistic view of world politics....Idealpolitik presumes a linkage between domestic and international politics and assigns to international law an overarching mission of maintaining world order conducive to the survival of constitutional and representative forms of government....Although seemingly irreconcilable, the positivism of realpolitik and the naturalism of idealpolitik do have a point of congruence in that both schools of thought recognize the utility of international law in providing for the reciprocity so necessary for the orderly relations of states" See James Wolfe, *Modern International Law: An Introduction to the Law of Nations,* (New Jersey: Pearson Education, Inc., 2002) at 4. Sampford *et al. supra* note 606 at 9 remark on the 'rupture' between making promises and implementing policies for their realization: "we have to be careful that our own actions do not undermine our promises by securing for ourselves trading arrangements so favourable that we benefit at the expense of those to whom we have promised beneficial trade liberalization. We would be making liars of ourselves!"

[643] See generally Peter Drahos, "Where the Weak Bargain with the Strong: Negotiations in the World Trade Organization" (2003) 8 International Negotiation 79-109 [Drahos, "Weak Bargain"]. See also Sarah Anderson (ed.), *Views from the South: The Effects of Globalization and the WTO on Third World Countries* (Chicago: Food First Books and International Forum on Globalization, 2000).

classic trade theory and ignore a state's concurrent human rights obligations. The contractual analysis (bargain theory) for reconciling the incongruity of trade theory with TRIPS is therefore inconsistent with the events leading up to the completion of the Uruguay Round discussed next.[644]

5.2.2 History of the GATT

A historical review of the purpose and origins of the multilateral trade system,[645] and the degree to which TRIPS deviates from these, provides the necessary contextual foundation for the interpretation exercise I engage in of trade texts and their latitude for prioritizing sovereignty (in chapter six). I will argue that the historical emergence of global governance rules (i.e. trade and human rights) supports their deployment in a complementary manner as well as the discretion of each state to diversify regulatory policies to meet their underlying objectives. With an end in sight to the atrocities of the Second World War, an important idea formed: world peace could be attained through international law; an institutional structure for a multilateral trade system emerged to increase security by fostering economic interdependence.[646] The First World War had

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[644] See Gervais, *supra* note 493 discussing resistance to the "TRIPS package" and the all or nothing nature of its adoption as part of broader negotiations in other sectors.

[645] Mendes & Mehmet, *supra* note 598; Trebilcock & Howse, *supra* note 237, chapter 1. See also Jeffery S. Thomas and Michael A. Meyer, eds., *The New Rules of Global Trade: A Guide to the World Trade Organization* (Ont.: Carswell, 1997); John Croome, *Reshaping the World Trading System: A History of the Uruguay Round*, 2d and rev. ed., World Trade Organization (Boston: Kluwer Law International, 1999); Ian Fletcher *et al.*, eds., *Foundations and Perspectives of International Trade Law* (London: Sweet & Maxwell, 2001); Steve Charnovitz, *Trade Law and Global Governance* (London: Cameron May International Law & Policy, 2002); Jon R. Johnson, *International Trade Law* (Canada: Irwin Law, 1998) [Johnson, *ITL*]; Malcolm N. Shaw, *International Law*, 5th ed. (New York: Cambridge University Press, 2003); Robert E. Hudec, *Essays on the Nature of International Trade Law* (London: Cameron May International Law and Policy, 1999); Ernst-Ulrich Petersmann, "Time for Integrating Human Rights into the Law of Worldwide Organizations: Lessons from European Integration Law for Global Integration Law" Jean Monnet Working Paper 7/01 online: <http://www.jeanmonnetprogram.org/papers/02/021201.html>.

[646] See Federico Ortino, *Basic Legal Instruments for the Liberalization of Trade: A Comparative Analysis of EC and WTO Law* (Portland: Hart Publishing, 2003).

been accompanied by an ensuing retreat from world trade[647] and a return to protectionist polices giving rise to the depression of 1920's and eventually the Great Depression of 1929.[648] The Second World War (1939-1945) again diverted the state's focus to national concerns and isolationist policies but as the war ended, enthusiasm renewed to rebuild relations and improve conditions for stable economic growth. It became apparent that a co-operative reconstruction strategy would be needed to avoid the devastating economic conditions that followed WWI. A series of conferences were organized to discuss this collective goal and the mutual gains of mobilizing efforts to increase market access, discourage and reduce monopolistic behaviours, and promote domestic and international policies to support economic growth, integration, and interdependence. The Bretton Woods, New Hampshire conference of July 1944 resulted in the Bretton Woods Agreement between the allies. "At this stage, it was evident that trade, economic stability, peace, international security and human rights *were clearly linked.*"[649]

There were three pillars to the Bretton Woods System that together provided the institutional infrastructure supporting to-be- agreed-to multilateral trade provisions in the provisional GATT: the International Monetary Fund (IMF),[650] the International Bank for Reconstruction and Development (IBRD referred to as the World Bank (WB)) along with

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[647] After the war, the international system unhinged as world trade shrank from $30.3 billion in 1929 to $20.3 billion in 1931and by "1932, the United States, the major provider of capital...had virtually stopped investing its funds oversees." Iriye, *supra* note 620 at 119.

[648] See Buckley, *supra* note 602 at 3. Buckley adds that "Trade liberalization is central to globalization. There is a tendency to assume that globalization is a given, and inevitable. This is not so. The period from 1870 to 1913 was one of intense globalization in trade in goods and especially in capital glows. Indeed, measured as a percentage of GDP of the capital exporting nations, it is arguable that capital flows were more globalized in this period than they are today" (*ibid.* at n. 8). However, the author notes that gross flows are much higher today because of significant capital flows from rich individuals in developing countries to developed countries as safe havens for investments.

[649] Mendez & Mehmet, *supra* note 598 at 68, emphasis added.

[650] The IMF was agreed to by 45 government representatives meeting at the UN Monetary and Financial Conference held in Bretton Woods, New Hampshire USA in July 1944 as a framework for economic cooperation designed to avoid the disastrous economic policies contributing to the Great Depression.

the International Development Association (IDA) and finally, the ill-fated ITO (the intended institution for negotiating and administering the envisaged multilateral trade regime). The IMF was to ensure stability of international financial markets by promoting international monetary co-operation; overseeing exchange rate stability; and assisting in the establishment of a multilateral system of payments and provision of resources with safeguarding conditions- so that members experiencing fiscal hardship would have alternative responses than resorting to restrictive trade measures. The WB, membership in which required IMF membership, was to:

> provide reconstruction capital from countries like the USA whose economies had not been devastated by the war to the shattered economies of Europe and Japan- the success of the Marshall Plan that the USA subsequently adopted in promoting this objective meant that the World Bank was able quickly to redefine its focus as providing development capital to less developed countries...[651]

In February 1946, the newly forged United Nations Economic and Social Council (UNESCO) accepted U.S. initiated proposals for establishing the International Trade Organization (ITO) for the negotiation of an international trade agreement within the context of a proposed United Nations Conference on Trade and Employment in Havana. A transitional agreement for tariff reductions was agreed upon pending the contentious comprehensive Havana Charter. By January 1, 1947, the *General Agreement on Tariffs and Trade* (GATT 1947) and its *Protocol of Provisional Application* (PPA)[652] had come into effect with 23 signatories including Canada. GATT 1947 was purposely a

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[651] Trebilcock & Howse, *supra* note 237 at 23. But see Walden Bello, "Building an Iron Cage: The Bretton Woods institutions, the WTO and the South" in Anderson, *supra* note 643 at 54-90 arguing that the Bretton Woods Institutions and the WTO are part of the same continuum of "a campaign of global economic containment of the legitimate aspirations to development on the part of Third World countries" marked by "the reorientation of the World Bank toward managing development in the South in the late 1950s," the IMF's role "as the watchdog of the Third World countries' external economic relations in the 1970s", the "universalization of structural adjustments in the 1980s" and the "unilateralist trade campaign waged against the Asian "tiger economies" by Washington beginning in the early 1980s" (*ibid.* at 55).

[652] The GATT had no expiry date but for further clarification, the PPA provided that the GATT would not come into force permanently but was only a temporary agreement that would govern so long as it did not conflict with any pre-existing inconsistent legislation. See Thomson & Meyer, *supra* note 645 at 4.

minimalist instrument that created few new obligations, other than preliminary tariff reductions and non-discrimination principles that were cornerstone of pre-existing bilateral agreements. In order to allow the American administration to approve it without obtaining the approval of Congress, it only applied to future legislation and did not mandate amendment to existing domestic law. GATT 1947 also had provisions to ensure commitments would be observed pending the formation of the ITO to administer and enforce the GATT, similar to what the WTO does today. But the ITO was "still-born" once the US administration announced it would not submit the Havana Charter to Congress for approval; further ratification by signatories was abandoned and what remained were the two financial pillars, the IMF and WB, and a *provisional* GATT:[653]

> By default, the GATT, a minimal code for trade relations, became the main game for the organization and coordination of international trade rules... [W]hat also died along with the ITO charter was the intention to have a world trade regime that would be infused with the social dimensions of trade, as well as global values of justice and human rights... [I]t is a moral, legal and indeed economic imperative that the world trade regime return to the original vision...[654]

Once the post-war urgency for full co-operation subsided, the significant compromise needed to achieve international agreement amongst stratified states with disparate needs became less tenable. Further attempts to establish a permanent ITO-like institution failed. The multilateral trade regime evolved instead without the intended central framework of the Havana Charter, based on a provisional agreement. GATT 1947's incremental development into a multilateral trade regime was facilitated through a series of formal arm-wrestling negotiation *Rounds*.

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[653] See John H. Jackson, William J. Davey, & Alan O. Sykes, Jr., *Legal Problems of International Economic Relations*, 3d ed. (St. Paul, MD: West Publishing, 1995) at 293-294, cited in Mendez & Mehmet, *supra* note 598 at 68.

[654] Mendez & Mehmet, *ibid.* at 69.

Eight Rounds have been successfully concluded[655] achieving a substantial reduction in the tariff levels from an average of 47% on manufactured products in the post war period to about 3% after the full implementation of negotiated reductions from the Uruguay Round.[656] The ninth Round, initiated in Doha, Qatar in 2001 was scheduled to conclude by January 1, 2005, was extended to December 2006 and seems to have collapsed altogether. The first six rounds, ending with the Kennedy Round in 1967, focused on and were very successful in significantly reducing tariff barriers (the most prominently used import restriction)[657] and negotiating reciprocal tariff concessions. Historically, tariffs had been negotiated on an 'item by item' bilateral basis which meant that between two negotiating countries, one would bargain for a reduction of tariffs on a specific class of products which would be met with a counter request but this proved too complex with the increase in participating parties. During the Kennedy Round, negotiations were made on a 'linear basis' wherein countries agreed as a group to reduce their tariffs by a specific percentage on large classes of products.[658] Sector specific discussions (i.e. for textiles) occurred for the first time. With marked success in tariff reductions underway, the focus of the negotiations expanded beyond lowering tariff barriers[659] to include other trade distorting measures.[660]

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[655] 1)1946, in parallel with a negotiation of the Agreement, in Geneva Switzerland; 2) 1949- Annecy, France; 3)1950-51, Torquay, England; 4)1955-56, Geneva, Switzerland; 5)1960-61, the "Dillon Round" in Geneva, Switzerland, 6)1964-67 the "Kennedy Round" in Geneva, Switzerland; 7)1973-1979, the "Tokyo Round" in Geneva, Switzerland, 8) 1986 to 1994, the "Uruguay Round" in Marrakesh, Uruguay. The negotiation period for concluding the rounds reflects increasing complexities and ambitions of the process.

[656] Michael Trebilcock and Robert Howse, "A Cautious View of International Harmonization: Implications from Breton's Theory of Competitive Governments" [unpublished paper presented March 1, 1999] at 1 [Trebilcock & Howse, "Regulatory Diversity"]. This is a shorter version of their article "Trade Liberalization and Regulatory Diversity: Reconciling Competitive Markets with Competitive Politics" (1998) 6.1 Eur. J. L. & Econ. 5.

[657] Other forms are quotas and subsidies. See Ortino, *Basic Legal Instruments, supra* note 646 at 8.

[658] Thomas & Meyers, *supra* note 645 at 6.

[659] A tariff barrier is also known as an import or custom duty and acts as a border based tax imposed on imported goods whereas a non-tariff barrier encompasses any trade restrictive measure including a "law,

The GATT 1947 succeeded in fulfilling its (provisional) mandate for tariff and quantitative restriction reduction; further linking international trade rules to domestic regulatory measures was an invasive intrusion on sovereignty that required, but failed to acquire, more thoughtful *public* consultation and approval. Instead, the GATT's prior success in reducing border measures was perceived to give rise to new protectionism. By the early 1970s states alternatively resorted to domestic measures as a permissible proxy for insulating protectionist policies, adopting non-tariff barriers to trade "such as quotas, voluntary export restraint agreements, orderly marketing agreements, industrial and agricultural subsidies and more aggressive unilateral invocation of trade remedy laws, particularly antidumping and countervailing duty laws."[661] Meanwhile, the LDCs, that had banded together in 1964 to form the United Nations Commission on Trade and Development (UNCTAD) in response to GATT as a "rich man's club", produced a report to address the special economic needs of these countries that could be met through trade liberalization policies. As a result, Part IV was added to GATT 1947, recognizing "special and differential status" of least developed countries (LDCs) and inviting

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regulation, policy, or practice of a government other than an import duty..." Federico Ortino contends that today, this distinction is less valuable due to the great success of lowering tariff levels and because the non-tariff barriers are 'negatively defined' as anything that is not a tariff barrier- a definition so broad it lacks significance. Ortino classifies trade barriers into four main kinds: tariff v. non-tariff measures; border v. domestic measures; market access v. market barriers measures; and government v. private barriers. *Supra* note 646 at 7-16, see also R. Baldwin, *Non-tariff Distortions of International Trade* (Washington DC, The Brookings Institution, 1970) at 11-12, cited in fn 22 and 24 of Ortino, classifying non-tariff barriers to trade within one of twelve categories: "quotas and restrictive state-trading policies, export subsidies and taxes, discriminatory government and private procurement policies, selective indirect taxes and selective domestic subsidies and aids, restrictive customs procedures, antidumping regulations, restrictive administrative and technical regulations, restrictive business practices, control over foreign investment etc." (*ibid.* at 8). Compare to L. Bartels, "Article XX of GATT and the Problem of Extraterritorial Jurisdiction: The Case of Trade Measures for the Protection of HR" (2002) 36 JWT 353.

[660] Such as the Anti-Dumping Code of 1967, formally the *Agreement on Implementation of Article VI of the Agreement on Tariffs and Trade,* GATT BISD 15S/24; this was the first agreement to move beyond tariff measures. It was said that like the draining of a swamp, "the lower water levels revealed all the snags and stumps of non-tariff barriers that still have to be cleared away..." BA Jones, *New York Times,* 10 July 1968 as cited in R. Baldwin, *Nontariff Distortions of International Trade* (Washington DC, the Brookings Institution, 1970) at 1 and in Ortino, *Basic Legal Instruments supra* note 646 at 8.

[661] Trebilcock & Howse, *supra* note 237 at 24. Full text of Tokyo Round Codes at <http://www.wto.org>.

developed countries to provide unilateral and voluntary concessions on trade items of export interest to the LDCs (these formed the foundation of the subsequent Generalized System of Preferences (GSP)). An understanding for dispute settlement (DSU)[662] and the "Enabling Clause,"[663] significant concessions obtained at the last minute under threat that the LDCs and DCs would abandon negotiations, were amongst new arrangements for the framework for international trading.[664] They aimed at promoting development through trade rather than *aid.* The 7th (Tokyo) Round of negotiations came at the behest of the Americans, and shifted focus to negotiating non-tariff barriers (NTB) to trade in order to address apparent protectionist policies emerging in domestic regulatory governance.[665]

5.2.3 The Uruguay Round & the WTO:

The Uruguay Round, the 'most ambitious' and lengthy multilateral trade negotiations ever undertaken with 100 governments participating in discussions on highly contentious agenda issues, resulted in 26,000 pages of documents comprised of several instruments designed to fulfill the promises of opening access to the world's markets, reforming the rules and institutions of the international trade system, and establishing a

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[662] *The Understanding Regarding Notification, Consultation, Dispute Settlement and Surveillance,* BISD 26S/210, which improved the existing dispute settlement process under GATT articles XXII and XXIII and incorporated certain customary practices.

[663] The *Differential and More Favourable Treatment, Reciprocity and Fuller Participation of Developing Countries,* BISD 26S/203, provides the enabling clause. With the word "notwithstanding", paragraph 1 of the Enabling Clause permits Members to provide "differential and more favourable treatment" to developing countries "in spite of" the MFN obligation of Article I:1 which requires that same be extended to all Members of the WTO "immediately and unconditionally". For example, The Generalized System of Preferences allows states to giver better and preferential tariff treatment to developing countries than bound tariff rates provided for all other WTO members. Preferences are voluntarily provided and are not binding on the granting state but nevertheless require the legal authority of the GATT or else it would violate the MFN clause of Article I.1. It additionally allowed developing countries to enter tariff reduction agreements amongst themselves without the strict application of GATT Article XXIV (on custom unions, territorial application, and free trade areas).

[664] DCs saw the failure to establish a new textiles and clothing arrangement to replace the MFA that restricted trade in both as a notable failure of the Tokyo Round as were agricultural issues, safeguards, voluntary export restraints and institutional improvements to the GATT which remained unsettled.

[665] Thomas & Meyer, *supra* note 645 detail the impetus for the Tokyo Round at 9.

new World Trade Organization to administer and enforce the system.[666] The Round saw greater participation of DCs after decades of 'virtual non-participation in trade negotiations.'[667] Jan Mcdonald notes the expansive reach of this Round:

> The Uruguay Round dramatically expanded the traditional portfolio of trade interests. The World Trade Organization (WTO) regime now extends to services, intellectual property, investment, national subsidies policies, and domestic regulation of product standards, food safety, and quarantine...This expanded agenda has blurred the boundaries between trade and other subjects of national and international policy, creating the potential for tensions between competing policy goals".[668]

The Uruguay Round Agreements (Agreements) were signed in April 1994 in Marrakesh, Morocco but were preceded by three very controversial Ministerial meetings[669] and a Ministerial Declaration premised on the understanding that the issues and concessions arising from the intellectual property discussions would *not* be directly linked to the other trade in goods issues.[670] Three formal bodies were established under the Declaration, each charged with overseeing negotiations in different areas including improving GATT as an institution for better global economic policy coherence.[671] Contentious subjects for negotiation were agriculture, intellectual property, textiles and clothing, and safeguards; much like the current Doha Round[672], they created intractable problems that threatened to undermine its successful conclusion.[673]

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[666] It took some four years to prepare and seven more to complete. For a detailed chronology and historical account of this Round, see Croome, *supra* note 645.

[667] Jordana Hunter, "Broken Promises: Trade, Agriculture and Development in the WTO" (2003) 4 Melbourne Journal of International Trade Law at 299. Consensus for including "new issues" (such as IP and trade-related investment measures) was obtained partially by agreeing to structure the negotiations to meet issues of concern for DCs and by agreeing to separate the negotiations for trade in services from goods.

[668] Jan McDonald "It's Not Easy Being Green': Trade and Environment Linkages beyond Doha" in Buckley, *supra* note 602, 145-169 at 145. She argues that progress made by the WTO in policy interpretation of texts have yet to be reflected in the institutional mindset of WTO members.

[669] In Punta del Este in 1986; Montreal in 1988; and Brussels in 1990.

[670] Gervais, *supra* note 493; Thomas & Meyer, *supra* note 645.

[671] Thomas & Meyer, *ibid.* at 16-18 and their Figure 1, "Structure of the Uruguay Round" at 19. For a detailed review of the individual negotiating groups, see the issue specific chapters in their text.

[672] In the 8th Round, some of the developing countries, including agricultural exporting countries of Latin America, refused to deal in any area unless there was agreement on the agricultural issues (i.e. addressing

To expedite the process, GATT Director General Arthur Dunkel changed the negotiating structure so that the fourteen groups negotiating were reduced to six and set new deadlines for the Round's conclusion.[674] He asked the negotiating group Chairs to submit "consensus" achieved drafts and if none were reached, the Chairs were to provide an "arbitrated" text based on their knowledge of the national objectives of the negotiating parties and their concerns. These were then compiled by the Secretariat into a further Draft Final Act (Dunkel draft) that the Trade Negotiation Committee reviewed for acceptance:

> The Director-General's hope was that, as a consolidated text, participants would be able to see a positive balance of concessions across the entire range of agreements for the first time. This, it was thought, might then persuade all participants to accept the Draft Final Act without alterations and conclude the Round... [although]...displeased with certain individual provisions.[675]

But the impasse on agricultural issues between the EC and US was menacing until 1992[676] when Peter Sutherland,[677] Dunkel's successor immediately re-launched negotiations that were finally concluded with "consensus" on all major aspects of the Final Act. The new "Members" (due to structural changes in the institution with the

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the domestic subsidy of agricultural products, reducing tariffs and eliminating quantitative restrictions). Also, the European Community (EC), which had been in a stalemate with the US over agriculture, eventually accepted that the conclusion of the Round required some agricultural concessions and thus recommenced the negotiations. In the current 9th Round, agriculture continued to be a dividing issue.

[673] "[For] the first time in GATT negotiations, it was a group of developing countries that demanded progress on agriculture and that were prepared to veto any package that did not include such progress." See Thomas & Meyer, *supra* note 645 at 21.

[674] The remaining groups were for 1. textiles, 2. agriculture, 3. intellectual property, 4. market access 5. rule making (including anti dumping and safeguards) and 6. institutional issues. The groups that had completed their work were either disbanded or merged into these six.

[675] Thomas & Meyer, *supra* note 645 at 22.

[676] The US, satisfied with settling its agricultural issues with the EC in the "Blair House Accord", redirected its attention to amending other areas of the Dunkel Draft such as TRIPS and wanted to abandon the proposed Multilateral Trade Organization (MTO), now the WTO. *Ibid.* at 29.

[677] For a full listing of all previous Director-Generals, see the WTO website at http://www.wto.org.

formation of the WTO)[678] signed on at the final Ministerial Meeting held in Marrakesh, Morocco in April 1994. Implementation was to occur by January 1, 1995.[679]

The WTO was a significant accomplishment and was later heralded as the "crown jewel" of the Round[680] despite the fact that the WTO was not originally on the negotiating agenda.[681] The WTO is now the permanent institutional framework for the conduct of trade relations as prescribed by the legal instruments included in its Annexes; these constitute an integral part of the Agreement (as a group, the *Multilateral Trade Agreements* (MTA)).[682] Some sixty different instruments are now included under the WTO Agreement;[683] most relevant to this dissertation are the GATT 1947 (incorporated by GATT 1994), the DSU Agreement, and TRIPS.[684] The WTO oversees the application

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[678] Signatory states to the GATT 1947 were labeled GATT "Contracting Parties" in accordance to consent theories that treated international law as little more than a contract. This signaled a common understanding that the provisional GATT 1947's authority was limited to basic tariff reduction. While GATT 1947 encompassed rules for voting, all important decisions- except waiver and accession-were generally based on consensus and without a formal vote. Signatories to GATT 1947- not WTO Members- are still "contracting parties" while under the WTO agreement, "Members" is used when referring to GATT 1994.

[679] Congress passed U.S. implementing legislation late in December 1994 and thereby secured the fate of the WTO and assured its implementation. For a historical list of the 128 countries that had signed GATT 1994 by the end of 1994 along with the date that they signed, visit <http://www.wto.org>.

[680] John M. Curtis, "Trade and Civil Society: Towards Greater Transparency in the Policy Process" online <http://www.international.gc.ca> at 302.

[681] "The possible creation of a new international trade organization was not even referred to in the negotiating agenda of the Uruguay Round....[I]f the 1990 Brussels Ministerial Meeting (which was to have concluded the Round) had not collapsed over agricultural issues, there may never have been a WTO...the delay occasioned by the collapse...probably resulted in a better global trading regime than might otherwise have been the case." Thomas & Meyer, *supra* note 645 at 28.

[682] Article 2. The Multilateral Agreements on Trade in Goods (GATT 1947 and GATT 1994), the General Agreement on Trade and Services, and the Agreement on Trade Related Aspects of Intellectual Property Rights all are included in Annex 1 (A, B, C, respectively). Annex 2 is the Understanding on Rules and Procedures Governing the Settlement of Disputes (DSU). Annex 3 outlines the WTO's Trade Policy Review Mechanism (TPRM) and Annex 4 includes four additional agreements which were not formally a part of the Punta del Este Declaration or the Uruguay Round of Negotiations: *The Agreement on Trade in Civil Aircraft; the Agreement on Government Procurement; the International Dairy Agreement;* and the *International Bovine Meat Agreement.*

[683] Pauwelyn, *Conflict of Norms, supra* note 12 at 23. The Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations, concluded in Marrakesh, Morocco, on 15 April 1994, published in WTO Secretariat, *The Results of the Uruguay Round of Multilateral Trade Negotiations, The Legal Texts* (Geneva, 1995), online: <http://www.wto.org/english/docs_e/legal_e/03-fa.doc>. Article 1 of the WTO Agreement establishes the Organization while its scope is articulated under Article 2.

[684] Full text of all agreements available online at http://www.wto.org/. Note that Contracting parties to GATT 1947 are not subject to GATT 1994 unless they sign on to the WTO Agreements.

of these new rules through a structured dispute resolution system- with panels and an Appellate Body (AB) - providing treaty based disciplines for unilateral remedies.[685] Some, however, believe that the WTO is not substantively or politically sustainable because "there is no real consensus among WTO members on many of the complex regulatory issues that the panels and the Appellate Body will be asked to rule upon."[686] Nevertheless, just as trade regulation and its discourse are dominated by the comparative advantage of the industrialized world in law, politics, human resources, technological capacity, linguistic dominance, intellectual capital, and rhetorical eloquence- all of which allow for better representation of first world interests in the negotiation process and, therefore, the negotiated outcomes[687]- so are the dispute settlement processes. Barfield reports, "[t]he united States has been the world's most active user of the new system- and the most successful. As of January 2001, the United States had brought fifty-seven complaints to the WTO... [and] lost only three cases."[688] Under Article 64 of TRIPS, IP complaints are made subject to the DSU and since TRIPS covers both substantive standards and procedural implementation requirements, both types of complaints may be raised before the DSU.

Prior to the Uruguay Round, IP is mentioned in only a few GATT articles. Article XX(d) of GATT 1947 created an IP *exception* to free trade which allowed for diverse regulatory measures.[689] While DCs and LDCs were being assured that stronger

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[685] Thomas and Meyer, *supra* note 645 at 259; Trebilcock and Howse, *supra* note 237 at 407-408.
[686] Barfield, *supra* note 640 at 7.
[687] See *e.g.* Drahos, "Weak Bargain", *supra* note 643, 79-109.
[688] Barfield, *supra* note 640 at 32.
[689] The exception was invoked in two GATT panel disputes. The panel's decision in *United-States-Imports of Certain Automotive Spring Assemblies* (1981) GATT Doc. L/5333, adopted on May 26 1983, BISD 30S/107, the first patent infringement case, reaffirmed that patent protection was an area in which Parties could take measures that otherwise would be non-compliant with GATT obligations. The panel in *United States-Section 337 of the Tariff Act of 1930,* (1989) GATT Doc. L/6439 adopted on November 7, 1989,

IPR regimes would benefit their development objectives, they were not oblivious to the political pressure from the Japan, US, Swiss and EU alliance at the rent-seeking insistence of their respective information, entertainment, and pharmaceutical industries during the Uruguay Round. It made the inclusion of TRIPS as part of the "final package" suspect to the end.[690] In the interim, the United States pushed for the inclusion of substantive IP protection in its regional agreement with Canada and Mexico in order to ensure its foothold as a major industry player in the knowledge economy and to create a precedent for the trade-related IPR regime being negotiated multilaterally. Chapter 17 of the *North America Free Trade Agreement* (NAFTA) preceded TRIPS by a year and, as the first treaty to regulate and enforce substantive IP rights, it served as the model for TRIPS.[691] Unlike prior Rounds, the shift to an "integrated" Round required participating states to adopt the entirety of WTO Agreements[692] so that in the end, notwithstanding the Ministerial commitment, IP *was* linked to the issues of trade in goods. After seven years of negotiation, the idea of a single package "trade-off" was considered more agreeable since it would reconcile disparate interests based on a larger set of issues inviting concessions in areas where a Member might otherwise be economically or politically disinclined on the basis that "somewhere in the package there should be something for

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BISD 36S/345, clarified that the Article XX(d) exception meant that the substantive patent law of a party was not challengeable under GATT but that parties remain charged with the obligation of ensuring that patent legislation was enforced in a manner not inconsistent with GATT. As a result, the domestic provision that allowed the International Trade Commission (ITC) to suspend the importation of patented goods allegedly infringing a US patent were held to violate GATT since the infringer could not avail himself of the same procedural rights as the aggrieved national plaintiff. See Gervais, *supra* note 493 at 6. Even IP disputes predating TRIPS stress the importance of the non-discrimination principle.

[690] Gervais, *ibid.* at 3-26.

[691] For a detailed discussion of special topics including dispute resolution in the WTO and NAFTA, see Gary Horlick, *WTO & NAFTA Rules And Dispute Resolution* (London: Cameron May Ltd., 2003).

[692] With some exceptions, e.g. government procurement, special and differential status of LDCs, longer implementation time frames for some Members etc.

everyone"[693] – even though this was not what Members had committed to when first undertaking the Round.[694]

DCs and LDCs constitute over 85% of WTO membership but given the degree of complexity and number of issues to be dealt with, the ability of DCs and LDCs to negotiate gains commensurate with those of developed countries remains questionable.[695] Some scholars write that TRIPS was simply the result of a "tradeoff" of concessions: what DCs and LDCs lost with IP standardization, they made up for in negotiations over agriculture and textiles.[696] There were some negotiated gains for DCs in the Round for trade in cotton and textiles but these could hardly be considered a *trade off* against strong universal standards in IPRs. Retrograde pressures and policies commencing in the 1950s had succeeded in the inequity of keeping the textile and agricultural sectors largely outside the purview of GATT 1947 such that any *trade off* here was based on justice concerns for *restoring* old promises rather than bargaining anew.[697]

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[693] http://www.wto.org/english/thewto_e/whatis_e/tif_e/fact4_e.htm.
[694] Gervais, *supra* note 493 at 3-26.
[695] Drahos, "Weak Bargain" *supra* note 643.
[696] See Trebilcock & Howse, *supra* note 237. Note, the *Agreement on Textiles and Clothing* in the Uruguay Round provided for full phase out of quotas in the area by the end of 2004.
[697] DCs, LDCs, and newly industrialized countries (NIC) have enjoyed a comparative advantage in textiles due to the large pool of unskilled labour accessible and modest technology needed. Cotton and textiles were considered a desirable point of entry for further growth and development through manufacturing and exports, yet trade in textiles and clothing largely occurred outside of GATT because of an apprehension by developed countries that their domestic markets would be flooded causing harm to their producers with resulting market disruptions. Any trade liberalization gains to be enjoyed by developing countries were quickly offset by the "voluntary" bilateral arrangements restraining cotton textile exports through quantitative restrictions that these competitive textile exporting countries were pressured into in the 1950s. The *Short-Term Arrangement on Cotton Textiles* in 1961- "in essence, a negotiated derogation from the then-existing GATT rules applicable to cotton fabrics"- formalized these bilateral agreements into an agreement under the GATT framework and within a year, was replaced by the *Long Term Arrangement Regarding International Trade in Cotton Textiles* "which continued the negotiated derogation for trade in cotton textile" until it expired in 1973 when it was replaced by the *Multi-Fibre Arrangement (MFA)*. With six extensions between the years of 1978-1993, LDCs and DC had been denied their comparative advantage in clothing and textiles for a near half century. See Trebilcock and Howse, supra note 237 at 21; Thomas & Meyer, supra note 645 at 6-7, 95-104.

In the end, the politics of trade effectively dictated preferential first world outcomes creating a 1) legalized trade linkage in IP when other trade linkages (like trade and the environment or trade and human rights) had not been readily or expressly embraced[698] and 2) legally enforceable standards for minimally prescribed monopolies antithetical to trade theory and policy (which link development and prosperity to the exploitation of comparative advantage). Although TRIPS is incongruent with the tenets of trade liberalization, it borrowed generously from the public benefit rationales of domestically strong IPRs of countries like the United States, Japan, Canada and Britain and the consumer benefit rationales of liberal trade, concealing at the time its heavy corporate impetus. During the ten years since TRIPS, a growing sentiment is that its inclusion in the multilateral trade regime was a sacrifice of territorial sovereignty, public good regulation, and individual human rights to corporate demands under the guise of (unsubstantiated) utilitarian claims.[699] TRIPS protects corporate interests in intellectual objects and, due to the nature of knowledge, creates the rules for the private provision of a public good but the exclusive nature of these rights, now internationally required, raises issues of equity and distributive justice traditionally most effectively addressed by the nation state. If as a society we want to encourage co-operation and discourage autarky, then we must assure each country that this is not a zero-sum game whereby any gains to be made for some Members will be countered by losses for others: "If no country is to be

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[698] See Steve Charnovitz, *Trade Law and Global Governance, supra* note 645 at 11. Charnovitz asks: "How should the World Trade Organization ("WTO") and the World Intellectual Property Organization ('WIPO') work together? Governments, multinational corporations, non-governmental organizations ('NGOs'), and academics have offered answers to these questions, but often the answers seem internally inconsistent. For example, business groups have generally favoured linking trade policy to intellectual property rights, but have typically opposed linking trade and environmental policies."

[699] Mounting evidence of the rise of anti-competitive behaviour and proliferation of "bad patents" suggests that despite normative justifications for IPRs, in practice these are not uniformly authentic claims and are in fact open to abusive exploitation. See discussion of bad patents in chapter 3.

made *worse* off as a result of cooperation, equity considerations have to be borne in mind."[700] The nature of global public goods, or their opposite, "public bads", is that their respective benefits or costs cut across borders;[701] particularly so, now that patent rights secured in one jurisdiction can be used to secure priority rights in others. Strong, universally mandated IPRs convert knowledge, an essential global public good for the attainment of other GPG, into a global public *bad* with significant adverse potential human rights impacts that raise the social, personal, democratic, and economic costs associated with this "trade-related" substantive code.

5.3 Rise of a Corporate Republic

We live in one world indivisible yet sated with contradictions: "[t]he world has deep poverty amid plenty. Of the world's six billion people, 2.8 billion - almost half - live on less than two dollars a day, and 1.2 billion - one fifth - live on less than one dollar a day..."[702] Such destitution persists, according to the World Bank, "even though human conditions have improved more in the past century than in the rest of history- global wealth, global connections, and technological capabilities have never been greater."[703] In 2000, Sarah Anderson and John Cavanagh reported that of the world's top 100 economies, 51 were corporations and only 49 were countries.[704] The world's Top 200 corporations accounted for over a quarter of global economic activity while employing

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[700] Inge Kaul *et al.*, "How to Improve the Provision of Global Public Goods" in Kaul *et al.*, supra note 108, 21 at 25.
[701] Inge Kaul *et al.*, "Why Do Global Public Goods Matter Today?" in Kaul *et al.*, *supra* note 14 at 2.
[702] The World Bank, *World Development Report 2000/2001: Attacking Poverty,* (Toronto: Oxford University Press, 2001) at 3.
[703] *Ibid.*
[704] "Top 200: The Rise of Corporate Global Power", Key findings, Online: http://www.ips-dc.org/reports/top200text.htm>. The report found the 1999 sales of each of the top five corporations (General Motors, Wal-Mart, Exxon Mobil, Ford Motor, and Daimler Chrysler) are bigger than the GDP's of 182 countries. List of the top 200 is also provided and is based on a comparison of corporate sales and country GDP, online: <http://www.corporations.org/system/top100.html>.

less than 1% of its workforce. Additionally, the authors found that the top 200 corporations' combined sales surpassed the combined economies of all countries other than the largest 10, and the combined sales of the top 200 were 18 times the size of the combined annual income of the 1.2 billion people (24% of total world population) that live in "severe" poverty. Eighty-two (41%) of the Top 200 corporations were American, followed by the Japanese who occupy 41 of the Top 200 spots;[705] it is no wonder these trading "nations" advocated for TRIPS; after all, traders trade, not countries.

In the life science industry, consolidation of market share, moreover, has resulted in a few transnational corporations having a dangerous amount of control in bioindustrial products related to agriculture, food and health. The Crucible Group (Group), a multisectoral group with representatives from industry, indigenous peoples, third world farming interests and lawyers, provides some startling statistics. The world's top ten agrochemical corporations account for 91% of the $31 billion worldwide agrochemical market while the top ten global seed companies control an estimated one –quarter to one-third of the $30 billion commercial seed trade with the top five vegetable seed companies controlling 75% of the global vegetable seed market (69% of the North American maize seed market is controlled by four companies and a single company, by the end of 1998, controlled 71 of the US cotton seed market).[706] Concentrated control exists independent of the debate on patenting life and needs to be addressed by competition policy since such power erodes the vigour and benefit that free and robust competition brings to the market and indeed the individual consumer. However, patents provide additional

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[705]See "Top 200: The Rise of Global Corporate Power," Institute for Policy Studies, online <http://www.ips-dc.org/downloads/Top_200.pdf>. For a list of the 135 countries with less GDP than the smallest of the top ten corporations, see Quigley, *supra* note 16 at 49.
[706] Crucible II Group, *Seeding Solutions, supra* note 2 at 16.

incentives for the consolidation of markets based on the importance of patent portfolios, the exclusive rights conferred, and the expense of licencing costs where patent rights are significantly fragmented. As the value of intellectual property assets have surpassed physical assets as the basis of corporate valuation, the quest for IP asset acquisition has provoked the restructuring of the industry (with mergers and acquisitions) and renewed the impetus for industry pressure for greater protection.[707]

Patents confer a major revenue generating asset for many of the large transnational life science corporations. The vast majority of IPR holders tend to be corporate owners[708] animated to "persons".[709] Patents are only valuable because of the tropes of property. The corporate *person* is similarly only meaningful because the state fictionally (institutionally) recognizes it as an entity entitled to "rights".[710] Having personified the corporation, society is unable to restrain its will or contain its (dysfunctional) personality[711] and, apparently, compete with its economies; the corporation amasses property and capital but does not suffer the destitution of which the

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[707] *Ibid.* citing W. Bratic, P. McLane and R. Sterne, "Business Discovers the Value of Patents", *Managing Intellectual Property,* September 1998.

[708] For statistics on the top 300 patent owners granted U.S. patents in 2005 and each year preceding since 1984, see Intellectual Property Owners Association, General Publications, http://www.ipo.org/.

[709] American patent law requires real persons be named as inventors on the application but no similar restriction exists in Canada. See discussion in text below under section 5.4.1regarding whether IPRs are human rights.

[710] Elizabeth Wolgast, *Ethics of an Artificial Person: Lost Responsibility in Professions and Organizations* (California: Stanford University Press, 1991) examines "Corporate Persons" and social problems associated with stressing the idea of "person" as western cultures do and then ascribing that title to corporations; a moral choice with clear costs. See also Jon Chipman Gray, *The Nature and Sources of the Law*, 2d ed. (New York: Macmillan, 1931). Compare this to legal theorist Hans Kelsen, who writes that "the concept of ...person means nothing but the personification of a complex of legal norms. Man...is only the element which constitutes the unity in the plurality of these norms." Hans Kelsen, *General Theory of Law and State,* trans. by Anders Wedberg (New York: Russell & Russell, 1961) at 95.

[711] See Joel Bakan, *The Corporation : The Pathological Pursuit of Profit and Power* (New York: Free Press, 2004).

World Bank speaks; it is impervious to the social costs of its assets and therefore any sense of duty, obligation, or justice that may correspond with its *rights.*[712]

Not surprisingly, civil groups and NGOs display a growing distrust of corporations[713] and by extension globalization given the transnational nature of business and facilitative function of international laws for corporate capitalist interests. By extension, the misgivings are often unqualifiedly extended to the WTO, which is credited with facilitating the corporate agenda for a republic deviating from the virtuous one[714] from which our global social conscience and our twin international institutions (UN and WTO) for governance were born.[715] The institutions for global governance espouse ideals communicated with a certain rhetorical eloquence that paradoxically recognizes a paternal and charitable duty towards, and responsibility for, others[716] while simultaneously contributing to the social conditions that manufacture the need to assist "them" by fostering hierarchies of dependence through coercively distinct imprints of dislocation, dispossession, and legal title concomitant with colonialism.[717]

By granting proprietary rights to life and defining these rights in terms of exclusion, society perpetuates dependency by creating a need to seek permission (licence) to use

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[712] Notwithstanding voluntarily assumed social consciousness at the behest of the United Nations, such as the 1999 initiated Global Compact which invited international businesses to support universal and social principles. See UN, "What is the Global Compact" http://www.unglobalcompact.org.
[713] Bakan, *supra* note 711.
[714] The ideals of America's Virtuous Republic were grounded in Christian values and the rule of law and served as a "new rallying cry for global missionaries." Expanding the international legal system towards greater state inclusion was a critical component of the proselytization of a political (democratic), religious (Christian), and economic (free market) ideology and the commitment to Republican values integral to America's search for economic and missionary opportunities abroad. For an insightful set of essays on the new legal orthodoxy, see Yves Dezalay & Bryant G. Garth, eds., *Global Prescriptions: The Production, Exportation, and Importation of a New Legal Orthodoxy* (US: University of Michigan, 2005) [*Global Prescriptions*].
[715] See Mendes and Mehmet, supra note 598.
[716] See Theodore J. Lowi, "The Welfare State, The New Regulation, and the Rule of Law" in Allan Hutchinson & Patrick Monahan, eds., *The Rule of Law: Ideal or Ideology* (Toronto: Carswell, 1987), 17-58
[717] See footnote 180, *supra* and discussion in accompanying text.

new technology of vital potential for food and health delivery. This hierarchy of need perpetuates existing power struggles between innovating nations -with new found international legal protection reaching into Member states' regulatory frameworks- and imitating nations whose activities are thereby rendered trespassory and illegal even within their own borders. While biotechnology has introduced a plethora of welfare promoting possibilities to further individual human rights interests, the legal response has typically surrendered to the corporate ideals of mass commodification and ownership of all things tangible and intangible with a corresponding "warehousing" of these assets for anti-competitive purposes. This has had an adverse affect on patent quality and has shifted the utility of the system from its primary social objective.[718] Corporations are not the only IP holders but they are the most vocal, persuasive, and predatory. Individual scientists holding letters patent over their inventions rarely have the time or inclination to mobilize a lobby- they are too busy with the science- or to sue. Perhaps if they did, a more balanced patent system would result nationally and internationally allowing for more generous research uses and preserving the basic stock of knowledge needed for competitors in developing down stream applications. Rather, US industry pushed its government to transplant strong domestic IPRs into international trade law -but without the corresponding necessary common law protections hard-won by litigants in courts or

[718] "[b]ecause the courts tend to ignore sociological, psychological and anthropological attitudes towards the body in their decisions and, instead, reduce everything to economics, they ignore signs of people's ambiguity about technological advancement...[I]t is accepted that the encouragement of commercial profit-making by users, primarily by the biotech industry, can only bring benefits to the community in the guise of more therapies and cures. But, as [Richard] Gold correctly observes, giving property right to biotechnological researchers focuses the medical industry primarily on cures and shifts attention away from the equally, or more important pursuit of determining- and eradicating- the underlying causes of illness and disease." See Mason & McCall Smith, *supra* note 452 at 489 referring to E.R Gold, *Body Parts: Ownership of Human Biological Materials* (Washington: Georgetown University Press, 1996).

the publicly-minded safeguards legislated into our patent system to maintain the necessary balance between private incentives and public interest.

Economist Gerald Helleiner writes,

> [l]arge private corporations purchase influence within all so-called democratic societies. As all Geneva trade diplomats know, their influence over ostensibly international negotiations is also considerable; witness the role of the pharmaceutical industry in intellectual property debates...The international activities of business lobbies are subject to no limits or registration requirements or regulation. The bulk of their activity is untransparent to the public. If the public sees them at all, it is only "through a glass darkly".[719]

Governments are very impressionable and responsive to corporate pressure:

> [I]f money impacts heavily upon both domestic and international political processes, there should be no illusions as to where the bulk of the power in decision making relating to the global economy is likely to continue to rest- that is, with those countries, firms and organizations that are economically (and, it must be added, militarily) the strongest.[720]

As early as the 1960's and 1970s, it was becoming apparent that representation of the needs and interests of the "weaker" nations would not be met by the growing trend to harmonize patent law. The "Andean Group" led a group of DCs through a review and reassessment of IP under the Paris Convention (Paris) and its implications for domestic development within their economies. As a result of this review, many DCs with existing patent legislation reportedly introduced measures or amendments geared at weakening domestic IPRs in an effort to make them more balanced and compatible with development goals.[721] This trend coupled with the appreciating value of knowledge-based technologies in an information economy resulted in a counter-push by industry in developed countries for the IP-trade linkage during the Uruguay Round and the incorporation of key Paris provisions into TRIPS. The fight for its inclusion came from

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[719] G. Helleiner, "Markets, Politics and Globalization: Can the Global Economy be Civilized?" UNCTAD 1-th Raul Prebisch Lecture, Palais des Nations, Geneva, 11 December 2000 online http://www.utoronto.ca/cis/working_papers/2000-1.pdf at 6.

[720] *Ibid.*

[721] Peter Drahos, "Developing Countries and International Intellectual Property Standard-Setting", Study Paper No. 8 Report to the IPR Research Commission, on the extent DCs influence standard-setting outcomes, online: http://www.iprcommission.org/papers/pdfs/study_papers/sp8_drahos_study.pdf>.

very strong and well resourced pharmaceutical and entertainment industries that lobbied aggressively their politicians for a trade-based approach to IP.[722]

5.3.1 TRIPS-Related IPRs

Developed countries of origin (mainly the U.S., E.U., Japan, and Switzerland) claimed that exports to countries with more lax IP standards were reduced as consumers could acquire similar created imitation goods, such as generic drugs, locally produced in their domestic markets cheaper without licence. But, as Trebilcock and Howse have written, "[t]he strength of the general claim for policy equivalence in this area is not straightforward."[723] As stand alone measures, TRIPS is likely to reduce welfare in DCs by undermining their comparative advantage in imitation and imposing costs on knowledge diffusion and access to technology. That reduction subsidizes an increase in first world corporate profits. Just as domestic IPRs were being strengthened by the administrative regulatory system and the judiciary in the United States with their expansion to new subject matter, firms and industry associations began to politicize IP by directing their energies to the legislative branch, looking for Congress to ensure protection for longer domestic periods as well as protections for international and foreign markets. As an initial response, these industries were successful in securing the IP-trade linkage in Section 301 of the US Trade and Tariff Act 1974, which allowed the US to pressure IP infringing states with the threat of unilateral sanctions.[724] Under Section 301,

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[722] See Drahos & Mayne, *supra* note 15; Sell, *Private Power*, *supra* note 613.
[723] Trebilcock & Howse, "Regulatory Diversity", *supra* note 656 at 18.
[724] In addition, section 337 of the US Trade Act provides inbound at the border protection by providing for unilateral retaliatory trade action against foreign products imported into the USA based on violation of IPRs of US producers under American law in the making of those foreign products prior to import. Section 337 does not require that injury to the American producer be established. A finding in violation of Section 337 will result in the exclusion of the product from United States unless the parties enter voluntarily into a licencing agreement and in this manner, has been considered a form of extra- territorial enforcement of domestic IPRs or a sanctioning of unfair competitive practices but the remedy provided is an import ban

the American President could take appropriate and feasible action to enforce US rights under trade agreements or to eliminate any act, policy or practice unreasonable, unjustifiable or discriminatory and which burdens or restricts US commerce. The USTR can be petitioned by American industries or firms, trade associations and individual corporations, such as MGL with the BRCanalysis example, to investigate actions of foreign governments (i.e. Canada) that are believed to harm US commerce. If the USTR investigates, it will consult with the foreign government in an attempt to resolve the problem, failing which, within a year, the USTR recommends appropriate action to the President -usually consisting of unilateral trade sanctions and/or the removal of concessions via the Generalized System of Preferences (GSP).[725] Two watch lists (one a priority list) are kept under Section 301 with out of cycle reviews on countries which pose a threat to US IP holders' interests. Canada was on the 2005 watch list and was one of the five countries reviewed out-of-cycle. Canada may be subject to unilateral action if it continues to disregard US pressures for greater protections and enforcement of IPRs.[726]

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rather than a counterveiling duty and the impact is disparate in the sense that local competitors taking an unfair advantage in domestic trade or trade for export by violating another American's IPRs will not be affected by this section. Special 301 of the Trade Act 1974 (section 1303 of the Omnibus Trade and Competitiveness Act of 1988) is different. It allows for outbound protection by providing for unilateral trade sanctions to be taken against countries identified pursuant to it as engaging in unfair trade practices due to a more relaxed IPP regime. The provision is designed to enhance the ability of the US to negotiate improvements to foreign IP regimes; usually, any level of IP protection that falls below that provided by US law is likely to be considered unfair. But, according to Trebilcock and Howse, such sanctions are likely to be against the GATT MFN principle. See Trebilcock and Howse, *supra* note 237 at 407 and chapter 16.

[725] Threats to withdraw voluntary preferential concessions given under the GSP are persuasive in eliciting desired compliance with the protection of American held IP protections and as Helleiner notes, "[c]orporate influence over US and other major powers' political decision-making can obviously carry profound spillover effects for rule-making in the global economy." Helleiner, *supra* note 719 at 6.

[726] See USTR's Special 301 Report 2006, <http://www.ustr.gov/Document_Library/Section_Index.html>.

Susan Sell provides a detailed history of the political economy of internationalizing IP protection[727] and concludes that effectively twelve corporate executives of US-based MNCs mobilized to form the Intellectual Property Committee (IIPC) that was ultimately victorious in persuading the parties in the Uruguay Round of its particular western based vision of IP policy. This enabled convergence of IP standards and provided measures for their enforcement. Additionally, locating TRIPS within a multilateral trade system renders unilateral actions of a state such as those available in domestic American law[728] GATT inconsistent for failure to deploy the multilateral regime's enforcement mechanisms and are thus subject to complaint. Deterring further unilateral action by developed countries was a major influencing reason for the acceptance of TRIPS by DCs and LDCs. Although the withdrawal of concessions under the GSP remains unaffected, TRIPS multilateralism held the prospect of achieving more *just* outcomes than unilateralism because "a standardized rule system can be a bulwark against bullying by the strong." "But", adds Helleiner, "if the rules are constructed by the strong to protect their own interests or if there is imbalance in capacity to implement them or both, such a system may be worse than useless to the relatively weak....Evidently, process is everything in these matters"[729]

As it turns out, Helleiner was correct; Drahos and Braithwaite observe that the threat of use of unilateralism seems to have *increased* rather than decreased with TRIPS:

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[727] Sell, *Private Power supra* note 613 chapter 4 on the domestic origins of a trade-based approach to intellectual property and chapter 5 on the Intellectual Property Committee effective in translating domestic changes into international law; see also Drahos & Braithwaite, *supra* note 7, chapter 6.

[728] For example, the United States used the threat of GSP withdrawal and priority watch lists under Special 301 to attack Thailand for the inadequate pharmaceutical patent protection it offered American firms in 1991. See Anthony D'Amato and Doris Long, (eds.) *International Intellectual Property Law*, (USA and Canada: Kluwer Law International, 1997) at 67-70.

[729] Helleiner, *supra* note 719 at 12.

> Perhaps the most stunning achievement of the 301 system has been its continued growth and use in the period after the creation of the WTO. There were intimations that the creation of a WTO dispute resolution system would see the US ease off on aggressive unilateralism. But if anything, 301 has acquired a more machine-like efficiency in the post-TRIPS period....The Clinton Administration... strengthened 301 by introducing immediate action plans for foreign countries on intellectual property rights as well as out-of-cycle 301 reviews, pushing developing countries into accelerating their implementation of TRIPS[730]

The paradox of TRIPS, as with all intellectual property regimes, is that while it is considered the economists' trade-off as more IP is presumed to lead to more knowledge, the implication is that stronger protection reduces diffusion and restricts rights of access and use (protecting private markets). This is why the corporate lobby pushed for their internationalization and how what was a domestic, administratively and judicially creeping form of sanctioned economic predation became *juridified.*[731] TRIPS demonstrates how *homogenization* efforts have now extended to the content of substantive rules. Once the "the ink was dry," it became apparent that the national representatives of the DCs and LDCs negotiating the Round may not have fully appreciated the implications of their agreement,[732] giving the South a "raw" deal with TRIPS' inclusion in the WTO agreements.[733] Its critics argue that TRIPS institutionally

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[730] Drahos & Braithwaite, *supra* note 7 at 106-107.

[731] Dezalay & Garth write: "[T]he prevalence of "money doctors" "selling competing economic expertises" has been matched in the 1990s with a "tremendous growth in "rule doctors" armed with their own competing prescriptions for legal reforms and new legal institutions at the national and transnational levels." Dezalay & Garth, *Global Prescriptions,* supra note 714 at 2.

[732] See Vaver, *IPL*, *supra* note 34 at 3: "International corporate power has effectively curbed national sovereignty in the field of intellectual property policy"; see also Vaver, "Uniformity", *supra* note 63 at 5.

[733] Martin Khor, Director of the Third World Network, a large coalition of public interest groups worldwide and a former member of the UN Human Rights commission's Expert Group on the Right to Development reports on the institutional factors that methodologically conspire to maintain the inequitable positional relations between the developed and developing countries. See generally Martin Khor, "How the South is Getting a Raw Deal at the WTO" in Sarah Anderson, ed., *Views from the South: The Effects of Globalization and the WTO on Third World Countries* (Chicago: Institute for Food and Development Policy Food First Books and The International Forum on Globalization, 2000) 7. But see Alan Sykes, "TRIPs, Pharmaceuticals, Developing Countries, and the Doha "Solution" (February 2002) U. Chicago Law & Economics, Olin Working paper No. 140, criticizing the Doha Public Health Amendment and defending TRIPS in terms of welfare gains to DCs and LDCs on the basis that strong patent protection in these countries protects R&D interests necessary to provide external firms incentive to undertake research important to these countries (i.e. malaria vaccines/drugs) with the assurance that the costs of the benefits would not simply be externalized through lax IP regimes. Nevertheless, such a Faustian bargain would not

reinforces and exacerbates the vast North/South inequities ostensibly the focal point for correction in the Doha "Development" Round.[734] This 9th Round of trade negotiations was launched with the agreement of 142 members at the 4th Ministerial meeting, on November 14, 2001 in Doha, Qatar and showed a renewed commitment to the development agendas of DCs and LDCs and a desire to facilitate the achievement of distributive justice through a commitment to return state deference for preserving regulatory diversity in some key contentious areas of trade including the regulation of health. The Doha Round was scheduled for completion at the end of 2006[735] but collapsed because, as The Economist put it, the "world's biggest economies prefer failure to compromise. What comes next?"[736] The "Development" Round of negotiations is prologue to the narrative that will unfold for the future multilateral trade system and the WTO's destiny.[737] The agenda for the "Development Round" indicated an attempt to remedy prior imbalances and to make future negotiations and obligations more equitable

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be necessary if greater attention were directed at ending poverty-linked diseases through the alleviation of poverty. It is well established that malaria is largely preventable with bed nets and environmental controls and the best approach to AIDS is prevention through education and condom use.

[734] "This is not the first time that we have seen the ascendancy of law among the recipes for state transformation- termed *modernization* in the 1960s and 1970s. The 'law and development' movement of that period was a similar effort to export a set of institutions and practices supposed to build the rule of law....The effort to export U.S. models of law failed....[Today], ...it is instructive that many of the prominent critics of the World Trade Organization and the World Bank tend to couch their criticisms in terms of procedural changes and expanded opportunities for legal representation of unrepresented groups.'" Dezalay & Garth, *Global Prescriptions,* supra note 714 at 2 [footnotes omitted]. See also Yves Dezalay and Bryant Garth, *The Internationalization of Palace Wars: Lawyers, economists, and the Contest to Transform Latin American States.* (Chicago: University of Chicago Press, 2002); Thomas Carothers, *Aiding Democracy Abroad: The Learning Curve* (Washington, DC: Carnegie Endowment for International Peace, 1999).

[735] See Director General Pascal Lamy's Speech, "Hong Kong Session of the Parliamentary Conference on the WTO, December 12, 2005, online at www.wto.org/english/news_e/sppl_e/sppl14_e.htm.

[736] "In the Twilight of Doha", *The Economist* (27 July 2006), online < http://www.economist.com/research/backgrounders/displaystory.cfm?story_id=7218551.

[737] Former WTO Director-General (1999-2002) Mike Moore believes "the meeting at Doha will be remembered as a turning point in the history of the WTO and the trading system and in relations between developed and developing countries within that system" Nov. 28 2001, 14th General Meeting of the Pacific Economic Cooperation Council, as cited in Terence P. Stewart, *After Doha: The Changing Attitude and Ideas of the New WTO Round* (Ardsly Park: Transnational Publishers Inc., 2002) at 2.

while promoting development. Its failure, however, in securing fairer distributive outcomes in negotiated concessions means that more than ever an equitable and remedial approach to evaluating trade contested measures and interpreting sufficient flexibility in trade agreements is necessary as an alternative means for achieving justice by allowing for state regulatory discretion in a human right optimizing manner as part of a coherent national and international order. Continued failure to address the social justice concern will regrettably prove Walden Bello correct. "From the very start", he writes,

> the aim of the developed countries was to push for greater market openings from the developing countries while making minimal concessions on their part. Invoking development was simply a cynical ploy to make the process less unpalatable.[738]

Left unchecked, the corporate capitalist imperative has achieved hegemony with continued common law derogations and, despite impositions on sovereignty, human rights, and the public interest, with new regional and bilateral agreements threatening far worse implications than TRIPS' multilateralism.

5.3.2 TRIPS, Plus or Minus: Deviating From Prescribed Standards

A growing number of regional negotiations are being modeled on TRIPS[739] and the United States has actively pursued a number of bilateral trade treaties[740] that strive to mirror the substantive protections prescribed by TRIPS and to exert political pressure for

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[738] Waldon Bello, "Why Today's Collapse of the Doha Round of Negotiations is the Best Outcome for Developing Countries" Focus on the Global South, 27, July 2006, online http://www.tni.org/archives/bello/dohacollapse.htm.

[739] See *e.g. Free Trade Area of the Americas* (FTAA), http://www.ftaa-alca.org/FTAADraft03/ChapterXX_e.asp. For an insightful discussion of how these collateral arrangements dealing with American perceived deficiencies in TRIPS create "a very complex legal environment" potentially challenging and conflicting with the TRIPS MFN principle in Article 4 and giving rise to potential de facto MFN discrimination, see Frederick Abbott, "Towards a New Era of Objective Assessment in the Field of TRIPS and Variable Geometry for the Preservation of Multilateralism" (2005) 8.1 J. of Int'l Econ. L. 77 at 97 [Abbott, "New Era"].

[740] A full list of US bilateral initiatives and their texts are available at the Office of the United States Trade Representative at www.ustr.gov. These include The US-Australia FTA (January 1, 2005); the US-Chile FTA (January 1, 2004), draft US-Central America Free Trade Agreement (CAFTA), and US-Singapore (January 15, 2003).

the adoption of "TRIPS Plus" protections which would further reduce critical policy space for signatory countries; "U.S. PhRMA stands strongly behind these efforts".[741] 'TRIPS Plus' refers to the requirement of greater (more stringent) substantive IP protection than that mandated by TRIPS.[742] For example, it may include a commitment that a negotiating party provide patentability for plants or animals, or that there be accession to UPOV[743] (which provides stricter and stronger protection for plant varieties than TRIPS mandates) or to the Budapest Treaty on the Deposit of Microorganisms for the Purpose of Patent Protection[744] (not mentioned in TRIPS), or to conform with the EPC (that allows patenting of transgenic plants and animals).[745] Having signed on to these TRIPS Plus agreements, countries can no longer take advantage of the flexibilities inherent in TRIPS' "wiggle room" nor of extended exemptions offered under the transitional periods. Moreover, they cannot make use of the equitable conduct defence I advance in chapter six.

Frederick Abbott explains the trend towards bilateral and regional arrangements as an attempt by the United States to *shift* to more restrictive and substantively protective regimes "as a result of the somewhat more balanced approach to TRIPS now achieved at

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[741] Frederick Abbott, "The WTO Medicines Decision: World Pharmaceutical Trade and the Protection of Public Health" 99 AJIL 317 at 349 [Abbott, "WTO Medicines"].

[742] For a detailed and insightful discussion of criteria for TRIPS Plus status and a helpful table of the bilateral and regional agreements whereby TRIPS-plus IPR standards have been secured by the developed countries on life in developing countries, see "TRIPS-plus" through the Back door: How Bilateral treaties impose much stronger rules for IPRs on life than the WTO" July 2001, online <http://www.grain.org/briefings/?id=6>.

[743] International Convention for the Protection of New Varieties of Plants (UPOV) (plant breeders' rights).

[744] *Supra* note 367. Online <http://www.dsmz.de/patents/bptreaty.htm>.

[745] For a list of existing or under negotiation agreements requiring TRIPS PLUS protection, see: "Bilateral Agreements imposing TRIPS plus Intellectual Property Rights on Biodiversity in Developing Countries" August 2005 http://www.grain.org/rights_files/bilats-TRIPSplus-0805.pdf. See also Susan Sell, "Industry Strategies for Intellectual Property and Trade: The Quest for TRIPS and Post-TRIPS Strategies" 10.1 Cardozo J. Int'l & Comp. L. 79 [Sell, "Industry Strategies"].

the WTO..., calling into question the relevance of the TRIPS Council deliberations"[746] In light of the important human development implications that TRIPS and TRIPS-Plus regimes have for public health, technology and biological resources, the UNDP endorses greater domestic regulatory diversity unimpeded by international obligations and recommends that one option is to revert to a "TRIPS-minus model that significantly reduces the length of protection and scope of coverage and increases national decision-making authority on standards and coverage of protection while maintaining a minimalist agenda at the international level."[747]

In the meantime, the *harmonization* offered by TRIPS through the imposition of universal minimum standards for IP protection which Members can implement as they see fit (Article 1) and the TRIPS Plus arrangements made in parallel are not enough to quell the protectionists' quest. New efforts are underway at the World Intellectual Property Organization (WIPO) for the complete *homogenization* of patent law *vis-à-vis* a Substantive Patent Law Treaty (SPLT) that would pave the way for a singular global patent. To this end, WIPO in 2001 adopted a "patent agenda," endorsed by the Director-General of WIPO,

> aimed at the further harmonization of patent law worldwide. The initiative, called the 'WIPO Patent Agenda' was envisaged as a process that would lead to the preparation of a blueprint for the future development and harmonization of the patent system. The Patent Agenda initiative has therefore placed the further harmonization of patent law as a top priority in WIPO's activities. The main activities under the Patent Agenda relate to the efforts to promote the ratification of the Patent Law Treaty (PLT); the reform of the Patent Cooperation Treaty (PCT); and, the ongoing negotiations on a Substantive Patent Law Treaty (SPLT). These separate, but interlinked, activities are ultimately oriented to set up an international legal framework for a global patent *with the result that the limited*

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[746] Abbott, "New Era", *supra* note 739. Abbott recommends that the new IP agreements be subject to objective prior impact assessment, that the WTO Members give greater recognition to the fact that IP rules have significantly different public welfare implications depending on a country's level of development and their field of application and with the gradual ending of transition periods, that the TRIPS Council assessment of its rules and provision for plus or minus adjustments be restructured along industrial subject matter and development lines to ensure positive outcomes supported empirically.

[747] UNDP, *Making Global Trade Work for People* (USA: Earthscan Publications Ltd., 2003) online: <http://www.undp.org/dpa/publications/globaltrade.pdf> [UNDP, *Making Trade Work*] at 221.

policy space left in the hands of national governments under the World Trade Organization's (WTO) Trade-Related Aspects of Intellectual Property Rights (TRIPS) will be further eroded.[748]

WIPO's agenda facilitates the *corporate* agenda and is not inconsequential. It threatens to further compromise justice for charity in an already seemingly biased system.

5.3.3 Sacrificing Justice for Charity

Because of distributional inequities and barriers to access, social welfare and justice are often usurped by the privatization of public goods. The imposition of strict IP regimes on DCs is justified by an inherently flawed theory which posits that IP producing companies (mainly drug, life science and biotech companies) are significantly harmed and disadvantaged in their R&D by the lax or absent IP regimes of developing countries. Jagdish Bhagwati expounds on the fallacy of this position. He writes that while poor countries have need, they do not have effective *demand*:

> There is little money to be made to recover normal profits on your invented drugs, if you think of poor markets. To see why the drug companies nonetheless see IPP [IP protection] in the poor countries as a money-spinner, it is necessary to distinguish between two types of diseases: those, such as malaria which are primarily in the poor countries, and those, such as AIDS which afflict rich and poor countries alike.... [In the latter], the drug companies make money in the rich country markets; IPP there is clearly something they value. But then they see piffling effective demand for those drugs in poor countries. So their strategy is to sell there at very low marginal costs and then charging the little that these poor markets will bear.[749]

Why, if poor countries are scarce able to afford the medications and other patented products of foreign firms (that also have developed markets) would IPRs matter in this impoverished context?[750] Although price discrimination can prove profitable for foreign

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[748] Carlos M. Correa and Sisule F. Musungu, "The WIPO Patent Agenda: The Risk for Developing Countries", online: <http://www.southcentre.org/publications/wipopatent/toc.htm>, from the executive summary [emphasis added]. The authors stress the importance of representation for the developing countries in the norm setting process at the WIPO and the need to foster an appreciation of the importance of IP as a tool for development policy and its prospects.

[749] Jagdish Bhagwati, "Pricing Medicines to Benefit Poor Countries" *UNDP Cooperation South 2002: Creativity, Innovation and Intellectual Property Rights*, (2002) at 38 [Bhagwati, "Pricing Medicines"].

[750] The value of commercialization will differ according to the price that the particular market will bear: "Empirical evidence shows that in developed countries industry recoups fifteen to twenty percent of its R&D costs through patents whereas in a country like India, the figure for a domestic inventor is 0.5 to two per cent." Shiva, *supra* note 90 at 5.

firms, these typically large MNCs, would like to *maximize* their return in poor markets rather than price discriminate by pricing at marginal cost. Their motivations for securing strong IPRs in poor countries are jaundiced and subtly compromise justice for charity; they mock the R&D *ex ante* incentive rationale and reveal the perversity of incentives created by a system of *ex post* rewards:

> The way [to raise *that* return] is to increase effective demand by using aid moneys addressed to health programs, so that the excess of what they will charge over their marginal cost is increased, raising profitability in the poor country markets. Medical economists have known for years that medical groups, for instance, favour insurance schemes that improve the patients' ability to pay (such as Blue Cross and Blue Shield insurance programs in the US), but oppose insurance schemes like the National Health Service of England, which instead reduce the returns to doctors.[751]

Effectively, merchants create the *need* for missionaries (often their own governments, international monetary and health agencies and NGOs). They perpetuate colonialist vestiges of dependency, and entrench, in addition to a financial indebtedness, a moral debt deep into the psyche and pocket books of developing countries thus defying any legitimate efforts at promoting economic self-sufficiency and sustainable development by these peoples for and by themselves.

Strong internationally mandated IPR protection contributes to the artificial growth of foreign debt for developing and least developed nations and increases the need for debt relief and foreign aid to help pay for the patent protected technology.[752] A less regulatory invasive TRIPS would have focused on increasing border measures to prevent counterfeits and not have linked substantive standards, which TRIPS did for the first time, with trade law. In the alternative, the rights of states necessary for maintaining

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[751] Bhagwati, "Pricing Medicines" *supra* note 749 at 39.

[752] See generally Ostergard Jr., *supra* note 96. Ostergard adds the additional quandary and short-sightedness of strong internationally mandated IPRs protection: "...the primary concern for developing countries is to adapt technology that will help maintain the physical well-being of their people. By putting up barriers, the developed countries delay the creation of markets that could support entry of technologically advanced IP, thus cutting short the potential profits that could be obtained if the developing countries could sustain themselves." (at 177).

important policy space, including the scope for TRIPS compulsory licencing now extended to generic exports to countries lacking internal manufacturing capacity under limited conditions,[753] should have been made more express in relation to other fields of patenting as well as specific statutory defences directed towards protecting the public interest in IP regulation. The domestic implementation of such high prescribed standards of IP protection based on the executive branch of government's undertaking in multilateral negotiations is implicitly instrumental to an existing economic pattern that simultaneously compromises attendant civil and political liberties[754] and creates potential conflict with social and economic rights. Even if market citizenship (as shareholders) is presented as the modern manifestation of citizenship, it is fallacious to assume that all can participate fully in the market-driven society in a manner that the value of equality of citizenship and the claim of universality would remain uncompromised. With the immense income disparity in the world, such participation is neither feasible nor imperative for peoples concerned with the satisfaction of more immediate needs like clean water, food, medicine and other essentials for their physical and spiritual survival.

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[753] See Section 5.4.4 of this Chapter.

[754] This assertion is based on the recognition of the inter-relatedness of these rights with social and economic ones. The case is not much different for new forays by BigPharma into growth sectors in the life sciences, such as nutraceuticals. Much of the opposition to GM food and organisms is based on a rejection of the disingenuous promises industry makes as justification for their development. Genetically engineered vitamin A rice ('golden rice') was "heavily promoted as a solution to hunger and malnutrition. Yet these promotional campaigns are clouding the real issues of poverty and control over resources, and serving to fast-track acceptance of genetically engineered crops in developing countries.... 'The main reason we are against GE rice', says BIOTHAI [Thai Network on Biodiversity and Community Rights] 'is the issue of control. Small farmers in the Third World can't achieve security when transnational corporations control these technologies and give away GE seeds like others give out food aid. It doesn't work, it doesn't help the farmers.' As Day-cha Sirpat of the Alternative Agriculture Network in Thailand has said: 'The poor, they don't need vitamin A rice. They need vitamin 'L', that's Land. And they need vitamin 'M, that's Money. Malnutrition is a problem of poverty, not technology.' The groups greeted with distrust the announcement of 16 May by the developers of Vitamin A rice about a deal struck with agricultural biotech giant Zeneca to license and distribute the crop." See Indo-Asian News Service, "GE-Rice Good for PR, Not the Poor" Masipag, *Third World Network* June 7, 2000, <http://www.twnside.org>.

Eric Cheyfitz offers some insight as to why typically western standards become the source for international prescriptive rules. The imperial and colonial history of Europe and America, according to Cheyfitz, is a history of *translation*[755] in its many manifestations; one of which, he asserts, has been the common law's process of ascribing title in order to override "legal" possession - a problem of political power and the struggle between orators.[756] This is similar to the current process of ascribing property in life and the genetic commons as a means of privately appropriating and excluding rightful inhabitants of that space. Borrowing from the medieval theory of *translatio*[757] Cheyfitz argues that the purpose and "primal act" of the nation-state was, from its inception, to *translate* itself into colonial forms in order to obliterate difference:

> For in its vision of a universal empire with a universal language, the *translatio* envisions the translation of all languages into one language; it envisions, that is, the end of the translation in the obliteration or complete marginalization of difference.[758]

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[755] "In English common law, title to land is that relation between a person or persons and a piece of real estate which allows the individual or individuals the lawful 'translation of [that] property,' to use a phrase out of Blackstone that itself translates as the legal term 'alienation'." Eric Cheyfitz, *The Poetics of Imperialism: Translation and Colonization from the Tempest to Tarzan*, (University of Pennsylvania Press, Philadelphia: 1997) at 47. Cheyfitz argues that kin-ordered societies, defining themselves primarily in terms of reciprocal relations "in contrast to tributary and capitalist ones, do not naturalize, or absolutize, cultural places. And, in Western thought, it is the figure of property that performs this naturalizing function. Locke's *The Second Treatise of Government* is exemplary here. For, as Locke figures it, property in the produce of the earth and in the earth itself precedes social life. And this property is founded on the primal fact that to begin with "every man has a property in his own person" (5.27), which, when invested through labor in the originally "common" things of the earth and the earth itself, converts the common to the proper." (*Ibid.* at 55 citing John Locke, *The Second Treatise of Government* (1690), edited by Thomas P. Peardon. (New York: Bobbs-Merrill, 1952).

[756] *Ibid.* at 49.

[757] Medieval *translatio imperii et studii* often involved translation from one language (usually Latin) into another (often French) in order to make works more accessible without regard for retaining the integrity of the original's vernacular. The *translatio* is valued not for its faithfulness to the original but for the display of skill, metaphor and eloquence that the translator has displayed. "This Latin phrase refers to the transfer or translation (*translatio*) of culture or knowledge (what one studies: *studium*) and of political power or legitimacy (what creates an empire: *imperium*) from one civilization to another. Online <http://cla.calpoly.edu/~dschwart/engl513/courtly/translat.htm>..

[758] Cheyfitz, *supra* note 755 at 122

Sovereignty's[759] new delegates- the so-called elite *mercatocracy*[760]- have been instrumental and effective in facilitating, expediting, and navigating this process of translation towards the obliteration of difference because a single homogenous market (with one language, set of regulatory compliance requirements, and standard price) is much easier to corner and requires no accountability.[761] If the corporate imperative has gained international authority without the accountability of a public participatory process, it is because some states have facilitated this agenda. Commenting on sociologist Boaventura de Sous Santos' central thesis that "transnationalization of the legal field" is a "constitutive element of globalization",[762] political scientist A. Claire Cutler adds that

> t]he modern law merchant is a form of transnationalized law embodying both the globalization of local law, as Anglo-American corporate laws are adopted throughout the world, and the localization of global law, as states are subjected to increasing discipline from legal regimes developed by international, transnational, and global organizations. Moreover, forms of transnationalized legal relations are discontinuous and uneven. In some cases, merchant laws operate dialectically creating deterritorialized transactions and agreements, but then reterritorializing them to facilitate enforcement.[763]

TRIPS exemplifies her point. Member states commit to internationally prescribed protective patent standards that are universal and transcend domestic authority in their

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[759] For a discussion of the idea of sovereignty, its origins, and its relationship to the international sphere, see Dennis Lloyd, *The Idea of Law: A repressive Evil or Social Necessity?* (England: Penguin Books, 1983) chapter 8. Lloyd expounds, "[i]n the sphere of international relations, state sovereignty meant that each state was entirely free to regulate its relations with other states" (*ibid.* at 174).

[760] "[T[ransnational corporations are identified as 'the central organizers,' the 'engines of growth,' the key agents of the new world economy,' and the dominant private institutions of the world economy'....[and] most importantly, are crucial participants in the creation and enforcement of merchant laws." See Cutler, *Transnational Merchant, supra* note 615 at 21, footnotes omitted.

[761] Cutler explains: "Derived from the medieval reference to the law merchant, *lex mercatoria,* the mercatocracy is comprised of transnational merchants, private international lawyers and other professionals and their associations, government officials, and representatives of international organizations. The mercatocracy operates globally and locally to develop new merchant laws governing international commerce...As a complex mix of public and private authority, the mercatocracy blurs the distinction between public and private commercial actors, activities, and law. It exercises near hegemonic influence through its material links to transnational capital and through its monopoly of expert knowledge, thought, and institutional structures. Indeed, the mercatocracy and its law are deeply implicated in the ordering of state-society relations because they operate to recast "public" concerns as "private" and thus are not subject to democratic methods of scrutiny..." *ibid.* at 4-5, 20-22.

[762] Boaventura de Sousa Santos, *Toward a New Common Sense: Law. Science and Politics in the Paradigmatic Transition* (N.Y: Routledge, 1995) at 252, cited in Cutler, *ibid.* at 19-21.

[763] Cutler, *ibid.* at 20 [footnotes omitted].

baseline yet rely on domestic enforcement measures. For political scientist Susan Sell, this is simply part of the inexorable march of *global capital/Western culture:*

> One hardly needs agency to account for the fact that the economically most powerful transnational actors acted in concert with the economically and politically most powerful states to devise global rules to benefit them all (and at the expense of most others).[764]

Governments of the day were neglectful of domestic economic costs and moral and political obligations owed to their respective "publics" when subscribing to TRIPS for reasons this thesis strives to make apparent: current patent practice in conjunction with TRIPS *plus* standards under negotiation in bilateral agreements may effectively impair access to agricultural and pharmaceutical products, vaccinations and methods of medical treatment, slow progress in the sciences, and privatize the common genetic and cultural heritage of humankind with potentially dire implications for the realization of human rights for all people, but most significantly for the most disadvantaged people of all nations, and disproportionately for those located in developing and LDCs which lack the relevant institutional capacity and a substantial innovation sector for IP development. As Braithwaite and Drahos suggest, "had TRIPS been framed as a public health issue, the anxiety of mass publics in the U.S. and other Western states might have become a factor in destabilizing the consensus that U.S. business elites had built around TRIPS."[765] Although the executive branch may have been shortsighted, the agreement deliberately (in order to get all Members to agree so that the Uruguay Round could conclude) retains enough ambiguities to allow for regulatory discretion in patenting life, an area that in our

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[764] "[l]ike a tidal wave, global capital/Western culture was reaching into every global nook and cranny eradicating difference, making the world ever safer for global capital/Western culture. In the material account, the process was eliminating obstacles to international commerce under the economic might and ideological orthodoxy of the transnational capitalist class. Global IP rules were just the latest triumph, neither the first nor the last." Sell, *Private Power, supra* note 613 at 3.

[765] John Braithwaite and Peter Drahos *Global Business Regulations* (Cambridge: Cambridge University Press, 2000) at 576.

geneticized future will matter most for health and other human rights. But will states utilize this discretion? The next section will consider the UN human rights (HR) system with its focus on dignity and respect for human difference. Key social and economic rights raised by the patenting of life are reviewed to argue that while TRIPS frustrates the role of the state in actualizing the complementary objectives of our global governance institutions, the human rights obligations of a state require it to act appropriately.

5.4 The International Human Rights System

"A law is valuable not because it is law, but because there is right in it" –Henry Ward Beecher

The 1919 Treaty of Versailles created the League of Nations in order to promote international cooperation, improve global welfare and to achieve peace and security.[766] *Jus Gentium* (the law of nations) governed relations between states but there was little to affect the treatment by states of their own citizenry and the Great War made apparent the atrocities that could result at the hands of one's own government entrusted, under the *social contract*, with safeguarding its citizens. Upon failure to prevent World War II, the League ceased its activities in 1946 but was eventually succeeded by the United Nations which formed the institutional framework for overseeing the promotion and protection of human rights. The political liberalism of Anglo-American constitutional law formed the basis for formally recognizing the new-found global secular religion of human rights.[767]

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[766] President Truman's closing speech at the San Francisco conference of April 1945, quoted in Mendez & Mehmet, *supra* note 598 at 9 identifies the objectives of the United Nations Charter as achieving peace and security through the achievement and observance of human rights for all, similar to the objective of the GATT 1947, to promote "peace and prosperity through trade". See Debra Steger, "Peace and Prosperity through Trade" PDF online: <http://www.rsc.ca/files/publications/transactions/2001/>.

[767] Immanuel Kant, *The Metaphysics of Morals*, trans. by M. Gregor (Cambridge: Cambridge University Press, 1991) has explored the moral characterizations of human rights as universal recognitions of the inherent worth of human beings and their inalienable human dignity. The secular religion metaphor has been used by Mary Robinson, UN High Commissioner for Human Rights, who in 1998 noted that the instruments for human rights in fact reflect a 'culture of human rights': "Today the Universal Declaration of Human Rights stands as...one of the great documents in world history...the authors sought to reflect in their work the differing cultural traditions in the world. The result is a distillation of many of the values

Earlier in this chapter we described the historical effort to encourage economic interdependence through multilateral trade. At the same time, parallel pains were taken to eradicate unauthorized use of force,[768] and to protect individual liberties against the tyranny of the state after the horrors of WWII. [769] It was President Roosevelt who named the international organization the "United Nations" – effectively fathering the institution with Winston Churchill after a meeting in 1941 in Canada.[770] By January 1942, 26 nations at first, later expanding to 46 nations, endorsed the Declaration of the United Nations[771] and committed to adhere to the Atlantic Charter, an ideologically principled plan of action which preceded the GATT and Breton Woods system, which "linked the imperative for a new global security institution and respect for human rights with improved labor standards, economic advancement, and social security."[772] The Charter was the prelude to the United Nations[773] formed under the Charter of the United Nations

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inherent in the world's major legal systems and religious beliefs including the Buddhist, Christian, Hindu, Islamic and Jewish traditions." Mary Robinson, Symposium on Human Rights in the Asia-Pacific Region, January 1998. See also Mendez & Mehment, *supra* note 598, preface. Their central thesis is that genuinely pursued principles meant to galvanize the world toward good are undermined by a natural tendency to pursue one's self interest in less volatile times: "The institutions of global governance and law that we know today have their roots in one of the darkest periods of human history. Their beginnings showed a mirror to the tragic flaw within the nature of humanity....the notion that there can be one or more particular characteristics of an individual, a group, a nation, or indeed institutions organized by humans that can eventually undermine their other good qualities and potentially threaten their existence. (*ibid.* at 1).

[768] Carlos Manuel Vazquez, "Trade Sanctions and Human Rights: Past, Present, and Future" (2004) 6(4) J. Int'l Econ. L. 797. See also UNC, Art. 2.4 "All Members shall refrain in their international relations from the threat or use of force against the territorial integrity or political independence of any state, or in any other manner inconsistent with the Purposes of the United Nations."

[769] Drawing on works of the prominent international human rights historian Paul Gordon Lauren *The Evolution of Human Rights, Visions Seen* (Philadelphia: University of Pennsylvania Press, 1998), Mendes & Mehmet, *supra* note 598 provide a detailed historical account.

[770] The meeting at Placentia Bay, Newfoundland was to discuss concerns over the growing threat of the axis of evil and Nazi Germany's aggression, mounting pressure for the US to assist the British in the war.

[771] Online, <http://www.ibiblio.org/pha/policy/1942/420101a.html>.

[772] Mendes & Mehmet, *supra* note 598 at 2.

[773] See Lauren, *supra* note 769 as cited in Mendes & Mehmet, *ibid.* at 2. Full text online: <http://www.un.org/aboutun/charter/>, signed 1945 and amended 1965, 1968, and 1973. See articles 62-72.

(UNC) at a more inclusive conference in 1945 in San Francisco.[774] In the post-war era, the commitment from the start was to *co-operate* in a mutually beneficial manner with a liberal commitment to "rights." Kirsten Hastrup writes that

> [r]ights are what unite us, as attributed to us by the global imagined community, glued together not by a sense of tradition and a shared past but by a hope for the future and a universal currency of rights....One could argue that the international legal language, including the language of rights, translates social, cultural and economic differences into 'linguistic' differences. In the process of producing a legitimate standardized language, sociologically and historically pertinent differences of various kinds are expressed in different *uses* of the same language and are evaluated accordingly. People will show more or less competence in expressing their rights within the idiom of international legal language, which now functions as the legitimate representation of a global moral economy.[775]

The Economic and Social Council was born under the UNC as the principal UN organ and was given a broad mandate pertaining to international economic, social, cultural, educational, health and related matters.[776] The 1948 Universal Declaration of Human Rights (UNDHR)[777] was the first international instrument which recognized "a common standard of achievement for all peoples and all nations"[778] without drawing any distinction of separateness or priority between civil and political rights (CPRs) and economic, cultural, and social rights (ECSRs). The UNDHR has served as the model for

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[774] Systemic inequities gave permanent membership and veto power to the "Great Powers" before the Security Council. Despite economic integration efforts, the emphasis "by the Great Powers at Dumbarton Oaks and in the period that followed was on national sovereignty, territorial integrity, and political independence, which meant non-interference in the[ir] domestic affairs..." Mendez & Mehmet, *ibid.* at 4.
[775] Hastrup, *supra* note 23 at 15. For a critical view, see Pierre-Marie Dupuy, "Some Reflections on Contemporary International Law and the Appeal to Universal Values" (2005) 16.1 EJIL 131-137.
[776] *Charter of the United Nations*, 26 June 1945, arts. 62-72, Can. T.S. 1945 No. 7.
[777] *Universal Declaration of Human Rights*, GA Res. 217(III), UN GAOR, 3d Sess., Supp. No. 13, UN Doc. A/810 (1948) [UNDHR], full text at http://www.unhchr.ch/udhr/lang/eng.htm. As a resolution of the UN General Assembly, it was not binding per se, but became the foundation for much of the later codified and customary international human rights law, and makes no distinction or priority between rights. The International Bill of Rights is comprised of the UNDHR, the ICESCR, the ICCPR and its optional protocols. The Human rights Committee charged with monitoring state compliance with the ICCPR decided in *Lubicon Lake Band v. Canada* (1990), Comm. No. 167/1984 that ICCPR (Article 27) protects the right of persons to engage *in economic and social activities* that are part of the *culture* of the community to which they belong. The expropriation of 10,000 square kilometers of land by the Alberta government for use by oil and gas interests violated Aboriginal group rights to engage in protected economic and cultural activities. But, at para. 32.1, the right of "peoples" to self-determination was considered non-justiciable.
[778] Hurst Hannum, "The UDHR in National and International Law" (1998) 3:2 *Health & Hum. Rts* 145.

codifying human rights protection in multilateral conventions including the *International Covenant on Civil and Political Rights* (ICCPR)[779] and the *International Covenant on Economic, Social and Cultural Rights* (ICESCR),[780] at least one of which most States are signatory to. Canada has ratified both covenants whereas the United States of America is one of only a handful of states to have ratified the ICCPR but not the ICESCR. Human rights (HR) are considered "birth rights"; in some contexts, human rights have reached optimal integration into state laws by virtue of being *constitutionalized*[781]- often serving as the foundation of liberal democracies.

While human rights recognize the equal entitlements of individuals as their subject, they do not assure equality amongst the rights recognized. The preamble to the UDHR provides "equal...rights of all members of the human family." Yet, some rights allow for *progressive realization,* limits, restrictions, and optional protocols or reservations, while others (such as political and civil rights proclaimed under the ICCPR) are more absolute and immediate. The fact that an internal hierarchy of rights may exist does not in any way diminish their solidarity or indivisibility.[782] CPRs are free and only

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[779] *International Covenant on Civil and Political Rights*, 19 December 1966, 999 U.N.TS. 171, Can. T.S. 1976 No. 47, 6 I.L.M. 368 (entered into force 23 March 1976, accession by Canada 19 May 1976), full text at http://www1.umn.edu/humanrts/instree/b3ccpr.htm [ICCPR]

[780] *International Covenant on Economic, Social and Cultural Rights*, GA Res. 2200A(XXI), UN GAOR, Supp. No. 16, UN Doc. A/6316 (1966), 993 U.N.T.S. 3 (entered into force 3 January 1976), full text at http://www.hrweb.org/legal/escr.html, [ICESCR].

[781] The paramountcy of civil and political rights is fundamental to any liberal democracy. Some advocate for the full recognition of socio-economic rights within that context but reject the view of a hierarchy. For a discussion of its potential and the challenges related to social and economic rights generally, see *Gosselin v. Quebec (Attorney General)* [2002] 4 S.C.R. 429, 2002 SCC 84 [*Gosselin* (SCC)] where the SCC rejected a s. 15 and s. 7 Charter challenge to a Quebec law excluding citizens less than 30 years of age from receiving social security benefits. The court proceeds to find four main problems with ESCRs. Since they are programmatic, they 1) do not provide for full benefits for those who participate in the program; (2) the design of the programs was not tailored in such a way as to ensure that there would always be programs available to those who want to participate; (3) the implementation of the programs present still more hurdles to overcome; (4) the government determines the availability of the program (*ibid.* at paras. 277-83).

[782] See discussion of Vienna Declaration and Program of Action, *infra* p. 285. Whether these rights are naturally derived inherent rights is contested in the literature. See *e.g.* J.P. Gardner, ed. *Human Rights as General Norms and A State's Right to Opt Out: Reservations and Objections to Human Rights*

require functioning political and infrastructural institutions for their realization. They are negative rights that exist independent of state action imposing obligations of non-interference on the state (the right to liberty requires state forbearance and restraint). ESCR, conversely, are considered costly rights that impose positive duties on the state to fulfill their welfare providing obligations to individuals (the right to education, food and health require state action for their delivery). These rights to (public) goods are captured by social democracies and the welfare states, such that "in essence...the classical liberty rights are concerned with processes, whereas welfare rights are concerned with outcomes."[783] ESCRs tend to be qualified by the availability of regulatory resources. Therefore, the ICESCR allows for their *progressive* implementation.[784] This distinction

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Conventions (London: British Institute of International and Comparative Law, 1997) [HR General]. Rosalyn Higgins writes, "[a]t the heart of it is the balance to be struck between the legitimate role of States to protect their sovereign interests [not to suppose that sovereign interests are necessarily inimical to the promotion of human rights] and the legitimate role of the treaty bodies to promote the effective guarantee of human rights". (*Ibid.*, introduction). See generally, Markus Schmidt, "Reservations to United Nations Human Rights Treaties- the Case of the Two Covenants" at 20-35; Catherine Redgwell, "The Law of Reservations in respect of Multilateral Conventions" at 2-30; Graham Hand, "Policy Aspects of Reservations and Objections to Human Rights Conventions" at 117-120; Jeremy McBride, "Reservations and Capacity of States to Implement Human Rights Treaties" at 120-185 (in HR General, *ibid.)*. The Human Rights Committee, General Comment 24(52), on issues relating to reservations made upon ratification or accession to the Covenant or the Optional Protocols or in relation to declarations under Article 41 of the Covenant, Un Doc. CCPR/C/21/Rev.1/Add.6 (1994) states under paragraph 1: "As of 1 November 1994, 46 of the 127 States parties to the International Covenant on Civil and Political Rights had, between them, entered 150 reservations of varying significance to their acceptance of the obligations of the Covenant....The number of reservations, their content and their scope may undermine the effective implementation of the Covenant and tend to weaken respect for the obligations of States Parties....[T]he Committee, in performance of its duties...must know whether a State is bound by a particular obligation or to what extent." John Rawls argued that a priority exists amongst HR in the *Law of Peoples*, supra note 18 at 80: "Human rights in the Law of the Peoples, by contrast, express a special class of *urgent rights*, such as freedom from slavery and serfdom, liberty (but not equal liberty) of conscience, and security of ethnic groups from mass murder and genocide. The violation of this class of rights is equally condemned by both reasonable liberal peoples and decent hierarchical peoples....Human rights set a necessary, though not sufficient standard for the decency of domestic political and social institutions. In doing so they limit admissible domestic law of societies in good standing in a reasonably just Society of Peoples." This narrow perspective is inconsistent with international texts confirming the indivisibility and interdependence of HR.

[783] David Kelley, *A Life of One's Own: Individual Rights and the Welfare State* (1998) in Henry Steiner and Philip Alston, eds., *International Human Rights In Context: Law, Politics, Morals,* 2d ed. (New York: Oxford University Press, 2000) at 258.

[784] Article 2.1 of the ICESCR, *supra* note 781 provides: "Each State Party to the present Covenant undertakes to take steps, individually and through international assistance and co-operation, especially economic and technical, *to the maximum of its available resources*, with a view to achieving progressively

was one reason for the adoption of separate legal instruments.[785] Another related reason was to allow states to assume only obligations which they were willing to undertake, recognizing that some protection would be better than none and alleviating criticisms that internationally mandated human rights protections were themselves a form of cultural imperialism. That there are two instruments is an artifact of the political economy at the time and does not detract from the normative interrelation of *all* human rights. As Eide and Rosas have argued, "fundamental needs should not be at the mercy of changing governmental policies and programmes, but should be defined as entitlements."[786]

The challenge with ESCRs is giving them *content* (how much food or health satisfy?) and thereby concrete legal relevance to make them justiciable. In fact, enforceability is a general issue. Although the 1948 UNDHR was adopted without a dissenting vote, its enforceability and legal status is an issue since "[a] Declaration of the General Assembly is not, by definition, legally binding though it has strong moral force."[787] Declarations, observations, guidelines, and certain international instruments are part of international soft law and thus not binding as part of current international law (*lex lata*), according to Freeman and Van Ert, but they may indicate what international law

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the full realization of the rights recognized in the present Covenant by all appropriate means, including particularly the adoption of legislative measures." See also related General Comment 3 contained in 5th Sess., art. 2, para. 1, UN Doc. E/1991/23 (1990) [ICESCR, General Comment 3].

[785] Draft International Covenant on Human Rights and Measures of Implementation: Future work of the Commission of Human Rights, General Assembly Res. 421 (V), UN GAOR, 5th Sess. (1950). In 1950, the General Assembly adopted a resolution emphasizing interdependence of all human rights and called on the UN Commission on Human Rights to adopt a single convention that would be legally binding on ratifying states. However, under the influence of Western States in the following year, the Commission reversed its decision and created the twin covenants.

[786] See Asbjørn Eide, Catarina Krause & Allan Rosas, eds., *Economic, Social and Cultural Rights: A Textbook* (Canada: Kluwer Academic Publishers, 1995) at 18.

[787] Rhona K.M Smith, *Textbook on International Human Rights*, (New York: Oxford University Press, 2003) at 39.

may or should become (*lex fernda).*[788] However, if the norms in the soft law are followed in state practice out of a sense of legal obligation (*opinio juris*) such that states do not generally feel free to disregard the norm then it may be elevated to customary international law and is thereby binding on all states, including non-signatory third parties, as a source of international law. The UNDHR is said to have achieved this status and is considered declaratory of binding customary law.[789] Similarly, many of the rights articulated in the UN Charter are so widely accepted that they now form part of the corpus of general principles of law although they have yet to mature fully into customary law.[790]

Most major UN HR treaties or their related protocols provide state undertakings to accept the oversight of specialized international supervisory committees (such as the HR Committee which monitors compliance with the ICCPR) known as treaty bodies in order to ensure compliance with treaty obligations- with the exception of the Committee on Economic, Social and Cultural rights which was established by ECOSOC under Resolution 1985/17 rather than by a treaty and monitors compliance with the ICESCR.[791]

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[788] Mark Freeman and Gibran Van Ert, *International Human Rights Law, Essentials of Canadian Law* (Toronto: Irwin Law, 2004) at 68.

[789] *Ibid.* at 68. See also Robert Howse and Makau Matua "Protecting Human Rights in a Global Economy: Challenges for the World Trade Organization" (2000) Rights and Democracy, online <http://www.dd-rd.ca/english/commdoc/publications/globalization/wtoRightsGlob.html>.

[790] Smith, *supra* note 787 at 39. See also Martti Koskenniemi, "The Pull of the Mainstrain" (1990) 88 Mich. L. Rev. 1946, in Steiner & Alston, *supra* note 799 at 78 writes: "The matter is particularly important in regard to norms intended to safeguard basic human rights... If the only states bound to respect such rights and freedoms are the states that have formally become parties to the relevant instruments- and even then only within the scope of their often compromised wordings and multiple reservations- then many important political values would seem to lack adequate protection.....Some norms seem so basic, so important, that it is more than slightly artificial to argue that states are legally bound to comply with them simply because there exists an agreement between them to that effect..."

[791] Art. 16 of the ICESCR, *supra* note 781 requires states to submit periodic reports to the UN Secretary General. Each body is comprised of state elected expert members and are responsible for four different procedures: (1) the review of periodic reports submitted by state parties; (2) investigation of systemic violations; (3) review of petitions filed by one state against another; and (4) and review of petition made by individuals against states parties. See Freeman and Van Ert, *supra* note 788 at 385.

Under the ICCPR, there is some provision for use of an inter-state complaint mechanism (under Art. 41, optional declaration) but none have been filed to date, and for individual complaint mechanisms (under ICCPR-OP1). Yet, neither the inter-state or individual complaints/petitions procedures are available internationally under the ICESCR.[792] Unlike customary international law which is automatically binding and like the common law needs no further domestic statutory incorporation, other international treaty norms including the ESCR, require domestic implementation (even by Canadian courts for example) in order to be justiciable; it is domestic law that provides for a legal remedy. Simply put, while civil and political rights can be enforced in international fora, you cannot enforce your social and economic rights such as the right to health in an international forum. Therefore for these rights, justiciability, the ability to have an international human rights claim judicially determined, relies on domestic mechanisms such as constitutional law and human rights legislation.

One approach is to incorporate ESCRs protection within domestic constitutional rights protecting civil and political liberties. The right to food and health, for example, may be subsumed within a right to life and security of the person.[793] Such an approach

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[792] Historically, only states had standing in international fora but due to changes in international law in the 20th century, non-state actors and individuals have acquired some limited international legal personality sufficient to maintain legal relations or enjoy rights or assume prescribed obligation. See generally Hugh M. Kindred et al., *International Law Chiefly as Interpreted and Applied in* Canada, 6th ed. (Canada: Emond Montegomery, 2000) c. 2 at 11-91.

[793] The ICCPRs can be applied to protect ESCRs reflecting an accepted interdependence between the twin instruments. See Bita Amani, "Patents, the *Charter,* and a Healthy Dose of Rights in Wrongs: *The Poison is the Elixir for Life, Liberty, and Security of the Person"*, U.N.B.L.J. [forthcoming, 2007], [Amani, "Patents & the Charter"] wherein I argue if the right to health has acquired constitutional status as a negative right subsumed within the s. 7 right to life and security of the person under the *Canadian Charter of Rights and Freedoms*, Part I of the *Constitution Act, 1982*, being Schedule B to the *Canada Act 1982* (U.K.), 1982, c. 11. as a result of *Jacques Chaoulli and George Zeliotis v. Quebec (Attorney General)*, [2005] 1 S.C.R. 731, 2005 SCC 35 [*Chaoulli*] and that a constitutional tort action may be lie against public authorities for harm related to the grant of gene patents. *Charter* damages, such as a declaration of patent invalidity, a moratorium on gene patents until further parliamentary action, or any other remedy possible under s. 24 of the *Charter* may be awarded.

reaffirms the indivisibility and interdependence of all human rights. Ideally, constitutional protection for ECSRs would be as express as civil and political rights and require *positive* baselines to be delivered by public authorities along with the negative freedoms and liberties. South Africa's 1996 Constitution, however, remains virtually alone in this approach.[794] In fact, Canadian governments have increasingly been criticized by the UN human rights bodies for failure to ensure the realization of social and economic rights for all Canadians: "in 1993 and 1998, the United Nations Committee on Economic, Social and Cultural Rights – which monitors Canada's compliance with its social and economic rights obligations- criticized Canada for its poor record of upholding these rights."[795] Although Canada continues to rank well, it did not fair much better in its May 2006 review. In its interim report, the Committee criticized Canada for:

> [t]he lack of legal redress available to individuals when governments fail to implement the Covenant [ESCR], resulting from the insufficient coverage in domestic legislation of economic, social and cultural rights, as spelled out in the Covenant; the lack of effective enforcement mechanisms for these rights; the practice of governments to urge upon their courts an interpretation of the Canadian Charter on Right and Freedoms [sic] denying protection of Covenant rights, and the inadequate availability of civil legal aid, particularly for economic, social, and cultural rights.[796]

Citizens cannot directly invoke human rights duties of their state in domestic legal forums, nor can they complain in international fora regarding their ESCRs; while the challenge is to encourage governments to give these rights some content, some

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[794] Constitution of the Republic of South Africa 1996, No. 108 of 1996. The 1996 South African Constitution expressly includes the right to education, an environment that is not harmful to human health or well-being, access to health care services, food, water, social security, and housing. For a comparative chart on constitutional protection of economic, cultural, and social rights, see online: Human Rights and Constitutional Rights < http://www.hrcr.org/chart/index.html>.

[795] The Centre for Equality Rights in Accommodation, online <http://www.equalityrights.org/cera/>.

[796] An advance unedited version of the UNCESR Review (May 1-19, 2006), future E/C.12/CAN/CO/5 is available online: <http://www.ohchr.org/english/bodies/cescr/docs/E.C.12.CAN.CO.5.pdf>, criticizing Canada for not doing enough to address social and economic rights such as food shortages, poverty, and homelessness as well as the absence of an official poverty line.

governments are simply ambivalent to do so[797] even though arguably, "...human rights most urgently need asserting and defending, both theoretically and practically, where they are most denied."[798] Without a mechanism for individuals to hold their governments accountable for the protection of their human rights, the rights pursuant to the ICESCR are no more than mere statements of aspiration.[799]

In Canada, just as there is a presumption that all domestic law will conform with our Constitution,[800] there is a presumption that Canadian law conforms with international treaty obligations such that even in the absence of domestic implementing legislation, "while a litigant may not be able to place direct reliance on a right guaranteed by a Canadian treaty obligation, she is permitted to raise that right and rely on it for the purposes of interpreting a domestic provision."[801] This presumably extends to patent law.

In other contexts, domestic implementing legislation may open the door for interpreting government measures to be compatible with international human rights obligations. K.D. Ewing, writing on the UK Human Rights Act of 1998, argues that if domestic legislation is incompatible with Convention rights a higher court is empowered under implementing legislation to declare incompatibility. However, the *duty* to *construe* legislation to comply with Convention rights is imposed on all courts. In addition, Ewing argues that the UK Act imposes an obligation on public authorities to comply with

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[797] The United States, for example, has not yet ratified the ICESCR and Canada although having ratified the ICESCR has not taken the additional step that the government of South Africa has to legislate these protections as positive rights within its Constitution, *supra* note 794.

[798] See David Beetham, "What Future for Economic and Social Rights" (1995) 43 Political Studies 41in Steiner & Alston, *supra* note 783 at 255. The author suggest that human rights advocates and proponents of development economics can find common ground "...on a minimum core of rights such as...the right to food of an adequate nutritional value, to clothing, to shelter, to basic (or primary) health care, clean water and sanitation..." (*ibid.* at 256).

[799] That is for practical reasons even though the ICESCR, General Comment 3, *supra* note 784 at para. 5 provides that: "Any suggestion that the provisions indicated are inherently non-self-executing would seem to be difficult to sustain."

[800] Peter Hogg, *Constitutional Law of Canada,* 3 ed., (Canada: Carswell, 1992) at 286.

[801] Freeman & Van Ert, *supra* note 788 at 350-1.

Convention rights and this obligation is directly enforceable in domestic courts. Summarizing the view of the Lord Chancellor, Ewing writes that the courts have a duty of acting compatibly with the convention not only in relation to cases involving public authorities but also in deciding cases between private citizens such that "Convention rights may be relied upon in litigation between private parties, but cannot themselves be the basis of a cause of action."[802] Rosemary Coombe echoes this position:

> The States' obligation to protect involve duties to prevent abuse of rights by third parties, including non-State actors, whereas obligations to fulfill involve active duties to take appropriate measures that create a framework for creating accountability.[803]

According to Ewing's and Coombe's analysis, these human rights, and their corresponding duties, could be raised as defence to domestic actions for patent infringement/validity proceedings between private parties and even in patent infringement actions against the government (e.g. Ontario, if it was sued by Myriad over BRCAnalysis). Extrapolating from these arguments, we see profound potential for our current study. Canada has allowed patents to issue on human genes and evidently these interfere with the realization of one's right to health under ICESCR. If constitutionalized, an individual could sue public authorities for measures in breach of her human rights but even without such express protection, such rights and their corresponding duties could be, according to Ewing's and Coombe's analysis, raised as defence to domestic patent infringement cases between private parties, against the government (e.g. Ontario), and also, I argue in the next chapter, as a defence to WTO trade complaints. Such an interpretation is consistent with Article 28 of the Universal Declaration on Human Rights confirming that:

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[802] See K.D. Ewing, "The Human Rights Act and Parliamentary Democracy" (1999) 62 Mod. L. Rev. 79 in Steiner & Alston, *supra* note 799 at 1010.
[803] Coombe, "IP, HR & Sovereignty", *supra* note 54 at 68.

> *[e]veryone is entitled to a social and international order in which the rights and freedoms set forth in this Declaration can be fully realized.*[804]

Article 28 creates a duty on governments to ensure that the "social" and "international" order allow for the articulated rights (including social, economic, and cultural ones under Arts. 25-27), meaning that international legal obligations must be reconciled coherently. Moreover, if human rights, indivisible and interdependent as they are, have achieved the status of customary law, the entire TRIPS Agreement may be a nullity. Rather than pursue this line of inquiry, a more conciliatory approach to resolving potential human rights conflicts would be to interpret the permission creating norms in Article 27 of TRIPS and the Article 8 Principles in a manner consistent with diverse regulatory policies and measures undertaken to fulfill human rights obligations. This would allow "that such rights can increasingly be justiciable and amenable to individual petition and complaint."[805] Freeman and Van Ert are quick to point out: "the relative ease or difficulty of implementation of any right or category of right has no bearing on the moral, legal, or political value of that right. A right is not accorded greater or lesser priority based on the degree of intervention or restraint required."[806]

The case by case and defensive nature of invoking international human rights obligations in domestic litigation, however, makes it less than ideal for affecting patent policy changes as well as protecting the underlying human right on a population basis. Of course, there are good reasons for governments to prioritize industrial and trade policy over health policy- to date, the risk of liability in domestic and international law as well as the simple cost of defending a patent infringement action was sufficient incentive-

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[804] UNDHR, *supra* note 777.
[805] Beetham, *supra* note 798 at 256.
[806] Freeman & Van Ert, *supra* note 788 at 33.

especially since there are no similar costs associated for disregarding the individual's human rights. The provision of *Charter* remedies would serve, however, as a basis for policy change, would address concerns expressed by the Review Committee, and would be consistent with Canada's obligations under Article 6 of the UN Declaration on the Right to Development which provides:

> All human rights and fundamental freedoms are indivisible and interdependent; equal attention and urgent consideration should be given to the implementation, promotion and protection of civil, political, economic, social and cultural rights. [807]

Also, the Preamble to the ICESCR mirrors that of the ICCPR, and both provide that

> the ideal of free human beings enjoying freedom from fear and want can only be achieved if *conditions are created whereby everyone may enjoy his economic, social and cultural rights as well as his civil and political rights.*[808]

All human rights are fundamental to a life of human *dignity*, inalienable and interrelated and dependent on the state for their realization, "with the net effect that the breach of one will affect the realization of another."[809] The preamble of the UNDHR declares "recognition of the *inherent dignity*...of all members of the human family" as "the foundation of freedom, justice and peace in the world...." The preamble preserves the primacy of individual human rights and complements the objectives of economic international organizations. The preambles of the ICCPR and ICESCR similarly decree that human rights "derive from *inherent dignity*, a divinity of the human person."[810] Protecting the *dignity* of the person is the essence of the living culture of our birth rights; as the common denominator for humanity, it transcends yet informs all other cultures.

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[807] 1986 GA res. 41/128.
[808] ICESCR, *supra* note 781.
[809] Rhona K.M. Smith & Christien van den Anker, eds., *The Essentials of Human Rights* (London: Hodder Arnold, 2006) at 37; Freeman & Van ert, *supra* note 788 at 37; See also Amyrta Sen, *Poverty and Famines: An Essay on Entitlement and Deprivation* (Oxford: Clarendon Press, 1981) observing that no substantial famine in the last fifty years has occurred in a state with a democratic form of government and free press.
[810] Yet, the scholarly literature is ripe with contested foundational theories. See J. Donnelly, *Universal Human Rights in Theory and Practice,* 2d ed. (Ithaca: Cornell University Press, 2003) 13-21.

The Vienna Declaration and Program of Action 1993 (Vienna Declaration)[811] is the most recent universal document recognizing diversity amidst universalizing ambitions. It confirms the universality, indivisibility, interdependence, and interrelation of all human rights and obviates former distinctions amongst the two Covenants, reiterating the duty of the state in Article 5:

> *All human rights are universal, indivisible and interdependent and interrelated.* The international community must treat human rights globally in a fair and equal manner, on the same footing, and with the same emphasis. While the significance of national and regional particularities and various historical, cultural and religious backgrounds must be borne in mind, it is the *duty of States, regardless of political, economic and cultural systems, to promote and protect all human rights and fundamental freedoms.*[812]

Protections for ECSRs are integral to the operations of the welfare state. Civil and political rights impose obligations through the state on all other human beings for their respect. Welfare rights impose obligations on the state for the attainment of basic necessities of life but so far as implementation is through government programs, the obligation is distributed to all taxpayers.[813] Kelley writes that to protect liberty rights of individuals, governments are under a duty to prevent incursions by other individuals whereas the implementation of welfare rights requires a much more activist government in terms of large-scale transfer programs, social safety nets, and other means of transfer. However, in order to retain a conceptual operational understanding that coherently reconciles *all* HR, we can recast welfare rights, although reducing the entitlements they confer, to at least *negative* rights which oblige states to *refrain from interference* in their realization, in the tradition of classic liberalism's "freedom from". Rather than determine

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[811] *Vienna Declaration And Program of Action*, World Conference on Human Rights, Vienna, 14-25 June 1993, UN Doc. GA/CONF.157/23 (1993). Report of the Conference, GA/Conf. 157/24 July 12, 1993.
[812] Available online: < http://www.unhchr.ch>. See also Article 6 of the *Declaration on the Right to Development*, GA Res. 41/128, annex, 41 UN GAOR, Supp. No. 53 at 186, UN Doc. A//41/53 (1986) which provides that states should co-operate towards these ends, and should "eliminate obstacles to development resulting from failure to observe civil and political rights, as well as economic social and cultural rights." (Article 6.3).
[813] Kelley, *supra* note 783 at 258.

what is the appropriate amount of food, or welfare, or health that must be delivered to fulfill its obligation, ECSRs as negative rights would require at a minimum that the state avoid implementing strict IPRs that would interfere with the individual's self-realization and fulfillment of her rights. But for state created IPRs, individuals would be fully *free* to use the knowledge as a public good; the right to do so may in fact be a human right as the analysis in the next section of this chapter will support. In short, the universal minimums of TRIPS should not be implemented in a manner that violates the universal minimums of human rights obligations. Current IPRs as institutional instruments of the state create private monopolies on genetic resources that directly affect plant varieties, food varieties, nutraceuticals and human health and thereby *violate* a state's *negative duty* owed (a duty of forbearance) not to interfere with the ICESCR rights. The universal declaration of these rights creates legal entitlements making them "less amenable to trade offs in the face of competing claims and interests."[814] Because it is with justice that human rights are concerned, ESCRs as negative rights removes the definitional limitations impeding governmental delivery and paves the way for accommodating cultural, economic, and developmental differences of a state in relation to its own peoples, making the culture of

[814] Freeman &t Van Ert, *supra* note 788 at 27. The Committee on Economic, Social and Cultural rights, charged as the authoritative interpreter of the ICESCR, has "provided specific guidance on how to implement the general and potentially conflicting responsibilities of States Parties." See Weissbrodt and Schoff, *infra* note 822 at 4. They add, "The Committee has declared that States Parties have a 'minimum core obligation to ensure the satisfaction of, at the very least, minimum essential levels of each of the rights.' In particular, the Committee "emphasize[d] that any intellectual property regime that makes it more difficult for a State party to comply with its core obligations in relation to health, food, [or] education...is inconsistent with the legally binding obligations of the State party.'" *Ibid.* citing General Comment No. 3, 5th Sess., para. 10 (1990), *The Nature of States Parties Obligations (Art. 2, par. 1 of the Covenant)* at para. 10 and *Substantive Issues Arising in the Implementation of the International Covenant on Economic, Social and Cultural Rights*, Economic and Social Council, Committee on Economic, Social and Cultural Rights, 27th Sess., Agenda item 3, para. 12, 17-18, U.N. Doc. E.C. 12/2001/15 (2001).

human rights more functional.[815] It is the first step towards the *progressive* realization of rights and remains morally imperative for distributional justice.[816]

The quasi-constitutional values successfully exported into the UN system's protection of human rights, a complementary institutional mechanism to, and consistent with, the GATT/WTO were devised in part to prevent the grave violations suffered by individuals at times of war and to ensure that the utilitarian principles (whether for improving aggregate social welfare through trade liberalization, for ensuring the security of territorial boundaries during times of war, or creating incentives for new innovation) did not compromise individual liberties. The "public interest" requires, at some level, the equal protection of the interest of the individuals that comprise its "public" in order to be meaningful. So, even in a welfare state or the kind of deliberative democracy envisaged in classic civic republicanism, individual liberties have, at least notionally, always triumphed and these liberties are increasingly required to fully accommodate ECSRs. Conversely, universal standards in IPRs deny and denigrate the civil libertarian protection that is to safeguard the individual interest from utilitarian claims of the common good by granting property rights that entitle holders the right not just to *use* but to *exclude*. Consequently, IPRs raise an interesting paradox in that they espouse the individualism of liberal rights rhetoric, impinge on a differing set of individuated (human) rights, and yet

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[815] This would include the presence of cultural and group rights that may be indispensable to the realization of individual rights. No person is completely a separate atomistic entity from their social context. According to Michael Ignatieff, "[i]ndividual rights without collective rights may be difficult to exercise, but collective rights without individual ones end up in tyranny" at 89-90, "Human Rights as Politics and Idolatry" in A. Gutman, (ed) *Human Rights as Politics and Idolatry* (Princeton University Press, 2001).

[816] Kristen Hastrup writes, "[t]he international community agrees surprisingly well across differences in local culture, belief, language and metaphysics on the demands for justice and mutual benevolence, and universal standards of rights that are increasingly specific are put forward and subscribed to as part of the international legal instrumentalization....few would openly question the basic assumption that they can further justice between people. In that sense, the universal declarations of human rights have come to represent a 'common good', something we should actively strive to realize on a global scale. They have taken root in the collective imagination of the natural order." *Supra* note 23 at 9.

are most commonly theoretically accepted for their utilitarian functionality. The problem is that despite the conceptual strangeness of IPRs, because of theoretical rights-based rhetoric used to justify their governmentality, there are those who assert that IPRs are themselves *human rights.* Next we will explore this contention and what such a claim would mean before dealing with the nexus of IPRs with *other* human rights under the ICESCR. We do this for two important reasons: first, it will eliminate the discussion of patenting life as a dialogue of *competing human rights* and thereby avoid the need to establish a just and equitable means of prioritizing amongst what are indivisible rights. Second, it will provide us with a greater understanding of the kind of intellectual right that *is* provided under human rights instruments- one which is consistent with a public domain or alternatively, a liberally defined commons that is inclusive of all of humanity.

5.4.1 Human Rights Dimensions of IP

Proponents of intellectual property may argue that IPRs are human rights pursuant to Article 15(1)(c) of the ICESCR which recognizes the right of everyone "to benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is author."[817] Article 27.2 of the UNDHR was its obvious predecessor.[818] There are two important restrictions however in recognizing IP as a natural human right. First, as a human right, fundamental to their enjoyment is that the holder of such rights be "human". While self-identification with a particular group or collective may mean that some human rights may be based on a collective identity (such as the right to one's religion, to practice one's culture), the individual

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[817] ICESCR, *supra* note 780.

[818] "Everyone has the right to the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author." UNDHR, *supra* note 777.

human is an essential dimension for these rights. Article 1 of the UNDHR asserts that "[a]ll human beings are *born* free and equal in *dignity* and *rights.*"[819]

Regardless of any legal fictions putatively impregnating domestic understandings of the corporation as "person", the essential matter remains that *that* person is *not* human. This is why on the U.S. patent application the *named* inventor must be an actual person even if the rights are assigned to a corporation.[820] But, even if IP can be *held* and owned by corporations, only humans could claim it is a *human right* - such as individuals who individually or as a member of a cultural community (on the basis of a cultural right) contest the private appropriation of traditional knowledge vis-à-vis a patent over, for example, turmeric as a stomach malady remedy to the exclusion of the original indigenous community from whom this knowledge was appropriated.[821] Article 15 ICESCR provides insight into the content of that right:

Article 15
1. The States Parties to the present Covenant recognize the right of everyone:
(a) To take part in *cultural life*;
(b) To *enjoy the benefits* of scientific progress and its applications;
(c) To benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author.
2. The steps to be taken by the States Parties to the present Covenant to achieve the full realization of this right shall include those necessary for the conservation, the *development and the diffusion* of science and culture.
3. The States Parties to the present Covenant undertake to respect the freedom indispensable for scientific research and *creative activity*.
4. The States Parties to the present Covenant recognize the benefits to be derived from the encouragement and development of international contacts and co-operation in the scientific and cultural fields.

This brings me to a second point: taken in the context of the other provisions in Article 15, Article 15(1)(c) does *not* confer a right of *exclusion,* or "property", or the

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[819] The presence of both words suggests that the two have different meanings but are complementary concepts; that is respect for rights promotes respect for dignity and vice versa.
[820] See Howard M. Eisenberg, "Patent Law You Can Use: Reading of a Patent" 2000, explaining the parts of the application, online <http://yale.edu/ocr/invent_guidelines/docs/reading_patent1_cover.pdf>. See also footnote 709, *supra* and accompanying text.
[821] Dutfield, *IPRs, Trade & Biodiversity, supra* note 22.

related market value based on the labour of 'authorship'- all matters of social policy-[822] but a right of *participation* and *access* consistent with the ideals of open sharing in science (supported by Article 15.3 and 15.4), to take part in cultural life and creative activity (Art. 15.1(b) and 15.3) and concomitant with the idea of a collective commons in which we may or may not locate (communal) property. To demonstrate, let us imagine that the concept of IPRs was captured with different rhetoric that did not centrally rely on exclusion or the idea of "property". For example, let us call this creature "information contribution and enjoyment rights" (ICERs). Termed this way, one has the right (a claim) to be able to *participate* in contributing to the information commons as a personal right rather than a *proprietary* claim to the products of that creative contribution once made, as is suggested under the rhetoric of intellectual "property rights" deconstructed in Chapter 2. This is not only a sound interpretation of the international human rights instruments, but is consistent with the institutionalist approach to patent legislation also adopted by the UN[823] Secretary General's Report, which recognized that such legislation,

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[822] See Hettinger, *supar* note 39. No doubt, it is the exclusivity of IPRs that has lead to the view that these rights are fundamentally in conflict with other human rights. See *e.g.* Intellectual Property Rights and Human Rights, Res. 2000/7, UN. ESCOR Comm'n on Hum. Rts, Sub.-Comm'n on the Promotion and Protection of Human Rights, 52nd Sess., UN Doc. E/CN.4/sub.2/Res/2000/7 providing: "actual or potential conflicts exist between the implementation of the TRIPS and the realization of economic, social and cultural rights." See also David Weissbrodt and Kell Schoff, "Human Rights Approach to Intellectual Property Protection: The Genesis and Application of Sub-Commission Resolution 2000/7" (2003) 5 Minn. Intell. Prop. Rev. 1, online: http://mipr.umn.edu/archive/v5n1/Weissbrodt.pdf. The authors discuss the significant influencing role this resolution had leading into Doha and the adoption of the declaration on public health at the Ministerial meeting.

[823] See *The Role of Patents in the Transfer of Technology to Developing Countries*, GA Res. 1935 (XVIII), UN GAOR, 18th Sess. (1963) 28, *Report of the Secretary - General, United Nations* (New York: Martinus Nijhoff, 1964) recognized that the Secretary General's task, as per a General Assembly resolution, to examine the national patent systems of a number of different jurisdictions could not be completed in time for this General Assembly due to the breadth of geographic and substantive coverage. Online, <http://daccessdds.un.org/doc/RESOLUTION/GEN/NR0/186/10/IMG/NR018610.pdf?OpenElement>. In "The Progressive Development of the Law of International Trade: Report of the Secretary General of the United Nations, 1966", it was reported that "[s]ince 1961 the United Nations General Assembly has had before it the problem of the role of industrial property legislation in facilitating the transfer of patented and

> [h]as never been based solely on the concept of the patent as the confirmation of an inherent rather than the creation of a statutory property right. Such a concept would have left no room for such restraints on the patent grants as its fixed duration, its exclusion for inventions in certain fields...and the forfeiture or compulsory licensing of patents for failure to work them.[824]

Consequently, while IPRs are appropriately refuted as human rights, our re-conception of the international provisions is marked by a notable absence of *exclusive* rights while allowing for a human right of access, a human right of use, creativity (including arguably auto-creativity), and enjoyment which may or may not be communal or cultural. Under Article 27.1 of the UNDHR, "everyone has the right freely to participate in the cultural life of the community, to enjoy the arts and to share in scientific advancement and its benefits." This is because intellectual products are social products located within a cultural context related, as the scientific paradigm reveals, to the mountain of preceding intellectual contributions as well as innovation supporting institutions and infrastructure (including those for public health and education).[825] In fact, the right to participate is integral for some individual's (i.e. scientists, academic researchers etc) right to work provided under Article 23 of the UNDHR.[826] Moreover, Article 12(b) of the Universal Declaration on the Human Genome and Human Rights (HGHRD) provides that

> [f]reedom of research, which is necessary for the progress of knowledge, is part of freedom of thought. The applications of research, including applications in biology, genetics, and medicine, concerning the human genome, shall seek to offer relief from suffering and improve the health of individuals and humankind as a whole.[827]

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unpatented technological and managerial know-how to developing countries. At its sixteenth session, the General Assembly adopted resolution 1713 (XVI) on the role of patents in the transfer of technology to underdeveloped countries, in which it requested the Secretary-General to study the issues involved, including specifically, the effects of patents on the economy of developing countries; patent legislation in selected developed and developing countries; and the characteristics of the patent legislation of developing countries in the light of economic development objectives." In addition, "the study emphasized, *inter alia*, that *properly adapted* patent legislation was essential if the patent system was to be beneficial to economic development and advancement of industry in developing countries." Online: LexMercatoria.org <http://www.jus.uio.no/lm/un.sg.report.itl.development.1966/doc.html>.

[824] *The Role of Patents, ibid.* at 9.

[825] See *e.g.* Martin, *supra* note 90.

[826] UNDHR, *supra* note 777.

[827] See also *supra* note 186 and in text discussion at page 71.

The real threat to human (natural) rights, cultural rights, and the scientific information commons posed by the property rights conception of IPRs is, according to Drahos and Braithwaite, to *liberty*:

> [T]he greater danger of intellectual property lies in the threat to liberty. When a group of scientists stop working on a protein molecule because there are too many intellectual property rights that surround the use of the molecule, a basic freedom, the freedom to research, has been interfered with. The liberty cost of intellectual property rights may seem remote because most of us do not carry out research on proteins. But we all have an interest in seeing public research programmes into diseases and health research being carried out. We want...public researchers to continue working on the genes for breast and ovarian cancer and helping to develop cheaper, more effective clinical tests...Companies are entitled to protect their treatment for disease but not, through use of their patents, to deter or prevent others from access to genes which are linked to the origins of disease.[828]

The reciprocal relationship between knowledge, liberty, and culture has long been appreciated. Founding fathers of modern political thought, such as Thomas Jefferson and Adam Smith, stressed the importance of education, knowledge and freedom of information, now underscored by Brian Martin:

> culture- which makes ideas possible- is built not just on intellectual contributions but also on practical and material contributions, including the rearing of families and construction of buildings. Intellectual property is theft, sometimes in part from an individual creator, but always from society as a whole.[829]

This is reaffirmed by the UN Educational Scientific and Cultural Organization. Under its Constitution, UNESCO provides that "the wide diffusion of culture, and the education of humanity for justice and liberty and peace are indispensable to the *dignity* of man and constitute a sacred *duty* which all the nations must fulfill in a spirit of mutual assistance and concern."[830] The Constitution adds:

> the States Parties to this Constitution, believing in full and equal opportunities for education for all, in the unrestricted pursuit of objective truth, and in the *free* exchange of ideas and knowledge, are agreed and determined to develop and to increase the means of communication between their peoples and to employ these means for the purposes of mutual understanding and a truer and more perfect knowledge of each other's lives; In consequence whereof they do hereby create the United Nations Educational, Scientific and Cultural Organization for the purpose of advancing, through the educational and scientific and cultural relations of the peoples of the world, the objectives of

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[828] Drahos & Braithwaite, *supra* note 7 at 3. See discussion of Wisconsin's stem cell patent, *supra* note 573.
[829] Martin, *supra* note 90, Chapter 3: Against Intellectual Property, at 55.
[830] Constitution of the UNESCO, *supra* note 187.

> international peace and of the common welfare of mankind for which the United Nations Organization was established and which its Charter proclaims.[831]

Articles 13-19 of the HGHRD establishing the conditions for the exercise of scientific activity places the responsibility of regulating human genomic research and its ethical and social implications on the public and private science policy-makers (Article 13) as well as "measures to foster the intellectual and material conditions favourable to freedom in the conduct of research on the human genome and to consider the ethical, legal, social and economic implications of such research, on the basis of the principles set out in this Declaration."[832] Article 15 deals directly with the nexus of access to genetic information with public health and human dignity:

> States should take appropriate steps to provide the framework for the free exercise of research on the human genome with due regard for the principles set out in this Declaration in order to safeguard respect for human rights, fundamental freedoms and human *dignity* and to *protect public health.* They should seek to ensure that research results are not used for non-peaceful purposes.[833]

It is the responsibility of the state to ensure that these declarations are realized. According to Article 18, states

> should make *every effort,* with due and appropriate regard for the principles set out in this Declaration, to continue fostering the international dissemination of scientific knowledge concerning the human genome, human diversity and genetic research and, in that regard, to foster scientific and cultural co-operation, particularly between industrialized and developing countries.

Rhetoric is crucial, but how does one get beyond rhetoric that effectively converts discretionary crown privileges related to the introduction of new industry and labour through imports into meaning "IPR" resulting in exclusion and ultimately to meaning liberty-restricting property, legally defined as a right in content, tenuously abstracted - or perhaps more accurately *extracted* in the genomic context - from the "intellectual"?

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[831] *Ibid.*
[832] Article 14, HGHRD, *supra* note 186.
[833] *Ibid.*

The effect of emphasizing the *propertization,* rather than the *creative contribution* of the individual has led to what Drahos and Braithwaite label "information feudalism": modernity's new distributional inequality transforming the relations of production through the search for new property acquisitions (like land holdings) ever present as biogopolies.[834] If patents do continue to issue in the field of genomics, a very generous research exemption should be legislated into domestic legislation to signal the recognition of the 'information contribution and enjoyment right' provided as a human right in Article 15 of the ICESCR. This imposes no cost on regulatory governments for their realization and only requires state forebearance much like the related right to liberty does. Moreover, the very rights that biotechnology promises to advance, discussed with greater detail next, may be endangered by modern patent law and practice which, for distributional reasons, threaten to expand the "genetic divide" in the interest of developed countries and their TNCs. The Bogève Declaration warns: "any new technology introduced into a society which is not, by its nature, a 'just' society will exacerbate the gap between rich and poor."[835] Biotechnology does this by affecting a range of human rights of all peoples but disparately so for those in poor and developing countries who suffer disproportionate burdens of disease.

5.4.2 The Right to Health, Food, Benefit from Scientific Progress & Farmer's Rights

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[834] Drahos and Braithwaite assert that "all of the prior institutional projects of world history, conceived narrowly for our purposes as projects to redistribute property unequally, have important surviving features today. They are never fully supplanted. So too with information feudalism. It will certainly not supplant industrial and financial capitalism, or the persistent residues of colonialism, or the king's power to tax centrally, or serfdom and slavery, or patriarchy.... [Information feudalism] contributes another layer of inequality." Drahos & Braithwaite, *supra* note 7 at 199.

[835] Online: ETC group <http://www.etcgroup.org/key_defs.asp>. Bogève Declaration (1987) "The Socioeconomic Impact of New Biotechnologies on Basic Health and Agriculture in the Third World." Declaration resulting from a meeting of twenty-eight civil society organizations from 19 countries in Bogeve, France, 7-12 March 1987.

Policies in some sectors, such as the regulation of industry, innovation, commerce, and the economy, may create tensions and potential unintended effects in other fields, such as the promotion of individual and population health. In addition to income, there are other non-income measures of poverty (such as health) that are affected by stronger IPR protection and, at once, aggravated by them. The HIV/AIDS pandemic in Africa, and countries such as Botswana and Zimbabwe where one in four adults is infected, means that AIDS orphans compound the poverty problem, in turn threatening civil and political security and stability and revealing the integrated relationship of social and economic with political and civil rights. Human health is polycentric, comprised of exigent social and political dimensions contemporaneous with and yet external to the insular solutions offered by technology and medical science.[836] The prevalent conception of health in western industrialized societies has traditionally been fragmented and *medicalized*, ignoring the social conditions contributing to it (such as poverty, dislocation, and unemployment). Similarly, food was sought for hunger or comfort.[837] In other parts of the world, where foods are used as preventative or alternative medicines,

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[836] A House of Commons Standing Committee on Foreign Affairs and International Trade report issued in June 2003 calls on the federal government to respond to the crisis in sub-Saharan Africa by tripling its current contributions to the Global Fund Fight AIDS, Tuberculosis and Malaria and to make access to medicines in poor countries a priority in its negotiating position within multilateral trade organizations. The Committee recognized that the AIDS programs "need to reflect the fact that in many African countries, HIV/AIDS is inextricably linked with other issues, including food shortages and famine, armed conflict and political violence, and problems of governance. See *HIV/AIDS and the Humanitarian Crisis in Sub-Saharan Africa.* House of Commons Standing Committee on Foreign Affairs and International Trade, June 2003, online at the Parliament of Canada website at www.parl.gc.ca (Substantive Reports of Committees).

[837] This paradigm has begun to shift in Western societies in the last ten years. See the population health programme of the Canadian Institute for Advanced Research (CIAR) and related publications considering social environmental factors affecting health care. See also R.G. Evans, M.L. Barer, and T.R. Marmor, *Why are some people healthy and others not? The determinants of health of populations.* (New York: Aldine de Gruyter, 1994) and Monica Townson, *Health and Wealth: How Social and Economic Factors are Affecting our Well Being"* (Canada: Canadian Center for Policy Alternatives, 1999).

peoples have long espoused a holistic approach to health[838] now embraced by the World Health Organization (WHO), a specialized agency of the UN established in 1948 for the attainment of the *highest available standard* of health for all people.

WHO recognizes human health is integral to the "happiness, harmonious relations and security of all peoples" and therefore defines health holistically in its Constitution as "a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity."[839] WHO also stresses the importance of state responsibility for ensuring the protection of health, the need for state co-operation because of the global public goods quality of health which creates positive spillover effects for the rest of the world, and the essential right of each individual for the full realization of the *highest available standard* without discrimination based on the ability to pay ("economic or social condition"). While the right to food is separately protected as a human right, because of the inclusive health definition, it may be subsumed in the right to health. Article 25 of the 1948 UNDHR reflects the confluence of health and food rights by recognizing these in the "standard of living":

> Everyone has the right to a standard of living adequate for the health and well being of himself and of his family, including food, clothing, housing and medical care and necessary social services...[840]

Implicit in this definition is the idea that a minimum standard is essential for a life of dignity. The ICESCR, on the other hand, gives the right to food and the right to health distinct recognition and adds a positive obligation on states to co-operate to ensure that

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[838] The two Indian cases that characterized the "no patents on life" campaign against the American researchers and corporations asserting patent rights were over Indian turmeric and the neem tree. The cases deal with the medicinal use of food and the desire to appropriate these uses, the traditional knowledge that they embody, to the potential exclusion of the very communities from which they are taken. See Emily Marden, "The Neem Tree Patent: International Conflict over the commodification of Life" (Spring 1999) 22 *Boston College Environmental Affairs Law Review* 279. See also the "Turmeric Example" in chapter 6.
[839] See World Health Constitution, Preamble, online <http://www.who.int/about/en/>.
[840] *Supra* note 777.

these human rights are met by making full use of scientific knowledge and safeguarding its access. Article 11 of the ICESCR recognizes the

> right of everyone to an adequate standard of living for himself and his family, including adequate food...and to the continuous improvement of living conditions...[841][and] recognizing the fundamental rights of everyone to be free from hunger, [State Parties] *shall* take, individually and through *international co-operation*, the *measures*...needed ...[t]o *improve* methods of production, conservation and distribution of food by *making full use* of technical and scientific knowledge, by disseminating knowledge of the principles of nutrition....[842]

There is a growing market for R&D investment in "functional foods" and "nutraceuticals" which enhance the nutritional and therapeutic value of foods (typically plants) or provide some resistance bearing qualities for cultivation (such as GM Maize). This convergence of food/medicine obviates traditional distinctions while simultaneously encouraging massive mergers of food processors, agrobiotech firms and drug companies on the basis of mutual interests in food, biotechnology, and pharmaceuticals, creating what IP scholars refer to as "biogopolies":

> Within those [Northern countries], the introduction also of patent protection for genetic resources has resulted in the concentration of agricultural biotechnologies in a few northern corporations ("biogopolies"). The effect of this concentration in restricting the number of seed producers, may be to restrict the number of seed varieties available to farmers, as those corporations focus upon the marketing of blockbuster seeds. Thus, it is suggested that in planting elite varieties, which have market acceptance, farmers, particularly in traditional areas, neglect the land-races and farmers' varieties which have acted as reservoirs of genetic diversity.[843]

These changes in the agricultural production industry also affect human rights in more implicit ways. Human rights advocates contend that agrarian communities, their lifestyles, right to work, culture and way of life are being destroyed by globalization and the hegemony of property as dislocated farmers migrate to the nearest urban centres and are replaced by large corporate agribusiness in the rural landscape. The mass migration exacerbates conditions of poverty and unemployment in some of these third world

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[841] "[P]arties will take appropriate steps to ensure the realization of this right, recognizing to this effect the essential importance of international co-operation based on free consent." ICESCR, *supra* note 780.
[842] See ICESR, *supra* note 780.
[843] Michael Blakeney, "Stimulating Agricultural Innovation" draft paper presented at Duke IPG, *supra* note 244 at 10. See also Drahos & Braithwaite, supra note 7, chap. 13 on this new form of inequality.

communities. Evidence suggests terminator technology may be depriving farmers of their traditional right to preserve and replant seeds each year from the prior year's crop. Patents have a similar effect in so far as farmer's traditional rights to save seeds for future harvests are restrained and farmers may now even find themselves to be accidental infringers.[844] Because of these concerns, the non-governmental organization Rural Advancement Foundation International (RAFI), now the ETC Group (Action Group on Erosion, Technology, and Concentration), mobilized on behalf of civil society with a mass mailing to one hundred and forty countries' senior officials responsible for agriculture, environment, and patent offices imploring their states to assert national sovereignty over their seed supply and to ban seed sterilization technology outright.[845] Where farmers do stay on the land, they are increasingly reduced to labourers toiling the land- losing control over their means of production and becoming ever dependent on companies to supply seeds, fertilizers, and chemicals, most of which require heavy licencing fee payments. Some HR advocates assert that the proper forum to address farmer's rights would be under the right to food. A 1999 Economic and Social Council (ECOSOC) study on the Right to Food submitted to the Commission of Human Rights urged that farmer's rights be promoted as part of the right to food since the future of our food supply may depend on it.[846] NGOs and farmer's agree, asserting that "food security

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[844] The controversy caused by terminator technology impeding the ability of farmers to continue their practice of saving seed for next year's crops and the efficacy of this technology in enforcing existing intellectual property protection is discussed in Jeremy P. Oczek, "In the Aftermath of the "Terminator" Technology Controversy: Intellectual Property Protections for Genetically Engineered Seeds and the Right to Save and Replant Seed" 41 B.C.L 627. See also discussion of *Monsanto* in Chapter 4.

[845] See "Call for 'Seed Sovereignty Ban' on Terminator Patents" May 29, 1999, online: The ETC Group < http://www.etcgroup.org/documents/news_callfor.pdf.

[846] See Crucible II Group, *Seeding Solutions, supra* note 2 at 76.

cannot be achieved without taking full account of those who produce food."[847] Additionally, the Committee on ESCRs also addressed the relationship between food, poverty, and dignity, affirming that the

> right to adequate food is indivisibly linked to the *inherent dignity of the human person* and is indispensable for the fulfillment of other human rights enshrined in the International Bill of Human Rights. It is inseparable from social justice, requiring the adoption of appropriate economic, environmental and social policies, at both the national and international levels, oriented to the eradication of poverty and the fulfillment of all human rights for all. [848]

For thousands of years farmers have been cultivating seeds, breeding new varieties, saving and exchanging them to advance the best crop producing seeds for food. Farmers have rallied to protest the erosion of their customary human rights[849] by MNCs with their drive for greater privatization under plant variety protection legislation, *sui generis* regimes or patents with strict (criminal) enforcement provisions.[850] Farmers, and their growing group of supporters, criticize governments for not doing enough to protect biodiversity, seed sovereignty and food sovereignty when faced with trade pressures:

> The Indian Government, bowing to World Bank and W.T.O. pressures, is pushing through laws such as patents on plants and plant variety legislation that allow private monopoly over seed. Multinational corporations have already taken out patents on basmati and other rice varieties, corn, cotton, mustard, and other agricultural crops. Corporations like W.R. Grace have taken out patents on neem, and others have patents on turmeric, ginger, pepper, jeera, karela, jamun, brinjal, and other gifts of biodiversity.[851]

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[847] Cia Campesna "The Right to Produce and Access to Land" http://www.voiceoftheturtle.org/library/1996%20Declaration%20of%20Food%20Sovereignty.pdf.

[848] See General Comment 12, The Right to Adequate Food, May 12, 1999, E/C.12/1999/5. The Committee observes that "a disturbing gap still exists between the standards set in Article 11...and the situation prevailing in many parts of the world. More than 840 million people throughout the world, most of them in developing countries, are chronically hungry; millions of people are suffering from famine as the result of natural disasters, the increasing incidence of civil strife and wars in some regions and the use of food as a political weapon." It should be noted that general comments by the Committee on ESCRs are "authoritative interpretations of the relevant international human rights law..." See Peter Prove and Miloon Kothari, "Human Rights Bodies Gear Up on TRIPs" 1 *Bridges* Comment, 13-14, online <http://www.iprsonline.org/ictsd/docs/ProveKothariBridgesYear4N6JulyAugust2000.pdf#search=%22peter%20prove%20miloon%22>.

[849] Martin Khor, "A worldwide fight against biopiracy and patents on life" *Third World Resurgence* No. 63 November 1995, 9-11. Special issues on patenting life: No. 57 (May 1995) and No. 84 (August 1997).

[850] Farmers protests predate TRIPS, See "Indian Farmers Rally Against Gatt, Bio-Patents" (4 October 1993) online <http://www.sunsonline.org/trade/areas/intellec/10040093.htm>. More recently, Navdanya, Bija Swaraj, online <http://www.navdanya.org/earthdcracy/seed/bija_swaraj.htm>.

[851] Bija Swaraj, *ibid.*

At the same time, giving seed patents to first world corporations ignores the work of farmers as historical creators, locating authorship in corporate investment by differentiating the "other" creative claims of farmers and rural communities in preserving traditional knowledge and biodiversity; ignored is the work of *cultures* in developing plants that thrive in specific geographic areas and under certain climatic conditions, culturally appropriate for consumption.[852] Part of the concern is that the corporate impetus towards profit will steer traditional plant variety production (through natural cross-breeding) towards inter-species genetic modification resulting in ever increasing GMO seeds that may eventually takeover the entire market (either through contamination of "pure" crops or through selective breeding out of traditional varieties) and thereby gradually erode consumer ability to chose "organic" or "GM free".[853] Not only is this a claim related to preserving biodiversity (and access to it) but also a matter of risk, risk assessment, and risk tolerance, given the uncertainties of the potential health implications of consuming inter-species manipulated plants, animals, and products and the possibility of cross-contamination of farmer's fields.[854] A contemporaneous debate has been launched on the use of the precautionary principle to refuse importing GM goods against the reductionist claims of science.[855]

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[852] Vandana Shiva, "Seeds of Discontent" (1997) online, http://www.organicconsumers.org/vandana.html.
[853] For Don Westfall, Vice President of the biotech consulting company Promar International, this may be a deliberate strategy: "the hope of the industry is that over time the market is so flooded [with GM food products] that there is nothing you can do about it. You just sort of surrender." See Stuart Laidlaw, "Starlink fallout could cost billions" Toronto Star, January 9, 2001 discussing the ramifications of failure to get drug approval for human consumption of StarlLink corn engineered to repel pests, made by drug and agriculture giant Avantis, on the basis that the GM corn could cause allergic reactions. But traces of the GM corn were found in over 300 different brands of taco shells that were recalled. See Julia Vorman, "Recall Climbs to Over 300 Different Items" http://www.organicconsumers.org/ge/starlink300.cfm.
[854] See Amicus Curiae Brief, WT/DS/291, 292, 293 http://www.ciel.org/Publications/ECBiotech_AmicusBrief_2June04.pdf
[855] The debate transcends national politics into the world of international trade. International NGO Greenpeace reports that already several countries (Poland, Germany, Austria, Greece, Luxembourg, France, and Hungry) have bans on GMOs and that recent events show resistance towards removing such bans

> On Friday 24, June [2006], EU members states inflicted a severe defeat to the Commission by voting down eight proposals aimed at forcing the lifting of national bans on the growing of certain genetically modified organisms (GMOs)...[I]t is the first time that the qualified majority necessary for governments to turn down a Commission's proposal is gathered. As many as 22 out of 25 member states voted against the lifting of national bans...These vote results mark a historic turning point in the debate on genetically modified food and crops in Europe....For Greenpeace, the clear majorities against the bans show that it is time for the EU executive to listen to the 80% of the public who are opposed to GMOs...[and] learn from this lesson and stop hiding behind technocratic procedures and confidential expertise to try and force GMOs into European fields.[856]

One news report headlined: "New EU States Block Monsanto- Twice."[857] Helke Ferrie welcomes this as an overdue resurrection: "the nation state is returning: people in rich and poor countries demand that governments act in the public interest."[858] And, as we know, although TRIPS requires that patents be available for all technology, imposing regulatory requirements outside of the patent system for the commercialization and exploitation of new technology is both Paris and TRIPS-consistent.[859]

Since farmer's in the North/West are heavily subsidized by government (one of the sticking points in the Doha Round for developing countries who want greater access

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under pressure from the United States, Canada, and Argentina under threat of WTO trade sanctions. See European Communities- Measures Affecting the Approval and Marketing of Biotech Products, WT/DS/291, 292, 293. The US complains of national safeguard clauses and against the European Commission's failure to have them lifted. The Panel in the interim ruling published February 2006 expressed views against the national bans but accepted that if these bans provided a risk assessment in conformity with the SPS agreement, then they would be justifiable. See *e.g.* Pennapa Hongthong, "Thai and Asian Farmer's Rally Against Frankenfood", online: <http://www.organicconsumers.org/ge/asianmarch.cfm>. See also Bita Amani, "Protection, Precaution, Pragmatism: Taking a GATT Look at the International Regulation of GMOs" on file with the author. The final Panel Report was circulated September 29, 2006 but has yet to be adopted by the DSB. The report concludes that scientific studies were offered by some banning states, "in no case did they provide an assessment of the risks to human health and/or environment meeting the requirements of the *SPS Agreement*." At page 1069, para. 8.10. It is available online along with a history, at: <http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds291_e.htm>.

[856] See Greenpeace, "Background briefing: National bans on GMOs", July 25, 2006, online: Greenpeace, <http://www.greenpeace.eu/downloads/gmo/NationalBans0507.pdf>.

[857] See Biotech Mailout, "New EU States Block Monsanto- Twice", July 2004, online: Friends of the Earth Europe, <http://www.foeeurope.org/publications/2004/Biotech_July04.pdf>.

[858] Helke Ferrie, "Thought for Food: Biotech under siege as European Nations Ban GM food", July 29, 2006, online: Straight Goods, < http://list.web.net/archives/food-news/2006-August/000063.html>.

[859] Randy Haillier, President of the Ontario Landowner's Association, however, believes farmers are disempowered by overregulation: [f]armers also sold out their future and freedom by accepting government regulations that dictate every use and activity on the farm. Farmers unknowingly surrendered themselves to a mild form of slavery, and have become slaves in the truest sense of the word. They are slaves to their farm groups and to the corporate monopolies that control them, and are caged by the regulations of safety and security. Slaves are never self-reliant, free, nor prosperous." "Sowing Socialist Seeds and Expecting a Harvest of Free Enterprise" July 16, 2006, online <http://www.quebecoislibre.org/06/060716-5.html>.

to developed markets in agricultural products), the public is again indirectly paying through tax dollars to subsidize mostly foreign (American) patent holders, like Monsanto, for the licences imposed on local agriculturalists only then to subsidize these same domestic agricultural producers- again adversely redistributing costs across the public. DCs and LDCs lose out twice: first because they are typically not IP creators and second because their agricultural industry will have greater difficulty competing in foreign markets with their subsidized counterparts in those markets. Here, the imposition of seed IPRs perpetuates cycles of poverty by imposing corporate imperatives on individuals in a manner that compromises human rights. The "poverty-health nexus is so strong that poor health keeps poor [sic] in absolute poverty and poverty pushes them in poor health status."[860] According to Brian Martin, if the "scale of such protests could be combined with other actions that undermine the legitimacy of intellectual property, the entire system could be challenged."[861]

The concern over distributive justice is integrated into HR instruments which focus on improving aggregate welfare through the protection of individual rights. The right to share in scientific progress under Article 27.1 of the UDHR and Article 15 of the ICESCR are articulated means of ensuring distributive justice. Article 15.2 imposes an obligation on states to take steps to achieve the full realization of this right, including "those necessary for the conservation, the development and the diffusion of science and culture." Moreover, Article 27.3 uses the language of "freedom" and "liberties" similar to the ICCPR and obligates states to "undertake to respect the freedom indispensable for

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[860] N.K. Nayak, "Imperatives of Global Health Law for the 21st Century" in R.K. Nayak, Chief ed., *Global Health Law: Proceedings, selected papers and recommendations presented at the Inter-disciplinary International Conference on Global Health Law Held December 5-7, 1997* (New Dehli: Indian Law Institute and the World Health Organization, 1998).

[861] Martin, *supra* note 90 at 53

scientific research and *creative activity.*"[862] Patent laws, *prima facie* are intrusions for the period of the patent term on this conception of scientific freedom and the ability of farmer's to engage in creative activity by saving, exchanging, planting, and cross-breeding seeds without securing a licence. They impede the direction of future research not just in medicine but also in food supplies through the creation of monopolies. As corporations and publicly funded researchers become more intimate bedfellows through the privatization of science, basic research will be diverted to areas that maximize commercial viability.[863] Michael Blakeney finds that

> [t]he market dominance of these private corporations also has an important influence upon the sort of biotechnological research which is undertaken. For example, it has been suggested that the dominance of private corporations in agricultural research direct that research towards Northern concerns and away from Southern food priorities.[864]

Who will safeguard the public's interest? How, in the presence of such limitations on medicine and food, will peoples have their rights to the *highest attainable standards of physical and mental health*, set out under Article 12(1) of the ICESCR, realized?[865]

For a system based on public health, cost of delivery is a significant determinant of the number of people who can receive the needed medical health intervention, whether governments are willing to undertake obligations for population health and public health genomics programs, and therefore the direction of policy formation and the ability of a state to meet its international human rights obligations optimally. Patent incentives, in so

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[862] ICESCR, *supra* note 780. See also Beetham, *supra* note 798 at 247.

[863] "As more and more researchers have one foot in academia and one foot in the industry, the lure of profits threatens to diminish scientific integrity in the biosciences." See Shand, *supra* note 143 at 233.

[864] Blakeney, *supra* note 282 at 10 referring J.P. Alston, G. Pardey, and J. Rosenboom. "Financing Agricultural Research: International Investment Patterns and Policy Perspectives" (1998) 26 *World Development* 1045.

[865] The provision reads: *The States Parties to the present Covenant recognize the right of <u>everyone</u> to the enjoyment of the <u>highest</u> <u>attainable</u> standard of physical and mental health.* ICESCR, *supra* note 780. It also obligates States to take steps necessary for *the full realization of this right* [which] *shall include*...the improvement of all aspects of environmental...hygiene..., [t]he prevention, treatment and control of epidemic, endemic, occupational and other diseases...[and] the creation of conditions which would assure to *all medical services and medical attention* in the event of sickness." *Ibid,* emphasis added.

far as they exist, may be important to promote new drugs, vaccines, and with genomics, prevention-based interventions and in this regard they can be said to serve a social and public health purpose.[866] But as the foregoing chapters reveal, there is ample evidence that a proper *balance* has not been struck nor that the system is operating efficiently; particularly in light of practices that seek to increase *ex post* rewards. Ancillary costs include barriers to the delivery of public health, effective cross-policy co-ordination, efficient allocation of resources, and the ability of a state to respond to the priorities of its constituents, meaning that despite biotech's promises, avowed by industry stakeholders to secure their investments, patents mean that society may not be able to afford the technological gains efficiently and certainly not *universally* nor at the *highest attainable standard* for each person despite the assurance under Articles 12 and 15.1(b) of ICESCR.

The biotech industry generated 1.1 billion in sales in 1997, half of which came from health care products according to a March 2001 report prepared for the Canadian Biotech Advisory Committee (CBAC).[867] Statistics Canada reports that Canada's biotechnology sector generated nearly $2 billion in revenues by 1999, $718 million of which was generated from exports. It was expected to exceed $5 billion in revenues in 2002.[868] The health sector continues to be the primary beneficiary of, and therefore is the most affected by biotechnology according to the June 2002 CBAC report: "more than 90 percent of the advanced biotechnology products on the world market are related to health. It is expected that about three-quarters of global biotechnology demand will continue to

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[866] This is the World Health's Position in its joint report with the WTO Secretariat; see "WTO Agreements & Public Health", *supra* note 636.

[867] See the Project Steering Committee on IP and the Patenting of Higher Life Forms, available online: CBAC Non-Government Organization Hearing on IP, online http://cbac-cccb.ca for this and other reports. Specifically, see the Canadian Biotechnology Advisory Committee (CBAC), Biotechnology and Intellectual Property: Patenting Life Forms and Related Issues (Interim Report) (Ottawa: Canadian Biotechnology Advisory Committee, November 2001).

[868] *Harvard SCC, supra* note 185, para. 16.

be in this area."[869] The social value of new innovations is undermined by the market value that is tied to their protection under letters patent. Recall the BRCA1/2 example. While an estimated 22,200 women will be diagnosed with breast cancer in 2006 and 5,300 die,[870] several provinces continue to be threatened of domestic infringement litigation by MGL. Breast cancer is the most frequently diagnosed and one of the most treatable cancers amongst Canadian women and the Cancer Society posits that deaths could be reduced further by one quarter if only 70% of women in this age group had routine clinical breast exams and biannual screening.[871] That means a population health approach to screening may become important in the future and more likely a prospect if the diagnostics and screening were readily available at marginal cost without being subject to the royalty demands of patent holders. Sometimes chronic diseases appear with genetic mutation variants affecting specific racial populations or genders.[872] If the circumstances merit, a population health approach to public health genomics may be necessary in this context too. The larger the target group, the more significant the impact of IPRs' costs.

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[869] Patenting of Higher Life Forms and Related Issues. (Ottawa: Canadian Biotechnology Advisory Committee, June 2002), CBAC, *supra* note 867 at 2.

[870] Canadian Breast Cancer Foundation, "Media Backgrounder: Canadian Cancer Statistics- Screening: Breast, colorectal, and cervical" April 11, 2006.

[871] Genevieve Beauchemin "More screening can cut cancer deaths: report" CTV report, http://sympaticomsn.ctv.ca/servlet/ArticleNews/story/CTVNews/20060411/cancer_screening_060411. See also Canadian Breast Cancer Foundation, http://www.cbcf.org/news/events.html#erin

[872] For example the Mediterranean variant is the prominent genotype (>83%) for G6PD deficiency in a newborn screening study. See I. Khneisser et. al. "G6PD Newborn Screening: Incidence of Neonatal Jaundice among Cases of G6PD Deficiency with the Mediterranean Variant", Poster Presentation at *Public Health and Genomics, supra* note 309. See also Nadja Kanellopoulou, "Pharmacogenomics and Racially-Targeted Drugs: A Marriage of Inconvenience?" Poster Presentation discussing population based genomic research leading to a "more refined understanding of ethnic and racial differences in drug response" and the controversy surrounding BiDil, the first drug approved by the US Food and Drug Administration to target a specific racial group (the first "ethnic drug"), for heart disease.

The tensions between patents and human rights are not new, however, as is evinced by the longstanding debate around patented medicines, generic drugs[873] and compulsory licences, the patentability of methods of medical treatment,[874] and the patentability of food.[875] Canada's exclusions have usually occurred without moral conflict. In the early part of the 20th century, Canada issued patents only for new *processes* for making foods or medicines which were subject to low royalty rates due to compulsory licensing. Food and medicinal *products* were not themselves patentable.[876] A prosperous generic drug industry resulted. However, David Vaver reminds us,

> [u]nder pressure from the U.S. pharmaceutical drug industry and its proxies in the U.S. government, this system was entirely dismantled between 1987 and 1993. Product patents for medicine and food are now granted, compulsory licensing is gone, and a Patented Medicine Prices Review Board monitors patented medicines for "excessive" prices...Overall prices are

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[873] Jonathan Putnam argues that patents are consistent with health policy; see "The Price We Pay for Drug Research" *Innovate Magazine* Spring 2004, 26-28, online: CILP, <www.innovationlaw.org>. Putnam observes that "[p]erhaps more than any other consumer purchase, the acquisition of health-related products and services is governed by norms and expectations that challenge the usual market allocation mechanism. Nowhere is that challenge mounted with greater official backing than in Canada, where universal health is a basic right...That is why intelligent policy making towards the development of new drugs rests on a kind of economic jujitsu: if one is to reach a public end, one must deflect private means in that direction".

[874] A common law exclusion arising from *Tennessee Eastman Co. et. al. v. Commissioner of Patents* (1974), S.C.R. 111 where the Commissioner of patents refused to grant a patent for a surgical method of applying specified new uses for known compounds to bond the surfaces of incisions or wounds in living animals. The Canadian position is articulated in the industry manual. See s. 16.04(b) of the Manual of Patent Office Practice (MOPOP) advises that "[s]ubject matter related to a process of surgery or therapy on living humans or animals is not considered to be within the scope of "invention" as defined by section 2 of the patent Act....Claims which could encompass both medical and non-medical methods are not patentable. Methods of testing which do not relate to any step of surgery or therapy or vital function of the body may be patentable. Articles or apparatus designed for use in the treatment of humans or animals are patentable, provided they conform to all other conditions of the Patent Act." Section 16.04 of the MOPOP also provides that plants, animals and seeds are not patentable subject matter.

[875] See s. 41 of the CPA, now repealed, as discussed in *Harvard* SCC, to explain the former exclusions of food or medicine from patentability. See also the discussion of this provision in Kevles, *supra* note 425 at 4: "urban Americans probably tended, like Europeans, to think of food as a scarce resource and to be reluctant to grant anyone a monopoly right over food products, even for a limited period."

[876] Section 41(1) of the Patent Act R.S.C. 1970, c. P-4; amended R.S.C. 1970, c.10 (2nd Supp.), s. 65, provided that "in the case of inventions relating to substances prepared or produced by chemical processes and intended for food or medicine, the specification shall not include claims for the substance itself, except when prepared or produced by the methods or processes of manufacture particularly described and claimed or by their obvious chemical equivalents." Subsections (3) and (4) dealt with licences in relation to food and medicine respectively. The section has been repealed in its entirety.

> nevertheless higher than when compulsory licensing was in full swing, thus creating one more problem for Canada's embattled health care system.[877]

More recently, the pendulum has begun to swing back. The tireless efforts of non-governmental organizations (NGOs) to increase access to patented medicines and generic drugs for the poor in both first and third world countries has been rewarded by amplified international attention to these issues. In Canada, the patent-human right controversy was (re)-politicized with the review of patent legislation and subsequent statutory amendment to allow the manufacture of generic pharmaceuticals for export to developing countries[878] whereby the hitherto industry appropriated spaces were reclaimed. But what has been omitted from the process is a full scale parliamentary review of the issues surrounding the patenting of life debate, a subset of the patent-human rights conflict, and recommendations for a legislated response to maximize benefits and minimize costs.[879]

When calculating harm and the cost/benefit of granting gene patents, the welfare loss is not limited to an underutilized technology but also the knowledge of the patient and the public that a possible measure exists but costs too much to access optimally.[880]

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[877] Vaver, *IPPL, supra* note 34 at 127. For a discussion of food security concerns, see Geoff Tansey, "Food Security, Biotechnology and Intellectual Property: Unpacking some issues around TRIPS" July 2002, online <http://www.geneva.quno.info/>. For a discussion of essential medicines, see Frederick Abbott, "The TRIPS Agreement, Access to Medicines & the WTO Doha Ministerial Conference" (2001) 5 J. of World Intellectual Property 15, online: < http://www.geneva.quno.info/> [Abbott, "Access to Medicines"].

[878] See CPA, *supra* note 82, under heading *Use of Patents for International Humanitarian Purposes to Address Public Health Problems* (ss. 21.01- 21.20) as implemented by 2004, c. 23, s. 1. This brought into force the *Jean Chrétien Pledge to Africa, Canada* Bill C-9, *An Act to amend the Patent Act and the Food and Drugs Act,* 3d Sess., 37th Parl., 2004, online <http://www.parl.gc.ca/PDF/37/3/parlbus/chambus/house/bills/government/C-9_2.PDF>. See also General Council's statement on the then draft Decision contained in document IP/C/W/405 to implement paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, on which Bill C-9 was based, online http://www.wto.org/english/news_e/news03_e/trips_stat_28aug03_e. (August 30, 2003).

[879] See the final recommendations of the Canadian Biotech Advisory Committee in their Report "Patenting of Higher Life Forms and Related Issues" (Report to the Government of Canada Biotechnology Ministerial Coordinating Committee, June 2002).

[880] There are other forms of welfare loss as well. See *e.g.* Trudo Lemmens, "'What About Your Genes?' Ethical, Legal, and Policy Dimensions of Genetics in the Workplace" *Politics and the Life Sciences* 16, 1 (March, 1997), 57-75.

And, if the system of health is a blend of private and public,[881] then the ability for some to pay for a licence and genetic testing *outside* of the public system threatens to widen the *genetic divide* as only the rich will be able to afford the licencing fee. If funded publicly, then the propriety of higher health delivery costs, distributed over the broader tax paying public should also be publicly debated through democratic processes since as a matter of simple arithmetic, a government can afford proportionately less testing for cancer-related genes and public health genomics if each test costs approximately five times more under licence from the patentee than without permission. Governments may become reluctant to undertake such screening routinely for fear that such intervention would create a standard of care that they may subsequently be unable to meet due to licencing fees even despite vast potential benefits from a public policy perspective.[882] For example, population based molecular testing of infants for deafness as well as familial forms of cancer, and nutritional genomics that look at how dietary intake interacts with one's genotype to influence health and disease, can have an important long-term cost reducing consequence for health delivery.

Patents also contribute to delays and wait times in testing, impacting further domestic health policy. MGL's exclusive rights to BRCAnalysis empowered it to demand that *all* testing proceed through them or a licenced lab. This raises complicated issues of sovereignty. Similar conditions were imposed in France such that samples had to be sent out of the country to MGL labs in the United States over which there were no

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[881] The Supreme Court of Canada in *Jacques Chaoulli and George Zeliotis v. the Attorney Generals of Quebec and Canada.* [2005] SCC 35, decided that legislation preventing privately insured services harmed human health and was an unjustified violation of the section 7 constitutional right to life, liberty, and security of the person. See discussion of case in Amani, "Patents & the *Charter" supra* note 794.

[882] See Emmanuelle Rial-Sebbag, "Genetics and State Intervention in France: New Powers" Poster Presentation at *Genomics and Public Health, supra* note 872 regarding state failure to prevent harm where the genetic knowledge and technology exist.

French regulatory oversight or control. In addition, researchers complained that they could not continue to test or develop alternative improved methods for testing because of the gene patent, undermining one of the main rationales for granting patents and making it difficult to scientifically validate the test. The B.C. Cancer Agency performed some 600 tests but MGL's cease and desist letters effectively forced the B.C. government to discontinue its testing, favouring the rights of the patentee, for approximately 2 years during which 150 female cancer patients were advised of Ontario's research study and transferred there for testing free of charge (although in alleged patent violation). Approximately 30 more elected to have the testing done by Myriad Genetic Laboratories.[883] Should a monopoly on the invention confer a monopoly on knowledge or health? TRIPS Article 8 (articulating overarching *principles*) does not require it and actually protects against it.[884] Adopting national or regional health policy based on fear of litigation or a WTO complaint and redirecting cancer screening patients to labs *outside* of the province within whose jurisdiction these patients fall is *not* a sound basis for regulatory governance. Although B.C. resumed testing in 2003, BC Cancer Agency reports that there is now a one year waiting list for counseling with 300 families waiting for testing.[885]

The Canadian Cancer Society (CCS) opposes the exclusive rights of gene patent holders if they are used to interfere with an individual's health. After the MGL scandal,

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[883] "Genetic Testing Resumes at B.C. Cancer Agency", 23/02/14, http://search.phsa.ca/cgi-bin/MsmGo.exe?grab_id=0&page_id=1377&query=myriad&hiword=myriad%20.

[884] Amani, "Patents and Public Health", *supra* note 352 at 89.

[885] "Genetic Testing Resumes at B.C. Cancer Agency", *supra* note 883. See Institut Curie, "Breast and Ovarian Cancer Susceptibility Gene BRCA1:Another Victory for Opponents of Patents Held by Myriad Genetics: European Patent Office Rejects the Essential Points of BRCA1 Gene Patents" (Press Release, January 31, 2005), <http://www.curie.fr/upload/presse/myriadpatents310105.pdf> In November 2004, Myriad Diagnostics sold its BRCA patents to the University of Utah Research Foundation but continues to hold exclusive licences.

they recommend that gene patents not be used in a manner restricting the development of knowledge about genes, or health, or limiting the access of Canadians to cancer-related genomic testing.[886] Through all of this, Ontario brazenly continued its testing supported by then provincial, now federal, Health Minister Tony Clement. Mindful of the limited resources and the duty on his government to respond to the health needs of its constituents, Tony Clement, along with then Premier of Ontario Mike Harris, consistently defended the position of the Ontario government to continue with the diagnostic screening for BRCA1 and BRCA2.[887] Because the patent belonged to a foreign firm, the event left lawyers, health policy analysts, and the broader public asking whether these actions were legal under domestic law and whether any illegality would invite scrutiny by the WTO. IP lawyers and academics knew that Canada could be sued domestically for patent infringement just as trade law specialists knew that Canada could be held accountable before the WTO for a violation of its international obligations under a TRIPS trade dispute if MGL successfully lobbies its US Trade Representative to bring the complaint.[888] Human rights scholars and public health practitioners, however, seemed more interested in a basic governance question: to what extent should patent law dictate or supersede public health policy (which is at the heart of the patents-human rights

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[886] http://www.cancer.ca/ccs/internet/standard/0,3182,3172_31282995__langId-en,00.html.

[887] For a comprehensive overview of the BRCA1/2 controversy in Canada, See Canadian Cancer Society and National Cancer Institute of Canada Position on the Patenting of BRCA1/2 Genes, http://www.ncic.cancer.ca/vgn/images/portal/cit_86751114/11/12/89486356postionstatements_BRCA1A_en.pdf.

[888] TRIPS was modeled on similar provisions in the North American Free Trade Agreement (NAFTA, Chapter 17) which provides a high level of IPR protection, mandating that parties to the agreement provide adequate and effective measures to protect and enforce IPR without the measures themselves becoming barriers to legitimate trade (Article 1701). A complainant party to both TRIPS and NAFTA may elect under which to proceed but typically the WTO/GATT system is preferred because of its formal rules based procedure, appellate review, and the fact that decisions are effective automatically; consensus adoption is unnecessary. This thesis only refers to TRIPS provisions. See discussion of liability under chapters 5 and 6.

debate)? Would answers to these questions explain the vast disconnect between domestic patent law and the failure to exercise available nuanced responses?

The controversy emphasizes that human health is complicated and requires a multifaceted approach by provincial and federal governments as the former are responsible for health policy and delivery and the latter for industrial policy. The BRCA1 example demonstrates the difficult and practical issues of policy and regulatory co-ordination, jurisdictional and regulatory conflict, and costs for domestic governments across ministries and to Canadian taxpayers. According to the Annual Report of the Canadian Institute for Health Information (CIFI), health care spending in Canada exceeded $120 billion in 2003.[889] The more private enterprise is subsidized for public scientific efforts already underway and therefore not in need of "incentives", the less available funds for other important government initiatives.

Patents on life, from BRCA1/2 genes to the treatment of AIDS,[890] for the genetic sequence for meningitis,[891] or SARS virus, and over GM vitamin A rice affect the full

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[889] Canadian Institute Health Information (CIHI) Annual Report 2003-2004, online: CIHI <http://secure.cihi.ca/cihiweb/dispPage.jsp?cw_page=GR_1131_E> as cited in Tony Clement "Just What the Doctor Ordered?" *Innovate* at 22: "further analysis showed that health expenditures represented 10% of Canada's GDP in 2003, matching the all time high reached in 1992 and keeping Canada 4th among comparable OECD countries...[indicating that] in Canada there are too many health care demands chasing too few public resources. It is not, however, a case of too few dollars; quite the opposite. Indeed the CIHI's report makes it clear that public and private investments in health care represent more of Canadian's tax dollars and discretionary income....The key question becomes whether health expenditures pass the test of being sustainable, accountable and accessible."

[890] Nelfinavir is an AIDS treatment drug patented by the Swiss pharmaceutical giant Roche. Putting the HR to health first, Brazil's Health Minister, Jose Serra has asked the public health lab to make a generic version which will reduce costs by 40%. The United States recently abandoned the TRIPS complaint it launched. See "Brazil to break AIDS Patent" http://news.bbc.co.uk/hi/english/business/newsid_1505000/1505163.stm

[891] Human Genome Science (HGS), an American company rival to Celera Genomics, has applied to the European Patent Office to patent one of the bacteria that causes meningitis that could lead to a demand for payment of royalties on every future treatment if a new meningitis vaccine is found. HGS strives to be the first to own the whole genetic sequence of bacteria. See http://lists.essential.org/1998/pharm-policy/msg00045.html. HGS boasts that it holds over 200 genomic patents. Under relaxed utility guidelines in the United States, HGS patented CCR5 even though they did not know nor disclosed of its application at the time. Later, another company discovered its utility as the entryway for the AIDS virus to

realization of a number of human rights from the most general right to sovereignty and self-determination, to more specific rights such as the human right to health and food, both of which share a special relationship with poverty, dignity, and development by raising the costs and efficiency of a population health approach to public health. The greatest potential for genomics is its use in preventative population-based medicine. And while incentives are necessary to promote the technology, what incentives and how much must remain public policy issues for regulatory governments consistent with the institutionalists' understanding of patents because these instruments need to be weighed and balanced against other public policy objectives of a state to ensure the public welfare benefiting rationale of granting patents is not undermined by proprietary impediments to governance. Most importantly, the ability to form coherent national public regulatory responses for disease control, vaccination,[892] pre-implantation, and newborn and adult screening programs for genetic susceptibility to hereditary based diseases for population health all require discretion to prioritize these, when framed in terms of human rights obligations, over trade obligations[893] not only because the economics would be prohibitive otherwise or that ethics require it, but also because the formation of policy and direction of research rely on it. The Bellagio Report, "Genome-based Research and Population Health" provides,

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infect cells but as a result of the prior patent, HGS is entitled to royalties on any drug that targets this protein even though HGS was not involved in inventing or even "discovering" its industrial application. See Pollak, A. (2000) "U.S Hopes to Stem Rush Toward Patenting of Genes," New York Times 6-28 (http://www.nytimes.com/library/national/science/062800sci-genome-patents.html

[892] Vaccination may be affected by patenting of genetic microorganisms or viruses as well as the imposition of patented plant derived vaccines. For a relationship between IPRS and vaccines, see WHO "Intellectual Property Rights and Vaccines in Developing Countries" 2004 http://www.who.int/intellectualproperty/events/vaccines_meeting/en/. See also Karen Lynn Durrell, *supra* note 258.

[893] The difference between genetics and genomics is that genetics is conceived of in traditional terms of Mendelian single gene disorders or mutations with high disease risk and possibly some environmental interaction whereas genomics is much broader in the literature, treating genetics as information to be applied to everything from research tools to biomarkers, and requiring a focus on utility of gene research.

> the human genome is not the only one of relevance to human health. Our genome interacts with those of a myriad other organisms, including plants and microbes, both in maintaining a healthy body function and in many disease processes. An understanding of pathogen genomes, in particular, is elucidating the molecular and cellular processes of infection and of the variation in human susceptibility to infectious diseases. We need, too, to emphasize the importance of human genetic/genomic diversity as a valuable resource for the human species.[894]

The WHO's Constitution encourages co-operation to ensure optimal health globally, recognizing the positive and negative externalities of human health. The Constitution provides:

> The health of all peoples is fundamental to the attainment of peace and security and is dependent *upon the fullest co-operation of individuals and States.* The achievement of any State in the promotion and protection of health is a value to all. Unequal development in different countries in the promotion of health and control of disease, especially communicable disease, is a common danger.[895]

WHO's co-operation ethic to maximize health through the agency of the state is sensible given the fact that individuals are first and foremost citizens of a state while simultaneously citizens of the world, mobile as the infectious diseases that plague them. The 2003 SARS "epidemic" taught us this.[896] It will be interesting to see how development of targeted treatments will be undertaken as well as national responses the next time given that various teams of scientists claim to have patented or all parts of the SARS virus; some arguing they have done so "defensively" to deny private profiteers from foreclosing liberal access and use.[897]

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[894] See Report of an expert workshop held at the Rockefeller Foundation Study and Conference Centre, Bellagio, Italy, 14-20 April 2005 [Bellagio Report] at 6.
[895] Emphasis added.
[896] SARS stands for Severe Acute Respiratory Syndrome. See Clifford Kraus, The SARS Epidemic: Canada; Toronto Officials Seek End to Travel Advisory, New York Times, April 29, 2003.
[897] See "Patent Applications for SARS Virus and Genes" May 29, 2003. http://www.who.int/ethics/topics/sars_patents/en/. WHO's position on the SARS patent is to monitor its use to ensure that collaboration of health professionals, infectious disease control and the realization of the right to health are not hampered. WHO does not formally oppose defensive patenting. When I contacted the BC CancerAgency, I was advised that the agency was the first to sequence the genetic make-up of the SARS virus and has applied for a patent in order to deny private proprietors from doing so- this is an alternative to publication espoused by the HGP.

Not surprisingly, the patent-health relationship is central to a number of important studies in jurisdictions grappling to devise better strategies for health and industrial management.[898] A recent study commissioned by the Department of Health (DOH) in the United Kingdom[899] examined the issue of whether there is a risk in the health sector that biotechnological IPRs may generate disproportionate claims from right-holders creating unacceptable barriers, impeding the delivery of healthcare, and thwarting the generation of health care products. The health department in commissioning the report recognized the growing importance that IPRs play in the UK health sector and thus adopted an active role in the discussion of IPR issues. The study made a number of recommendations based on the laws of the UK and EU, and was specifically geared to the context and issues faced there. It also made some general *procedural* recommendations that all countries would benefit from adopting, emphasizing the need for consultation between trade and health industries and the possibility of establishing a single (UK) policy on IPRs and healthcare provision (encompassing both internally generated and externally sourced innovation), a framework for partnership between the DOH and commercial providers of IP (such as pharmaceutical companies and universities), and the adoption of a "robust central policy for 'licencing in' designed to moderate excessive demands by licensors by considering, as possible options, the use of compulsory licensing, competition law and Crown use."

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[898] See for example the Nuffield Bioethics Report, *supra* note 383; The European Commission's Report on the *Development and Implications of Patent Law in the Field of Biotechnology and Genetic Engineering* (Brussels: The Commission, 2002), online: <http://europa.eu.int/eur-lex/en/com/rpt/2002/com2002_0545en01.pdf>.

[899] See W.R. Cornish, Dr. M Llewelyn, Dr. M. Adcock, *Intellectual Property Rights (IPRs) and Genetics: A Study into the Impact and Management of Intellectual Property Rights within the Healthcare Sector*, (Cambridge: Public Health Genetic Unit, July 2003), online: Public Health Genetics Unit Homepage <http://www.phgu.org.uk/about_phgu/s-ipr1.doc>. The study also considers other forms of IPRs that would privatize genetic information including certain analogues to copyright, unregistered design rights in the structure of DNA molecules, and database protection which this thesis does not discuss.

What reports emphasize repeatedly is that any policies adopted necessarily need to be country specific and correspond to the domestic needs and laws of a given state. This is consistent with WHO's approach asserting "[g]overnments have a responsibility for the health of their peoples which can be fulfilled only by the provision of adequate health and social measures."[900] Consequently, the state is charged with acting to determine, within each jurisdiction, in accordance with its own context and values, to what extent patent policy imposes additional inefficient costs[901] on the health sector and how these costs can be reduced without compromising innovation of new medical/health technology and drugs.[902]

5.4.3 Government Use and Compulsory Licencing

Where a patent in which the government has an interest has been granted, such as for a disease-linked gene or diagnostic testing, such as BRCAnalysis, even if a court subsequently upholds validity upon challenge, a viable means for regulatory governments to meet users' interest in the patented invention while meeting their own international human rights and trade obligations is through the statutory provision for government use

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[900] WHO Constitution, *supra* note 839.

[901] This is in addition to the regular deadweight loss attributable to a patent monopoly.

[902] Colleen Flood and Greig Hinds emphasize the need for comprehensive cost benefit analysis and the co-ordination of cross-sector policies in "Future of Health Care in Canada: The Who, What and How Much of Publicly Funded Health Care" at 38, *Innovate* (Spring 2004) 23 state that regarding health care expenditure, "[i]n theory, the choices or decisions made should be a function of public values, available resources, and information regarding relative costs and health benefits. For example, if we spend an extra $150,000 on health care, that money will not be available for education. We must ask ourselves, does the health care system benefit from that funding, as compared to the benefit that the education system would have received from the same amount of funding? It seems clear, however, that decision-making about what is publicly funded in Canada's Medicare is not made like this. Instead, the choices are a function of accidents of history and long held accommodations between governments and the medical profession; inflexible and inadequate regulations and law; and turf protection and lobbying by different stakeholders and interest groups." The costs of operating the patent system should also be borne in mind. The more patent friendly domestic policy is, the greater number of patents applied for and therefore the greater institutional and financial resources required for the system to operate effectively. In the absence of such resources, there are increased risks of patent quality problems. See Dutfield, "Sharing the Benefits," *infra* note 1150 at 908-911 discussing patent quality problems in relation to natural products and the potential and actual harmful effects such patents pose (using the maca and yellow bean plant as patents examples).

vis-à-vis compulsory licences. In an insightful article concerned with distributive implications of patents on indivisible goods, economist Dan Usher argued that the normal distributional implication of a patent is that benefits of the invention are a shared consumer surplus from the newly-invented good but that benefit is reduced by the patent monopoly for its limited term in order to protect the incentive to invent. The result is that consumers are better off than they would be without the invention but worse off than they would be if the good was 'un-monopolized.' Due to monopolistic pricing, the surplus might be enjoyed more by the rich than the poor.[903] However, Usher contends that in some cases this distributional story is distinctly *wrong*. Examining indivisible goods as a case study, he finds that:

> patents direct all benefit to the wealthy when the newly-invented good is what might be called *indivisible*...in this sense of the term when each person wants to buy either one unit of the good or none at all because less than one full unit is useless and any amount over the above unit is of no additional benefit. Indivisible goods are exemplified by medical procedures which you adopt entirely or not at all. You cannot have half a heart transplant. Nor can you have half an AIDS treatment or half a course of antibiotics; you must take the entire treatment if it is to do you any good.[904]

There are some qualifications to the study Usher makes but ultimately he uses the findings to rationalize, in the public provision of medical services, the expropriation of key drugs by the state in order to make these drugs available at their cost of production may be appropriate, so long as the drug companies are compensated for that use.

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[903] The ability to isolate genes and link them with specific protein functions associated with a propensity for associated diseases is a significant contribution that biotech has made to medical diagnostics and treatment but when doing a cost/benefit assessment, we must also factor into our calculation of the net welfare loss and harm to the public and would be users of a patented invention in knowing that a possible solution exists but costs too much to access optimally. There are other forms of welfare loss as well, unrelated to patents, such as how the role of genetics in the workplace may increase with the technology, see Trudo Lemmens, "'What About Your Genes?' Ethical, Legal, and Policy Dimensions of Genetics in the Workplace." *Politics and the Life Sciences* 16, 1 (March, 1997), 57-75.

[904] "Where the story is distinctly wrong, where every penny of benefit of the appearance on the market of a newly-invented good accrues to people whose incomes exceed some critical amount, where everybody else is excluded altogether, and where patents focus all benefit onto an even smaller and wealthier segment of the population." See Dan Usher, "The Distributive Implications of Patents on Indivisible Goods" (April 2004) Queen's Economic Department, Institute for Economic Research Working Paper No. 1018, online: http://qed.econ.queensu.ca/pub/papers/abstracts/download/2004/1018.pdf at 2.

Compensated taking need not be limited to key drugs, however. Usher's study can be a useful response to dealing with other areas of importance for health provision where the patented goods are indivisible (and demand inelastic due to public funding as with healthcare), including genomics and genomic testing for gene-linked diseases.[905]

If the government wishes to use a patented invention and negotiations for licensing between it and the patentee are unsuccessful then the government can seek a compulsory licence from the Commissioner of Patents who has statutory discretion to provide non-exclusive licenses when conditions precedent are met.[906] The government must still pay a licencing fee in an amount the Commissioner considers adequate under s. 19(4). This method is useful for dealing with specific cases in order to respond to public health needs *after* the patent has issued, such as with the BRCA1/2 controversy, but it should not be relied upon often to forge patent-health policies in an ad hoc manner. Moreover, it raises quantification challenges for the Commissioner: what is "adequate" compensation? Compulsory licences in limited contexts by a state for national use are a TRIPS consistent means for provincial governments to make use of patented "inventions", MGL's BRCA1/2 patents, for example, but they are remedial, offer no long term comprehensive solution to the patent-health tension, and are a poor substitute for policy co-ordination and resource management.

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[905] Section 64 of the CPA, *supra* note 82 allows for compulsory licencing in abuse of patents cases upon application by the Attorney General of Canada or "any interested persons" to the Patent Commissioner. Clauses 65(2)(c)-(f) define what constitutes abuse under the Act. Section 19 gives the Commissioner of Patents statutory discretion to grant government use by way of a non-exclusive compulsory licence over a patented invention in order to supply a domestic market, with the patentee receiving adequate compensation. This provision could have been resorted to in response to the public health concerns surrounding BRCA1/2 testing in a publicly funded health care system so long as the government had first tried and failed to negotiate a licence. The negotiation requirement can be dispensed with in cases of "national emergency or extreme urgency or where the use for which the authorization sought is a public non commercial use." See s. 19.1(2). For a further discussion of compulsory licencing as a means of dealing with issues at the intersection of health and patent policy, see Amani, "Patents and Public Health", *supra* note 352.

[906] CPA, *supra* note 82, s. 19.

Article 31 of TRIPS provides comprehensive procedural requirements for *other uses* and allows for compulsory licencing and government use as long as the same set of necessary domestic preconditions (negotiation of a licence on reasonable commercial terms have been unsuccessful within a reasonable time of request etc.) are satisfied, with similar special provision for waiving negotiations in cases of national emergency, other circumstances of extreme urgency, or in the case of public non-commercial use.[907] It offers a "fast track" whereby preconditions for prior negotiations with the patentee may be waived. Otherwise, for ordinary commercial uses, the applicant must first seek a voluntary licence from the patentee on reasonable terms and conditions (Article 31(b)). Licence applications are to be considered on their merits and the provision does not limit the grounds on which such licences may be issued, however, so long as the patentee is paid adequate remuneration in the circumstances of the case and the licence is "non-exclusive". Once the conditions for invoking this provision to grant the licence are resolved, the licence terminates. This provision assuages concerns over the right to patented food or health inventions in the biotech industry and could potentially support Canada's infringement of a foreign firm's IPRs in relation to food and health.[908] But, unauthorized and uncompensated use by the government, even if for well intentioned reasons as delivery of public health to Canadians in the BRCA1 example, is effectively considered "theft" and may not only lead to a domestic infringement suit, but can form

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[907] See also TRIPs Article 44 regarding injunctions: "...and provided that the Provisions of Part II specifically addressing use by governments, or by third parties authorized by a government, without the authorization of the right holder are complied with, Members may limit the remedies available against such use to payment of remuneration in accordance with sub-paragraph (h) of Article 31..."

[908] It is worth exploring whether greater government use of patented inventions for the delivery of health can be characterized as *public non-commercial use* for the purposes of s. 19.1 in Canada given our health care system. The reality is, however, that if it were to be used routinely by governments to meet the needs of their peoples, then it may discourage R&D into the discovery of inventions whose primary use would be in the third world and encourage instead luxury inventions of less social utility like fat-free French fries.

the basis of a WTO complaint.[909] It is an ineffective way to deal with the need for comprehensive cross-sector coordination and may be perceived as undermining property rights. A major problem with Article 31 is its limitation to local use and manufacture since the licence issued should be "predominantly for the supply of the domestic market" of the Member (Article 31(f)) but it can also authorize export of a *non-predominant* portion of production. The restriction on exports in Article 31(f) and the conditions necessary for granting a licence under Article 31(b) do not apply when a compulsory licence is issued to remedy anti-competitive practices (Article 31(k)). This leaves some scope for a Member to determine what constitutes anti-competitive practices sufficient to warrant a compulsory licence to issue without meeting the conditions set out in the provision. It is foreseeable that a complaint may be raised to challenge the invocation of Article 31(k) and Article 31 may be of little effective assistance to countries lacking the necessary infrastructure and manufacturing capacity to imitate the invention for domestic supply, e.g. to supply genetic tests domestically under a compulsory licence scheme. These countries would need to rely on parallel imports to meet their demand. As the next section will show, there may be an outstanding concern over TRIPS based limitations.

5.4.4. Amending TRIPS: The Patents-Public Health Declaration Arising from Doha

TRIPS provides, under Article 71, that the Council of TRIPS (Council) committee as whole shall evaluate TRIPS and its implementation as a group upon expiry of the transitional period set out in Article 65 para. 2. The Council may undertake reviews in light of relevant new developments that might warrant modification or TRIPS amendment. The TRIPS Council is also responsible for monitoring the operation of TRIPS and Member's compliance in domestic law (Article 63.2), affording consultation

[909] See Amani, "Patents and Public Health", *supra* note 352.

opportunities, assisting Members in the context of dispute settlement procedures if requested and fulfilling other duties assigned to it by the Members (Article 68). Despite the provision for review by the Council, there is no authority to make changes to TRIPS obligations- which must occur through waiver or amendment by the Members- although advisory opinions concerning Members' interpretations of TRIPS may be provided.

General concerns over the legitimacy of the WTO or the fairness of TRIPS were increasingly vocalized in the decade following their origin with sober realization of their impact. The growing number of deaths of millions of people, and resulting social, economic, political, and civil instability, in Africa, Brazil, India, Thailand and elsewhere due to the AIDS pandemic rallied civil society and various NGOs against their states in demand for just outcomes.[910] The significance of TRIPS-mandated patent rights in severely curtailing the availability of affordable essential medicines as a result of the exclusive rights of patent holders to set the prices on these medicines and preclude others from selling cheaper generics had become apparent. Public outcry ensued, targeting as much the WTO for prescribing protection, as BigPharma for setting the prices.[911]

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[910] As the deadliest infectious disease in the world, AIDS claims 8000 lives each day with over 95% of them in the developing world. See UNAIDS, (Joint United Nations Program on HIV/AIDS). "AIDS epidemic Update" December 2000. See how some of these countries used political will and public mobilization as a response for achieving desired health outcomes, in Hannah E. Kettler and Chris Collins, "Balancing Health Needs and Drug Research Incentives", Cooperation South, UNDP 2002 *Creativity, Innovation and Intellectual Property Rights* 10-37; see also Access to Essential Drugs May be Undermined by Global Patent Agreement, http://www.globalpolicy.org/socecon/bwi-wto/wto/2002/1201panos.htm stating that the WHO suggests that "patent protection where it does not already exist would result in the average price of drugs rising, with projected increases ranging from 12 to 200 percent. See also the Panos Report, "Patents Pills and Public Health: Can TRIPS Deliver?" http://www.panos.org.uk/resources/reportdetails.asp?id=1053&null=1000&, referred to therein. Would these costs be offset by the welfare gains encouraged in terms of foreign direct investment? Not for those bearing the costs since, according to the World Bank, middle income countries may benefit from increased foreign investment but the drug costs are rising due to patent protection spreading throughout the developing world and this has a direct bearing on access to such medicines.

[911] For a discussion of the access to medicines debate and its role in further derogating the WTO in the public eye see Frederick Abbott, "The TRIPS Agreement, Access to Medicines, and the WTO Doha Ministerial Conference" (2001) 5 J. of World Intellectual Property 15; Frederick M. Abbott, "The WTO Medicines Decision: World Pharmaceutical Trade and the Protection of Public Health" 99 A.J.I.L. 317.

Entering the Doha Round, developing countries, in particular Brazil and India, aligned themselves as a negotiation strategy along common interests and objectives to protect public health and domestic regulatory diversity not to the extent *permissible* under TRIPS but rather in *priority* of it.[912] The language of their draft Ministerial Declaration stated that "*nothing* in TRIPS *shall prevent* members from taking measures to protect public health."[913] In contrast, the version backed by Canada and the United States going into the Doha meeting more modestly acknowledged the right to take measures necessary to protect public health *only* to the extent that is TRIPS *compliant.*[914] This created the oft referenced 'North-South' divide going into Doha and threatened, according to WTO Director-General Michael Moore, to be "the deal breaker at this conference."[915]

Meanwhile, during the launch of the Doha Round of trade negotiations, developed countries like Canada showed disregard for foreign patent rights with not only the BRCA1/2 controversy but also the violation of patent rights of the foreign firm of Bayer in relation to an anticipated national anthrax outbreak emergency post September 9/11. This accentuated the need for a public health exception to patent rules as much for developed countries as for DCs and LDCs concerned with access to essential medicines

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[912] We can expect a continuation of this South-south trend towards greater development joint initiatives and co-operation. For example, six countries (Brazil, china, Nigeria, Russia, Thailand and Ukraine) signed an agreement to increase co-operation in developing and producing generic drugs with India and South Africa considering participation, at the XV International HIV AIDS Conference. See "Brazil to Coordinate Six-country Anti-AIDS Network," BBC Monitoring International Reports, 16 July 2004, as cited in Frederick Abbott, "The Cycle of Action and Reaction: Latest Developments and Trends in IP and Health" ICTSD-UNCTAD Dialogue on Ensuring Policy Options for Affordable Access to Essential Medicines, Bellagio 12-16 Oct. 2004, http://www.iprsonline.org/unctadictsd/bellagio/docs/Abbott_Bellagio3rev1.pdf.

[913] See Draft Ministerial Declaration From Group of Developing Countries, at http://www.wto.org/english/tratop_e/TRIPS_e/mindecdraft_w312_e.htm.

[914] *Ibid.*

[915] Steven Chase, "Drug patent skirmish threatens WTO talks," *Globe and Mail,* 9 November 2001, B6.

for AIDS and malaria. Cross-policy co-ordination is needed for efficient governance regardless of where in the world you are.[916]

Developing countries endeavoured to exploit divisions in the positions of developed countries (the North-North divide):

> The severity of the AIDS crisis in many parts of the developing world, combined with the duplicitous policy of Canada and the United States regarding patent rights, contributed to a North-South divide with respect to this issue. The European Commission and Norway took fairly flexible positions regarding the developing countries' positions. In addition, important sectors of civil society within developed countries shared the same concerns as those of developing countries, as abundantly shown in the international public opinion during the pre-Doha debate.[917]

As a result, not only did the Doha Ministerial Declaration support social and economic rights by locating the trade imperative within the objectives of maximizing welfare through more equitable distribution of economic gains, but it also resulted in the very important Declaration on TRIPS and Public Health.[918] The Public Health Declaration reaffirmed within its final text the right of developing countries to take a public health perspective to *interpreting* TRIPS obligations:

> 4. We agree that the TRIPS Agreement *does not and should not prevent* Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular to promote access to medicines for all.

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[916] This point is underscored by a dispute between the European Union and Canada on stockpiling and regulatory approval of generic drugs. See *e.g.* the WTO dispute in *Canada—Generic Medicines* case (Panel Report, *Canada – Patent Protection of Pharmaceutical Products,* WT/DS170/AB/R, R, adopted 12 October 2000) challenging Canadian policies allowing generic manufacturers to commence testing of patented products three years prior to patent expiry but disallowing stockpiling six months prior.

[917] For a thorough discussion of the how the Ministerial Conference in Doha was influenced by the converging threat of AIDS and terrorism, the Brazilian response to the former and the North American response to the latter vis-à-vis patent rights for medicines, see Condon, *supra* note 606 at 251-284. Canada's "illegal" response is set out at the start of chapter 3 of this dissertation- illegal because it bypassed proper procedure under national and international law in order to obtain a million pills of Cipro, a Canadian generic version manufactured from Apotex in violation of Bayer's patent rights, making public health its number one priority. See Condon, *ibid.* at 606.

[918] Declaration on TRIPS Agreement and Public Health, WT/MIN(01)/DEC/2, Adopted 14 November 2001, Ministerial Conference Fourth Session Doha, 9-14 November 2001, online http://docsonline.wto.org/DDFDocuments/t/WT/Min01/DEC2.doc. Paragraph 6 of the Declaration recognized that some WTO member states would have insufficient or no manufacturing capacity in the pharmaceutical sector and would therefore be unable to make effective use of the compulsory licencing and therefore the Declaration charged the TRIPS Council with devising a solution before 2002.

> In this connection, we reaffirm the right of the WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.[919]

This declaration is consistent with human rights prioritizing recommendations based on UN inquiries into the intersection of TRIPS and human rights. In August 2000, leading up to the WTO Ministerial Conference in Doha, Qatar, the UN Sub-Commission on the Promotion and Protection of Human Rights adopted a resolution on "intellectual property rights and human rights" which reaffirmed the primary obligation of governments under the Vienna Declaration are its human rights responsibilities and urged governments accordingly to take full account of existing HR obligations when engaged in trade negotiation (naming food and health rights in particular), when reviewing TRIPS in the context of the new Doha Round, and for Special Rapporteurs and the Committee on ESC rights to consider the HR impact of TRIPS when assessing compliance. It also asked the UN Secretary General to provide a report on the IP/HR nexus in 2001. That report strongly urged a human rights approach to trade arguing that not only was it the law, but it made good sense too for welfare maximization, poverty reduction, and development.[920] Additionally, the release of a joint study by the WTO and WHO on the relationship between trade and public health has made it cogently clear that the WTO can no longer operate and evolve in an institutional vacuum.[921] In short, civil society and

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[919] *Ibid.*

[920] Office of the High Commissioner for Human Rights, "Human Rights and Trade' 5th WTO Ministerial Conference, Cancun, Mexico, September 10-14, 2003, online <http://www.unhchr.ch/html/menu2/trade/cancunfinal.doc >.

[921] WTO Agreement & Public Health, *supra* note 636. See also reference to TRIPS in a resolution by the World Health Assembly at WHO, Resolution WHA 57.14 on Scaling up treatment and care within a coordinated and comprehensive response to HIV/AIDS, Fifty-Seventh World Health Assembly, Agenda item 12.1, 22 May 2004, para 2(6). TRIPS discussions occupy debates in other international UN based agencies, such as the Food and Agricultural Organization (FAO), "The TRIPS Agreement and Agriculture" Online, <http://www.fao.org/documents/show_cdr.asp?url_file=/docrep/003/x6730e/x6730e06.htm>; and the UN Human Rights Commission, see "Intellectual Property and Human Rights" http://www.unhchr.ch/Huridocda/Huridoca.nsf/0/c462b62cf8a07b13c12569700046704e?Opendocument.

domestic governments can no longer afford to remain oblivious to the social costs and human rights compromises of the TRIPS' trade-related IPR regime.

TRIPS, however, has not been implemented fully in most developing countries and a further extension has been granted for compliance in doing so. When TRIPS took effect on January 1 1995, developed countries were allowed one year to ensure compliance of their laws and practices with TRIPS; developing countries were given a transition period ending January 2000 (for other than the general principles in Articles 3-5); LDCs were given until January 1, 2006 and possibly longer upon approval to ensure conformity with the agreement.[922] The Doha Declaration granted the LDCs an extension until January 2016 for pharmaceutical patents.[923] But, as Peter Yu observes, "[h]ad the level of intellectual property protection been adjusted to reflect the countries' needs, interests, and conditions, those transitional provisions in the TRIPS Agreement might not be needed."[924]

According to a 2003 UNDP report critical of TRIPS and urging governments to take action to replace it,[925] the Public Health Declaration may have a significant effect on the future interpretation and implementation of TRIPS:

> There is little indication, apart from the Doha Declaration, that TRIPS has really been interpreted in the true spirit of balance between rights holders and users. From a legal perspective, the generalist language employed in TRIPS has worked both ways for developing countries; it has allowed for flexible interpretation, but also left the text open to dispute. The latitude in the text requires tremendous specialized legal capacity, which most developing countries lack. Moreover, the experience of Brazil... [in terms of free access to drugs with extensive health infrastructure

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[922] Part VI, *supra* note 8. Summary online <http://www.wto.org/english/tratop_e/TRIPS_e/tripfq_e.htm>.
[923] See TRIPS & Public Health, *supra* note 918.
[924] Peter K. Yu, "Four Common Misconceptions about Copyright Piracy" (2003) 26.1 Loy. L.A. Int'l & Comp. L.J. 127 at 135.
[925] "Member nations need to begin dialogues to replace TRIPS—and equivalent top-down schemes of substantive IPR harmonization-with alternate intellectual property paradigms that are unrelated to trade sanctions and may include, but are not restricted to: an intellectual property ladder, where more stringent laws apply to countries at higher levels of income and technology use, and countries progress from one level of protection to another with improvements in their Human Development Index/Millennium Development Goals indicators..."UNDP, *Making Trade Work*, *supra* note 747 at 221.

> supported by national legislation in relation to AIDS treatment and the US challenge that ensued through the request of a WTO dispute panel which it eventually withdrew based on an agreement reached with Brazil] has shown that efforts to use this flexibility provoke strong opposition from the developed world. Finally, the enforcement mechanism—the cross-retaliation mechanism of the dispute settlement process—takes little account of differences in capacity to retaliate. This is costly and harmful for developing countries. Exceptions are limited and specific, and the burden of proof falls on the alleged violator. In practice, this considerably reduces the power of the exceptions.[926]

Some critics did not consider the Declaration a "win" for developing countries, noting that its significance has often been grossly exaggerated as a major achievement.[927] In fact, *The Economist* aptly noted that "the declaration is political and not legally binding."[928] This is unmistakably true. However, the Declaration is well rooted in the text of the TRIPS which *is* binding on parties to a dispute and offers forward looking insight for future interpretation. In a sense, the Declaration is a pastiche of the TRIPS, accentuating the built in flexibilities of the text albeit with greater political panache. It had the positive impact of leading to an important waiver of TRIPS in 2003 to

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[926] *Ibid.* at 210 and 222. For a discussion of the IP related portions of the Report, see also GRAIN, "New Report Urges Governments to Replace TRIPS" February 20, 2003, http://www.grain.org/bio-ipr/?id=188. The reference to the burden and limits of exceptions relates to the manner in which exceptions have been "adjudicated" by TRIPS panels or the AB. For example, in *Canada- Generic Medicines* case (Panel Report *Canada- Patent Protection of Pharmaceutical Products)* WT/DS170/AB/R adopted 12 October 2000 regarding Canadian provisions which allowed for testing for regulatory compliance and stockpiling of medicines by generic manufacturers, Canada used Article 30 in its defence to argue that such provisions were permissible exceptions that Members may provide to patent protection. The panel significantly narrowed Article 30 by stipulating three criteria which Canada had to prove to establish that the exception was "limited" (the measure did not unreasonably conflict with the normal exploitation of the patent, did not unreasonably prejudice legitimate interests of the patentee and took into account legitimate interest of third parties). For an insightful discussion critiquing the panel's interpretation of "limited" see Trebilcock and Howse, *supra* note 237 at 419. The authors argue that the exception should have been interpreted in light of the purpose of TRIPS set out in Article 7: "To do justice to this purpose, the panel would, at a minimum, have had to consider the scope implied in the word "limited" not only from the perspective of how much rights-holders' interests were being curtailed, but also from the perspective of how limited the exception could be while affording sufficient scope to protect public health and the interests of consumers generally."

[927] Walden Bello, "Learning from Doha" at http://www.focusweb.org/publications/2001/learning-from-doha.html stating that developing countries' were actually losers of the Conference by launching a new round with an ambitious mandate to extend the purview of the WTO to new agreements, like industrial tariffs, and for negotiating new (the "Singapore issues") non-trade areas such as investment, competition policy, government procurement, and trade facilitation when the over 104 implementation concerns of developing countries leftover from the Uruguay round had yet to be resolved. Little commitment seemed to be made on a quick phase out of agricultural subsidies or textiles quotas.

[928] http://archives.econ.utah.edu/archives/pen-l/2001m11.3/msg00039.htm.

temporarily allow generic exports under the compulsory licence provision. The TRIPS Council and the WTO General Council decided to convert the temporary waiver of TRIPS' Article 31 (f) and (h), made by the WTO general Council Decision of August 2003 into a permanent amendment to justify compulsory licencing and parallel imports for countries lacking manufacturing capacity for pharmaceutical drugs.[929] By 2005, the first amendment ever to be made to a "core WTO agreement" provided substantive change to TRIPS and created permanent conditions allowing production of generic drugs and the effective use of compulsory licences in third party countries for parallel importation; so long as a compulsory licence has also been granted in the importing country.[930] The flurry of international activity and public protest was finally having the desired impact in providing some accommodation to Members' for the disparity of

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[929] See Press Release, "Members OK amendment to make health flexibility permanent", Press 426, 6 December 2005, online http://www.wto.org/English/news_e/pres05_e/pr426_e.htm.>.

[930] See "Members OK Amendment to make health flexibility permanent" Press Release 426, December 6, 2005, online: WTO < http://www.wto.org/English/news_e/pres05_e/pr426_e.htm>. The WTO General Council adopted the Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health (See WT/L/540 (Sept 1, 2003)), *supra* note 918. For a detailed discussion, see Abbott, "WTO Medicines", *supra* note 74 wherein he warns that the decision, though "a helpful piece of a much larger public health puzzle," cannot adequately deal with the economic and political power exerted by the US in its forum shifting strategy to TRIPS plus agreements outside of the WTO. He provides and overview of how the decision is operationalized, the need to give notice to the TRIPS Council of the intention to use the system in whole or in part as an importer, and the determination of whether domestic manufacturing capacity and know-how is insufficient in accordance with criteria set out in the Annex of the Decision (at 327-349). Abbott criticizes Canadian implementation of this decision, see *Jean Chrétien Pledge to Africa Act*, S.C. 2004 c.23 to amend the *Patent Act*, R.S.C. 1985, c. P-4 and the *Food and Drugs Act, Food and Drugs Act,* R.S.C. 1985, c. F-27, in its requirement that a voluntary licence first be sought before a compulsory one can be issued. Additionally, the legislation "does not make any provision for use of the fast track for emergencies and public noncommercial use, but it does provide that thirty days are adequate period for seeking a voluntary licence....The argument that the procedure in the exporting country should be based on its domestic situation turns the object and purpose of the Decision on its head. If Canada is going to export ARVs to Africa, this is not because there is a public health crisis in Canada but, rather, because there is a public health crisis in Africa." (at 342). At 347, Abbott adds that the Decision does not preclude members from initiating dispute settlement regarding actions they consider inconsistent; this is an ordinary WTO mechanism but the decision does exclude non-violation nullification or impairment actions.

resources affecting their ability to invoke the government use provisions of Article 31.[931] The amendment is very limited in scope, however, applying only to pharmaceutical patents over essential medicines and does not address lack of manufacturing capacity in the larger context (i.e. licencing of parallel imports for nutrient enriched GM food like "golden rice", GM seeds, or arguably plant derive vaccines).[932]

The TRIPS preamble recognizes public policy objectives of domestic IPR regimes[933] but simultaneously reaffirms the need for strengthened IP protection through a trade linkage[934] which thereby subjects IP to the underlying normative economic force of the multilateral trade system that further reduces IP to one dimension: as exclusively *tradeable* commodities rather than public goods, infrastructure for the delivery of public goods, and the national cultural artifacts that they are.[935] It does this, additionally, by emphasizing a rights based thesis for IP by "*Recognizing* that intellectual property rights

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[931] See *e.g.* International Federation for Human Rights, "Understanding Global Trade and Human Rights: Report and Resource Guide for National Human Rights NGOs in View of the 2005 WTO Ministerial Conference, Hong Kong, MC6" May 2005, Geneva, online <http://www.fidh.org>.

[932] The limitations imposed by this solution exceed the field of pharmaceuticals and extend to the practical ability to operationalize on the interim waiver provided by the 2003 decision based on the extensive conditions that must be fulfilled (such as differentiating the export product from the patented version in get-up, the responsibility of the generic producer to prove bio-equivalence, and the contestability of the "capacity" for domestic manufacture by the importing country) that effectively render the waiver, according to Carlos Correa, of no practical effect. See Carlos Correa, "Access to Drugs under TRIPS: A Not so Expeditious Solution" Bridges International Centre for Trade and Sustainable Development January 2004 at 21. The rationale from the agreeing countries was to limit the solution to enumerated lists of diseases and thereby limit the economic implications of the waiver and amendment.

[933] Paragraph 5 of the Preamble states: "*Recognizing the underlying public policy objectives of national systems for the protection of intellectual property, including developmental and technological objectives;*"

[934] TRIPS, *supra* note 8, Preamble Para. 1 reads: "Desiring to reduce distortions and impediments to international trade, and taking into account the need to promote effective and adequate protection of intellectual property rights, and to ensure that measures and procedure to enforce intellectual property rights do not themselves become barriers to legitimate trade" –by proving "for new rules and disciplines" under paragraph 2.

[935] For a similar analogy made in the context of international copyright under TRIPS, see Myra J. Tawfik, "Is the WTO/TRIPS Agreement User-Friendly?: Final Report to the International Trade Treaties Committee of the Canadian Library Association" January 30, 2005, online <http://www.cla.ca/resources/tawfik_final_report.pdf> at 11.

are *private rights* [.]"[936] This may be why Peter Drahos portrays TRIPS "as a prime example of 'business sovereignty over regulatory standard setting.'" But the territorial history of IPRs and the statutory basis for their existence confirms that these "rights" are *institutionally* created privileges - defined by each Member as a matter of self-determination - and must remain culturally sensitive while "pressed into service on behalf of human rights."[937]

5.5 Sovereignty and Self-Determination: The Role and Right of the State

In the wake of 9/11, UNESCO's unanimously adopted Declaration on Cultural Diversity[938] provides some recognition that cultural pluralism is essential to world peace and sustainable development.[939] The preamble, notes that "culture is at the heart of contemporary debates about identity, social cohesion, and the development of a knowledge-based economy." Article 1 of the Declaration provides,

> Cultural diversity is as necessary for humankind as biodiversity is for nature. In this sense, it is the common heritage of humanity and should be recognized and affirmed for the benefit of present and future generations.[940]

Article 3 recognizes the link between cultural diversity with development:

> Cultural diversity widens the range of options open to everyone; it is one of the roots of development understood not simply in terms of economic growth, but also as a means to achieve a more satisfactory intellectual, emotional, moral and spiritual existence.

Article 9 preserves the role of the state and supports the general thesis advanced here that matters of appropriately balancing interests should be left within the sovereign dominion

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[936] TRIPS, *supra* note 8, Preamble para 4.
[937] Peter Drahos, quoted in Prove & Kothari, *supra* note 848 at 14.
[938] UNESCO UNDCD, *supra* note 119, online: http://www.unesco.org/culturelink/review/35/cl35un.html.
[939] "Previously the notion of sustainable development embraced economic, environmental and social parameters, yet largely ignored those pertaining to cultural issues. A change in strategy is clearly a must, UNESCO believes, if the promotion of cultural diversity is to be given a central, rather than peripheral, place in the debate." UNESCO, News Release, "Sustainable Development" (3 September 2002).
[940] UNESCO UNDCD, *supra* note 119.

of a regulatory state in policy making.[941] Article 11 is dedicated to building bridges between civil society and the public/private sectors towards these ends, since "market forces alone cannot guarantee the preservation and promotion of cultural diversity, which is key to sustainable human development."[942]

It will be recalled from the last chapter that TRIPS Article 1 allows Members to implement their obligations as they see fit and Article 7 provides the objectives of IPR protection and enforcement require *mutual advantage* to producers and users "in a manner conducive to social and economic welfare, and to a balance of rights and obligations". Article 8 articulating TRIPS' guiding principles respects sovereignty and a right to self-determination by allowing Members to

> adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the *provisions* of this Agreement.

Consistency with the *provisions* in the text is substantially less onerous than the language used in an earlier draft of Article 8 which required no *derogation* from TRIPS *obligations*. The latter would have rendered Members substantially more vulnerable to non-violation complaints (NVCs)[943] based on domestic regulatory measures taken to protect public health.[944] NVCs, by their name are based on allegations of nullification or impairment and tend to focus on domestic measures (such as a new product subsidy on

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[941] "While ensuring the free circulation of ideas and works, cultural policies must create conditions conducive to the production and dissemination of cultural goods and services....It is for each State, with due regard to its international obligations, to define its cultural policy and to implement it through the means it considers fit, whether by operational support or appropriate regulation." *Ibid.*

[942] "From this perspective, the pre-eminence of public policy, in partnership with the private sector and civil society, must be reaffirmed." *Ibid.*

[943] A Member's complaint would allege that the negotiated balance of concessions between Members is upset by the application of a measure and would seek monetary compensation as the remedy, regardless of whether the measure is inconsistent with *provisions* of an agreement. Their inclusion in the GATT 1947 Article XXIII: 1(b)("nullification and impairment") was modeled on earlier US bilateral trade agreements.

[944] It is important to note that the 1990 Brussels draft of Article 8 (paras. 1 and 2) used broader language in the text "Provided that PARTIES do not derogate from the *obligations* arising under this Agreement..."

which a tariff concession has been made) or actions that are measured against WTO *obligations* rather than *provisions:*

> [S]ome delegations expressed concern about the possible use of the provisions of Article 8 to justify measures which, while not inconsistent with obligations under the Agreement, might have the effect of impairing benefits that other Members could legitimately expect under the Agreement; in other words, that the provision could be used as a *defence* in a non-violation case on the grounds that the taking of the measures envisaged by Article 8 could only have been reasonably expected at the time that the TRIPS negotiations were concluded.[945]

NVCs incorporated into TRIPS by Article 64.1 and the DSU would have intruded further than the TRIPS substantive obligations by holding different technically compliant government measures accountable for their (restraining) trade impact in such a way as to deprive Members of *expected* trade benefits. Article 64.2 of TRIPS, however, provides temporary relief by banning such disputes for the initial period of 5 years (1995-99) which was extended at Doha because of its potential implications.[946] Currently, most members have stated their opposition to the inclusion of NVCs under TRIPS, favouring instead a permanent ban or the continued moratorium the TRIPS Council has recommended pending Ministerial consensus.[947] The potential for such complaints will

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[945] Emphasis added. TRIPS Council, Note by the Secretariat, *Non-Violation Complaints and the TRIPS Agreement*, 28 January 1999, IP/C/W/124, paras13-14. Online http://www.dfat.gov.au/ip/secretariat_paper.doc For country specific submissions, visit online: <http://www.iprsonline.org/submissions/nonviolation.htm>.

[946] See WTO "Non-Violation Complaints: Background and the Current Situation" http://www.wto.org. In the interim, the TRIPS Council charged under Article 64.3 with examining the "scope and modalities" of IP NVCs and their relationship with the DSU was further instructed pursuant to para 11.1 of the Doha Declaration on Implementation Related Issues and Concerns to report on its investigation and make its recommendations until which members agreed not to make NVCs. At the Cancun Ministerial Conference in 2003, the Council made four recommendations: (1) banning non-violation complaints in TRIPS completely, (2) allowing the complaints to be handled under the WTO's dispute settlement rules, (3) allowing non-violation complaints but subject to special "modalities" (i.e. ways of dealing with them), and (4) extending the moratorium. Failure to reach a consensus on the Draft proposed by the TRIPS Council meant failure to reach any acceptable change according to Article 64.3. While most Members favoured the complete ban or the extended moratorium, the US and Switzerland strongly voiced support for TRIPS related non-violation complaints in order to minimize Members from "creative legislative activity" that would alter the 'negotiated balance of benefits' by allowing them to effectively circumvent their TRIPS commitment while remaining technically compliant.

[947] Further discussion took place during preparation of the July Package which expressly extended the moratorium until the Sixth Ministerial Conference, December 2005. However, no substantive agreement on the issue was reached, online < http://www.ictsd.org/pubs/dohabriefings/Vol3/V3_05.pdf>.

therefore not be dealt with further but also because the language of Article 8 makes the consideration of NVCs in the context of ECSRs intersecting with the patenting of life superfluous. Article 8, setting out the Principles of TRIPS, gives express deference to domestic regulatory diversity directed at certain listed public policy objectives "provided that such measures are consistent with the *provisions* of the Agreement."[948] In short, Article 8 appears, at a minimum, to restrict the *kind* of TRIPS related non-violation complaints that could be brought before the DSU even if consensus is reached on the *status* of non-violation complaints generally under TRIPS.[949] Put differently, even if the moratorium on such complaints were to be lifted, a Member may not complain that a domestic "measure necessary to protect public health and nutrition" or "to promote the public interest in sectors of vital importance to their socio-economic and technological development" can lead to nullification and impairment of an expected benefit *unless* it is inconsistent with the "*provisions of this Agreement.*" That is, a non-violation complaint (based on derogation of *obligations*) will *never* be appropriate in relation to measures captured under Article 8. One necessarily needs a violation complaint if attacking domestic measures embraced by the language of Article 8 because it has internal to it a public interest defence in relation to NVCs. I argue in the next chapter that this defence also logically extends to violations complaints. This is important because social and economic rights require state action and agency, in part due to an institutional deficit and instrumental gap in the UN system which makes these general laws "based on nature"

[948] See also discussion of Article 8 in text at page 428.
[949] In Chapter six, I provide a detailed analysis of the role of Article 8 in TRIPS and argue that its greatest utility is its potential as a defence to TRIPS violation complaints.

only justiciable if domestically implemented through "particular laws" of the state – laws that are culturally nuanced within ideological and political frameworks.[950]

The state's right to self-determination has a moral force since human rights need to be implemented in highly stratified contexts, and are therefore conditioned on the state's appropriate exercise of its right. This means that diversity of regulation is constitutive of universal principles while at the same time preserving their cultural landscape. When the patenting of life first became a public issue, for example, Isidora Acosata, President of the Guayami General Congress, declared:

> I never imagined people would patent plants and animals. It's fundamentally immoral, contrary to the Guayami view of nature, and our place in it. To patent human material...to take human DNA and patent its products...that violates the integrity of life itself and our deepest sense of morality.[951]

Debra Harry, for The Indigenous People's Diversity Network similarly objected to the Human Genome Diversity Project (HGDP):

> They have come to take our blood and tissues for their interests, not for ours...genetics is a violation of our ethics, it attacks our culture's worldview. *We don't view our genes as protein, actions ready to be interpreted, for us our genes are sacred.*[952]

State signatories to UN human rights instruments are charged with the duty to protect and promote human rights; it may be done by granting patents if the necessary safeguards are there and if doing so is consistent with the cultural values and social mores of a given

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[950] Aristotle, in his seminal work, *Rhetoric*, contends: "Justice and injustice have been defined in reference to laws...in two ways. Now there are two kinds of laws, particular and general. By particular laws I mean those established by each people in reference to themselves, which again are divided into written and unwritten; by general laws I mean those based upon nature." Cited in Hastrup, *supra* note 23 at 3.

[951] Cited in Rural Advancement Foundation International (RAFI), *Indigenous People Protest U.S. Secretary of Commerce Patent Claim in Guyami Indian Cell Line,* Press Release RAFI October 26, 1993.

[952] Debra Harry, (1995) 377 *Nature* 372 as cited in Baljit K. Dhadda, "Patenting Human Genetic Information: IS Nothing Sacred?" in Lionel Bently and Spyros Maniatis, *Intellectual Property and Ethics, Perspectives on Intellectual Property Series,* (Carswell, Canada: 1998) 89-108, emphasis added.

peoples.[953] The capacity for the state to act as primary causal agent relies on the state's right to self-determination, essentially a sovereign discretion to govern without undue external interference by other states as paramount as the right to liberty is to the individual so long as it does not deprive another of same. The right to self-determination is cornerstone to all other human rights because it allows for the implementation of all other human rights in domestically contingent culturally diverse frameworks. Article 1.1 of the ICCPR and ICESCR provide:

> All peoples have the right of self-determination. By virtue of that right they freely determine their political status and freely pursue their *economic, social and cultural development.*

In addition, Art. 1.2 of both agreements adds that "[i]n *no case* may a people be deprived of its own means of subsistence".[954] Strong, internationally mandated IPRs, if extended to life, may be contrary to these provisions, the human rights outlined above, as well as numerous other sovereign rights including the free and full use of natural wealth and resources (Article 47 ICCPR and Article 25 ICESCR), the sustainable use, equitable sharing and access to genetic resources under the Convention on Biological Diversity (CBD)[955], and all of the other means for protecting human *dignity*, including the recognition that the human genome is part of our common heritage.[956]

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[953] See article 2 of the ICCPR, *supra* note 779 and the ICESCR, *supra* note 780. Art. 1 of the UNC, *supra* note 11 codifies the supremacy of territorial integrity and political independence of the nation state supporting my argument that states should be able to give priority to human rights if they so choose.

[954] See also Article 2.7 of the UNC, *ibid.* confirms the sovereignty of Nations: "Nothing contained in the present Charter shall authorize the United Nations to intervene in matters which are essentially within the domestic jurisdiction of any state or shall require the Members to submit such matters to settlement under the present Charter…"

[955] See Chapter 6 discussions.

[956] Recall the Declaration on the Human Genome and Human Rights. Article 1 of the HGHRD, *surpa* note 186 provides that the "human genome underlies the fundamental unity of all members of the human family, as well as the recognition of their inherent dignity and diversity."

In 1997, the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine[957] provided in Article 1 that Parties to the Convention "*shall protect the dignity and identity of all human beings* and guarantee everyone, without discrimination, respect for their integrity *and other rights* and fundamental freedoms with regard to the application of biology and medicine." Article 2 confirms the primacy of human beings: "*The interests and welfare of the human being shall prevail over the sole interest of society or science.*" Article 3 obliges Parties taking account of health needs and available resources, to take measures with a view to providing *within their jurisdiction* equitable access to health care of appropriate quality. And, Article 15, articulating the general rule on scientific research provides that "Scientific research in the field of biology and medicine shall be carried out *freely"* subject to any legal provisions *ensuring protection of the human being.* The 1998 Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, on the Prohibition of Cloning Human Beings, further demonstrates the expansive and dynamic content of universal human rights by extending these individual protections to prohibit the offensive threat of cloning people that new stem cell and cloning technology will one day enable. Domestic laws reflecting such a ban would be permissible to prevent commercial exploitation if cloned people or human chimeras were patentable.

In October 2003, UNESCO adopted the International Declaration on Human Genetic Data as a standard setting instrument designed to guide states in developing domestic legislation in recognition of our "common genetic heritage" and in support of the use of human genetic data in a manner respectful of human dignity and human rights

[957] See full text, online <http://conventions.coe.int/treaty/en/treaties/html/164.htm>.

including the freedom of research (Article 1) and benefit sharing (Article 19). These instruments reflect the emergence of a growing ethical standard found on human *dignity* which transcends the political, cultural and economic nature of patent law and emerging new technologies while obligating the state for its mediation.[958] It is consistent with some past and current exclusion of patents in Canada over food, seeds, and methods of medical treatment. Additionally, strong IPRs may additionally slow *development* which trade law tries to promote, by restricting the free pursuit of economic, social and cultural development through the elimination of the comparative advantage in imitation enjoyed by poorer states. TRIPS may consolidate new forms of protectionism, not exercised through tariffs but through monopolizing knowledge applied to produce goods:

> The new highest expression of protectionism is, in the view of developed countries, a necessary condition to promote innovation and to stimulate technology and capital flows to developing countries. Their assumption is that people from developed and developing countries will benefit alike from this kind of intellectual property rights.[959]

Using foreign IPR law and policy under political and legal pressure to spur domestic innovation makes for poor local governance; it belies the right of a people to determine their own fate without compulsion based on their own governance requirements rather than the monetary interests of the "first world" and their MNCs. The UNDP reports:

> [t]he expected gains from TRIPS are unlikely without a range of complementary policies such as investments in tertiary education and research capabilities, reward mechanisms in research sectors and an appropriate investor climate- all of which depend on different government policies.[960]

The OECD also recognizes the need to locate IPRs within a context of existing infrastructure:

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[958] See Brad Sherman and Lionel Bently, "The Question of Patenting Life" in Bently and Maniatis, supra note 952, 111-125 discussing ethics and patent law with particular attention to the European experience.
[959] B.K. Keayla, "Agreement on Patent Laws: Impact on Pharmaceuticals and Health for All" in *Global Health Law*, *supra* note 860 at 259.
[960] UNDP, *Making Trade Work, supra* note 747 at 208.

> ...government policies, particularly those relating to science and technology, industry and education, will need a new emphasis. The central role of the firm, the importance of national innovation systems, and the requirements for infrastructures and incentives that encourage investments in research and training have to be acknowledged.[961]

Public education, free and open access to information and sharing in knowledge, and health delivery are all public goods that create assets for the poor and are an essential obligation of the state to balance against its industrial policy as part of its right to self-determination. The World Bank underscores the importance of state agency:

> Why does the state have a role in expanding poor people's assets? For two main reasons. First, markets do not work well for poor people, because of their physical isolation and because of market failures in financial, health, and insurance sectors, for example. Second, public policy can *reduce initial inequalities and increase the opportunities for poor people to benefit from growth.* Equity and efficiency considerations can be largely independent, but they generally overlap...Among the most effective antipoverty policies are those that achieve more equity through redistribution and simultaneously enhance the efficiency of markets used by poor people.[962]

These *assets* help tackle asset inequalities only if state regulatory power is appropriately used to redistribute these assets rather than to facilitate their private control. Any reservation or restraint on IPRs is often critically characterized as "government interference" in the normal operation of the free market, which ignores the fact that the regulatory recognition of a property right in the first place is a "government interference" that creates a subsidy for certain parties in the knowledge economy. Moreover, "[a]n active national competence in basic research is...a necessary condition for benefiting from research undertaken elsewhere in the world; indeed it can be viewed as a national

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[961] OECD 1996 Knowledge Based Economy Report, *supra* note 28 at 237.

[962] The Report adds, "[s]ome health services, such as mosquito and other pest control and health education on basic hygiene and nutrition are pure public goods....Governments are responsible for infectious disease control on efficiency grounds. But such policies have important equity benefits as well. While the poor suffer more from almost all diseases than the nonpoor do, the difference is greatest for infectious diseases. In India, the poorest tenth of the population is seven times as likely to suffer from tuberculosis as the richest tenth": World Bank Development Report, "Expanding Poor People's Assets and Tackling Inequalities" (2000-01), online < http://www1.worldbank.org/prem/poverty/wdrpoverty/report/ch5.pdf>, c.5 at 79 and Box 5.3 outlining "win-win" policies in public health sector.

scientific intelligence system." [963] That means domestic skilled labour is critical for determining the social value of basic research and its commercial potential. DCs and LDCs may not have the same kinds of public infrastructure necessary to become better innovators, offering strong IPR protection for foreigners without the potential for similar gains for themselves.

Countries where educational infrastructure *is* strong but policies supporting application development is not may become source countries for foreign held patents.[964] *Leakage* depends, "as a first approximation, on the proportion of a country's corporate technological activity that is controlled by foreign firms, which reflects their capacity to monitor and absorb local basic research skills and knowledge." By the same token, Keith Pavitt contends, "the importance of the foreign technological activities of nationally owned firms will reflect a country's capacity to benefit from basic research undertaken in other countries."[965] TRIPS would facilitate a western firm's absorption of leakage from countries with strong university systems, like India or Iran, and facilitate the means of their foreign commercialization.[966] Considering their infrastructure and labour markets, developing countries that adhere to stronger protection standards of the Northern developed countries may be providing further subsidies (through this leakage) to an

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[963] Keith Pavitt, "What makes research economically useful?" (1991) 20:2 Research Policy 109 at 115, see also P. Patel & K Pavitt, "Do Large Firms Control the World's Technology?" (mimeo) in *Science Policy Research Unit* (Brighton: University of Sussex, 1989), cited therein at 115-16.

[964] Stable markets and governments lacking corruption, and a well operating legal system are important.

[965] Pavitt, *supra* note 963.

[966] See reference to Iran's burgeoning R&D in scientific sectors including biotech and stem cell research despite the lack of strong IPRS and their enforcement which have not proven to be a significant impediment, *supra* note 184. University educated human resources is one of Iran's major exports according to a national Iranian newspaper, the *Iran Daily* which reports that some 180,000 who hold university degrees permanently leave Iran each year in search for a better life: "The sad truth is that Iran ranks first in the world in terms of the phenomenon of brain drain [due to lack of favourable social conditions for the youth and the high unemployment rate]...A recent survey by the International Monetary Fund (IMF) shows that 15 percent of Iranian experts migrate to the U.S. while percent of migrate to the European Union member states." Taking with them, of course their subsidized knowledge, a form of cultural capital, in search of a better life. *Iran Daily* September 17, 2005 at 2.

already subsidized foreign export market (through local IPRs) in knowledge goods thereby domestically absorbing the costs for an external gain by large MNCs. Professor Vaver explains how else IPRs are domestically subsidized:

> True, the state may pay no money from general revenue, but it sheds this responsibility by dictating that one person or one class of people should pay another person or another class a fee- that is, subsidize them- ostensibly for the benefit of the community as a whole. It is a subsidy with a difference. Questions of who can benefit directly and who must pay directly or indirectly are constrained by the classification of intellectual property.[967]

Globally protected IPRs, through extrapolation, become globally subsidized by the people least likely to generate them (by western standards) or afford them. Moreover, Vaver's characterization is not completely accurate because in the developed world the (welfare) state *does* pay money from general revenue by supporting public education, subsidizing universities, public health, health and safety standards and other generally supportive and necessary infrastructure whereby a healthy and functioning labour force can "create".[968] Since this general revenue is our tax dollar and modern IPRs are so often conditioned on labour and investment, in some sense we are *all* "contributing authors."[969]

This mismatch of institutions compounds existing inefficiencies by "[i]mposing higher standards of IP protection on developing countries that suffer from severe shortages of skilled labour," writes Drahos. For them, granting exclusive rights in the domestic market would have little impact on domestic innovation if the capacity to innovate is lacking. This "means that intellectual property rights are less likely to

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[967] Vaver, *IPL, supra* note 34.

[968] "If, for example, the efficiency of or returns from one public good is improved by the presence of another they can be said to complementary [sic]. The returns from intellectual property systems, for instance, will be affected by other public goods, such as education. Strong intellectual property regimes that deliver the public good of knowledge through the market have their efficiency improved if they are complemented by labour markets that allow skilled workers to move from firm to firm (restrictions on the use of codified information are counterbalanced by regulation that allows for the movement of skill-embodied information)." Drahos, "Public Goods", *supra* note 160 at 332.

[969] We may need to re-imagine the TRIPS dynamic as one in which the protections prescribed are complied with but imports are subject to a countervailing duty based on the foreign market subsidy in order to level the playing field now that the comparative advantage in imitation has been eliminated by TRIPS.

achieve their incentive effects and may simply worsen a developing country's terms of trade."[970] A nation whose comparative advantage lies in imitation rather than innovation may stand to gain significant consumer and producer benefit from adopting *weak to no IP* protection. Trebilcock and Howse suggest that

> [t]he level of intellectual property protection each country decides to afford will thus be rationally related to whether its comparative advantage resides more in innovation or imitation and adaptation of innovations made elsewhere, and the relative weight it gives to the interests of consumers (including its own producers who are consumers of inputs), imitators, and innovators.[971]

Best policies would move beyond accessing technology that could sustain development, under licence, to free *distribution* of knowledge to DCs and LDCs, recognizing that meeting individual human rights and promoting development in target countries will have possibly greater positive externalities.[972] As Ostergard Jr. notes, "[b]y putting up barriers, the developed countries delay the creation of markets that could support entry of technologically advanced IP, thus cutting short the potential profits that could be obtained if the developing countries could sustain themselves."[973]

Often IPRs are hailed as the exemplar of an unsubstantiated standard that posits that if IPRs are strongly enforced and expanded they *will* increase technology development, flows, and transfer of capital by attracting innovation and foreign direct investment necessary to establish local economy boosting enterprises in developing

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[970] *Ibid.* at 333.
[971] Trebilcock & Howse, *supra* note 237 at 396.
[972] Drahos, "Public Goods", *supra* note 160 at 333. Drahos writes that" [m]arkets are dependent upon a range of primary public goods that come in the form of rules and institutions (the rule of law, contract, property, banking, corporations, securities and stock exchanges). A flourishing capitalism equipped with such institutions allows entrepreneurs the freedom to act, to create the spontaneous ordering that is said to characterize markets. The regulation of public goods that serve as inputs into the exercise of skill by individuals also has important effects on these processes of spontaneous ordering. For example, over time societies have evolved different regulatory models for the intellectual commons (an information commons). An intellectual commons can be negative (open to individual appropriation) or positive (in the co-ownership or co-use of all and not open to appropriation) and inclusive (open to all) or exclusive (open to a select group)." See also Drahos, *Philosophy*, *supra* note 164 at 57-60.
[973] Ostergard, *supra* note 96 at 177.

countries. However, there is no evidence to support the MNCs' claim that strong IPRs are good for developing countries and the growth of their economy. In fact, corporations are drawn to establish plants where the human resources are more educated, the political climate offers stability, the rule of law operates, and not just where labour is cheap and IPRs strong.[974] It is more likely that MDCs will just engage in *trade,* exporting goods to a country which in turn offers them strong IPRs without reciprocal economic benefit. A UN based study confirms that innovatory companies would prefer to *sell* the products or services incorporating the innovation than establish a local presence that would facilitate transferring the technology or licencing agreements.[975]

These findings support Bhagwati's theory explaining the interest of multi-nationals in poor markets where products are nevertheless purchased through "borrowed" money or foreign aid resulting in "more exports by developed countries, and less opportunities for industrial and technological development for developing countries."[976] The human rights violations here are more tacit as uniform IPR standards erode all incentives for price differentiation based on capitalist desire, and ability once legalized, to seek maximum profits under patents without due consideration of poor consumers' buying capacity.[977] That is, since standard prices are subsidized by foreign aid funds that allow for full profit, there will be little incentive for geographic price discrimination which, although profitable, is less so than full market price. If TRIPS obligations are expansively interpreted, the impact of this on sovereignty is that not only will a state be

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[974] See *Global Health Law, supra* note 860.
[975] Keayla, *supra* note 959.
[976] *Ibid.*
[977] uniform prices would "avoid the downward ratchet effect of cross-country comparisons." *Ibid.*

unable to adopt policy preferences of its people towards the realization of human rights but TRIPS would create obligations to safeguard their *violation*.

The binding dispute settlement process of the WTO Agreement, provided by the *Dispute Settlement Understanding* (DSU)[978] is designed to provide "security and predictability in the multilateral trading system."[979] The 'rules based' system it prescribes provides a judicial model for decision making and establishes an effective means of enforcing decisions.[980] A request may be made for a dispute resolution Panel to hear the complaint and make its ruling (Article 6). Because of the judicial nature of the system, appeals are allowed from Panel decisions to the Appellate Body (Article 17(6)) but the jurisdiction of the latter is limited exclusively to "issues of law covered in the panel report and legal interpretations developed by the panel." Much like domestic judicial systems in common law jurisdictions, the AB will not engage in the hearing or determination of new facts. A panel report shall be adopted by the DSB (unless there is notice of an appeal or consensus not to adopt the report as per Article 16). The final decision adopted by the DSB is binding on all parties to the dispute. Prior to the Uruguay Round, GATT decisions had to be adopted by consensus which meant that a losing party could effectively veto an adverse finding. However, as a result of this provision in the DSU, a final decision is *automatically* adopted unless the DSB decides unanimously against it. Once adopted, if the offending party does not comply with the ruling, trade sanctions may be imposed on other areas of export in respect of which the

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[978] Annex 2 to the WTO Agreement, *supra* note 617.
[979] Article 3(2) DSU *ibid.*
[980] The Dispute Solution Body (DSB) administers the dispute resolution process (Article 2) if Members are unable to resolve their disputes at first instance informally through consultations (Article 4), conciliation or mediation (Article 5). It is only after such procedures have failed that a formal complaint should be brought.

parties ordinarily trade.[981] Just as TRIPS provides transitional and special provisions regarding LDCs, so too does the DSU.[982] The formality of the DSU makes it a very powerful institution. But, the TRIPS/DSU mechanism is *not* a court of last resort for corporations and private firms. Again, only Member states have standing to bring a complaint and as such, usually there would need to be a pattern of violation before a complaint will be made by a Member's trade representative. However, just as in litigation, some complaints may be made for tactical advantage and strategically as leverage against other existing complaints between disputing parties. For example, the US Trade Representative may agree to bring a complaint based on Ontario's continuing breach of MGLs BRCA1/2 patents for the breast cancer gene without licence and in violation of their patent rights as a political tool for resolving the existing US-Canada softwood lumber dispute.

Since these international norms are meant to legally bind nation states, they naturally derogate from the full sovereignty of their subjects. Jurisprudence professor Dennis Lloyd normalizes the relationship between internal sovereignty and international duty in order to derive a rational understanding of how this relationship fits with external rules of law. Lloyd contends:

> [e]very rule of international law imposes a legal fetter on national states in the international sphere, for this is the very sense and meaning of an international legal community. But within its own internal sphere the national sovereign still retains domestic sovereignty and may legislate or act in disregard of international obligations. But by so doing it cannot alter, abrogate, or lessen the force of these obligations *vis-à-vis* other states, and *will have to take whatever consequences its default may entail, having regard to the existing state of international law* and the sort of pressures which can be brought upon it in the particular circumstances.[983]

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[981] *Canada-Certain Measures concerning Periodicals*, March 14, 1997, WT/DS31/R (Panel); June 30, 1997, WT/DS31/AB/R (Appellate Body).

[982] Article 24 articulates special procedures involving least-develop country members for both violation and non-violation complaints and provides that "Members shall exercise due restraint in raising matters under these procedures involving a least-developed country."

[983] Lloyd, *supra* note 759 at 190.

Liability would be harmful to the state and its people but misgivings regarding the role of the WTO and its proper jurisdiction may prove more harmful as states may decide not to take human rights promoting actions that would otherwise be a regulatory priority, in order to avoid risking the costs of defending a complaint. Instead, just as in patent law, the weaker party may simply rationally acquiesce to demands in order to avoid "litigation" costs. Yet, "[s]tates *must* make rules for the effective functioning- in the social interest- of markets"[984] and should be able to defend these domestic measures.[985]

The public interest criterion appears at first blush to be totally absent in the TRIPS agreement, referred to as "a "charter of rights" for the patent holders..."[986] Respect for sovereignty, however, translates into respect for cultural diversity, domestically nuanced preferences, differences in morality, ethics, economics, politics, and social objectives of any given "public", and the ability to respond with diverse regulatory measures to universal (HR) claims. Such respect is essential for encouraging continued co-operation between the state and its citizens.

Michael Trebilcock and Robert Howse question the more extreme and indiscriminate claims for policy convergence and international harmonization of "within-the-border" domestic policy diversity. In their article, "Trade Liberalization and Regulatory Diversity: Reconciling Competitive Markets with Competitive Politics",[987] they argue that the welfare implications of policy harmonization are ambiguous and highlight the importance of competitive governments and politics over competitive

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[984] *Ibid.*
[985] The Doha Declaration lists 'the relationship between existing WTO rules and specific trade obligations set out in multilateral agreements (MEAs)' as a topic for negotiation, see Doha Ministerial Declaration, *supra* note 12. See also Pauwelyn, *Conflict of Norms, supra* note 12.
[986] Keayla, *supra* note 959 at 263-264.
[987] Trebilcock & Howse, "Regulatory Diversity" *supra* note 656.

markets while acknowledging that mutual benefits may be gained in consensual forms of harmonization of policy convergence through reducing the costs of divergence. The authors make the case for "substantial national political autonomy in formulating domestic regulatory and related policies even though such politics will often have significant impacts on resulting trade flows[,]"[988] so long as the principle of non-discrimination is observed. That is, domestic regulatory diversity should be encouraged so long as the policies or practices do not violate the National Treatment principle and are not forms of disguised or unjustifiable discrimination offensive to trade. One of the benefits of regulatory competition is that it allows the possibility of making informed evaluation of different approaches to regulation (and its efficacy) which may in turn lead to more transparency and regulatory competition at both the domestic and international level. Whatever the approach taken to the trade-human rights issues raised by the patenting life, it necessarily must be a sovereign one.

5.6 Conclusion

Economic theories that direct the trajectory of domestic fiscal policy and accompanied the emergence of social welfare programs *within* the State preceded the social and trade policy initiatives internationally marshaled in institutions like the World Bank, the IMF, the GATT/WTO and the UN in a postwar era. Trade liberalization proponents continue to recognize the neoliberal maxim that "creating wealth is a precondition to redistributing it."[989] Despite growth in production and world wealth,

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[988] *Ibid.* at 28

[989] Trebilcock & Howse, *supra* note 237. The authors observe that the post-war period of trade liberalization also witnessed significant real income and employment increases in Canada and the emergence of the welfare state: "Public expenditures in Canada on education rose from $147 per capita in 1947 to $1,237 per capita in 1983-4 in real terms (1986 $), or 1.99% of GDP to 6.79%. Public expenditures on health care rose from $54 per capita in 1947 to $1,202 per capita in 1985 in real terms (1986 $), or .72% of GDP to 6.18%. Direct financial benefits paid to Canadians under various social

however, "[p]overty amid plenty is the world's greatest challenge"[990] Neoliberal trade policies increase the wealth of a nation and thereby *allow* for its internal redistribution but they do not *ensure* it. It is true that liberalizing trade is a means of effecting *redistribution* of wealth *internationally,* by allowing for the transfer of goods, technology, and services from one state to another and ensuring that market competition maximizes the protection of consumer interests worldwide but it does not do this when it comes to IPRs. Neither the theory nor history of trade is incompatible with redistributive functions that underlie (social and economic) human rights and ideally inform state agency for their protection,[991] but TRIPS is. What is important is that the protection, promotion, and fulfillment of human rights remain at the forefront of political and regulatory agendas both domestically and internationally when debating patenting life because it is the human rights instruments that require, and in principle enable through the recognition of *rights,* redistribution to be effective *locally* and individually.[992] As Louis Henkin aptly stated: "[E]very individual has claims upon...society- both claims to freedom from undue governmental intrusion and claims for governmental support for economic and social welfare."[993]

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welfare programmes amounted to $49, 136 million in 1985, compared with 1947 expenditures of $3,838 million...Trade liberalization and trade expansion have not been inconsistent with these redistributional, social and cultural policies....[O]nly relatively prosperous countries can afford generous social policies. Impoverished third world countries...do not have the wealth to afford them" (*ibid.* at 13).

[990] See World Bank Development Report 2000/2001, *Attacking Poverty, supra* note 702 at v.

[991] See generally Michael Trebilcock, "Critiquing the Critics of Economic Globalization", (2005) v. 1(102) J. of Int. Law & Relations 213.

[992] Generalized indicators for growth and redistribution may be misleading. It is the difference of looking at growth of individual incomes *between* countries (and making the erroneous assumption that all people in one country earn the average income for that country) and using the more accurate measure for income inequality that would consider disparities of individual incomes *within* a country. See Branko Milanovic, "True World Income Distribution, 1988 and 1993: First Calculations Based on Household Surveys Alone" (2002) 112 Econ. J. 51.

[993] Louis Henkin, *The Rights of Man Today* (Boulder: Westview Press, 1978) at 10.

Although IPRs are "in essence, government tools for regulating markets in information" write Drahos and Braithwaite, "the problems of government capture...have led us to the view that there should be a presumption against the use of these rights to regulate markets rather than a presumption in their favour."[994] Regrettably, that has not been the case. In Canada, Parliament has created IP rights but failed to regulate the application of this system in relation to biological and genetic matter. Other jurisdictions should be forewarned of the implications of leaving such a sensitive and human rights impacting issue for judicial determination. And, civil society should continue to bring public awareness to an issue that has for too long escaped formal scrutiny and debate, demanding compliance with the various instruments protecting their birth rights, especially at a time when other countries can incorporate human rights sensitivity as they establish their national IPRs regimes in order to comply with TRIPS. Any encroachment on individual liberties, social, and economic rights should occur by parliamentary will in a participatory democracy rather than a creeping common law expansion by the judiciary in the course of patent litigation as judicial agency cannot substitute for state agency here- there is far too much at stake and markets often fail.

While the global capacity for food production has increased exponentially with the advent of new technologies, for example, famine continues to exist despite the promises of biotech used to justify patent monopolies in food, plant, and seed sectors. These failures may be better characterized as *political* ones since the correction of market failure relies on the will of government(s) to intervene, and not just on behalf of property

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[994] Drahos & Braithwaite, *supra* note 116 at 3.

owners.[995] A state needs to be made accountable for its failures and able to defend its successes in terms of a just world order. Protecting human dignity from political failure is a dominant function of human rights instruments and is further promoted by trade liberalization efforts which are premised on a reasonable assumption that greater economic interdependence and greater market competition would lead to friendlier and peaceful relations, global prosperity, and lower consumer costs. These were the goals of both institutions for global governance as the historical and institutional review in this chapter has revealed.[996] They protected against state intrusions on fundamental values of humanity which could not be compromised in the name of politics, economics, efficiency, utilitarianism, totalitarianism, racism etc. Regrettably, an adverse effect may materialize from the felt injustice of increased global aggregate wealth in absolute terms (due to economic liberalization) but a heightened sense of poverty and perceived human rights violations in relative terms- due to the neglect of these rights as an effective means for achieving wealth redistribution.

The new WTO rules post Uruguay have been criticized for their more ambiguous domestic and global welfare effects when compared to the traditional GATT rules:[997]

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[995] "Often people are simply *fleeing* from starvation, as in the Irish famine of the 1840s. Yet famines are often themselves in large part caused by *political failures* and the absence of decent governments." See Rawls, *supra* note 18 and reference to Amartya Sen, *Poverty and Famines* (Oxford: Clarendon Press, 1981) and Sen with Jean Dreze *Hunger and Public Action* (Oxford: Clarendon Press, 1989) – *"confirms these points and stresses the success of democratic regimes in coping with poverty and hunger*(at 109).

[996] The purposes of the United Nations are set out in Article 1 of the UNC and includes the maintenance of international peace and security, (Art. 1.1) the development of friendly relations among nations based on respect for the principle of equal rights and self-determination of peoples (Art. 1.2), and the achievement of international co-operation in solving international problems of an economic, social, cultural, or humanitarian character, and in promoting and encouraging respect for human rights and for fundamental freedoms (Art. 1.3) and to be a Centre for the harmonization of state actions for the attainment of these 'common ends' (Art. 1.4).

[997] See *e.g.* Howse, Technocracy, *supra* note 603 at 99 and 102: "The belief that the removal of trade restrictions is Kaldor-Hicks efficient cannot be reduced to *just* blind ideological faith- in many situations the empirical evidence suggests that one could and should replace trade restrictions with other policy instruments, and make everyone better off." See also Michael J. Trebilcock, Marsha A. Chandler, &

> These rules could not be justified through the idea of Kaldor-Hicks efficiency- there is no particular reason to believe on the basis of economics that increasing intellectual property protection will increase aggregate domestic welfare. Some countries gain from increased patent protection and some countries lose; aggregate welfare may increase or decrease. And the issue of who gains and who loses *within* a given society rears its head and cannot be avoided or suppressed by any idea tractable to technocratic management of the trading system.[998]

While economic ideology has seemingly replaced the 'embedded liberalism'[999] foundational to the origins of the trading system, ultimately, it is a moral and not an economic question we are left with, because, as Thomas Cotter concludes, "economics may help us to predict the possible consequences of various legal rules, but the ultimate decision whether those consequences are good or bad, and therefore whether the rules should or should not be adopted, must rest upon moral principles to which economics does not speak."[1000]

Foreign-based subsidies of first world intellectual objects through universal prescriptions under TRIPS increase the size of the pie but some parties continue to go hungry while others have secured a larger slice. Within developed contexts, we need greater political accountability for the broad indirect subsidy of innovation through taxation to pay for public goods clustering infrastructure (i.e. public education and health) for private benefit.

If the WTO were to remain insensitive to modernity's social demands, as an institution it would risk being undermined by a reasonable apprehension of bias in favour of private capital, corporate interests, and the dominant cultural and legal imperatives of the North and developed members that shape *its* institutional culture and politics. The

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Robert Howse, *Trade and Transitions: A Comparative Analysis of Adjustment Policies* (United Kingdom: Routledge, 1990).

[998] See Howse, Technocracy, *supra* note 603 at 102. See also Alan V. Deardorff, "Should Patent Protection Be Extended to All Developing Countries?" 4 *The World Trading System: Critical Perspectives on the World Economy* 37 (Robert Howse ed., 1998).

[999] See in text, *infra* page 358.

[1000] Thomas F. Cotter, "Introduction to IP Symposium" (2002) 14 Fla. J. of Int'l L. 147 at 151.

impact of this risk is increasing public protest, gradual non-participation, and disregard by the vast majority of less privileged member states. At this time, efforts to recalibrate the balance in favour of justice and fairness has developed countries, like the United States, aggressively pursuing negotiations for greater protections and gains bilaterally and regionally in preferential treatment agreements (PTAs). This is the WTO's dangling sword. It is no wonder that social movements animating counter-narratives of anti-globalization activism equate the politics of globalization and economic integration woes with the WTO as an institution;[1001] they embrace, in the debate as they often do, vocabularies of human rights and the discourse of cultural difference.[1002] But, as the UNDP report has outlined, TRIPS "future will depend on the decisions taken by the dispute settlement body, which will determine to what extent the agreement is implemented *in line with the social and economic development objectives of member nations.*"[1003] We are, by law, entitled to such an order[1004] and would do well to heed UN Secretary General, Kofi Anan's eloquent appeal: "Let us choose to unite the powers of markets with the authority of universal principles."[1005] To do so would reconcile human

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[1001] "Unsurprisingly, skeptics extend many of the criticism they make of the IMF and the World Bank to the World Trade Organization…If anything, they detest the WTO even more." See "A Survey of Globalisation" *supra* note 621at 3-30.

[1002] Even though, according to Coombe, "These new social movements express forms of aspirations that deploy the rhetoric of international human rights, indigenous rights, and environmental agreements in ways that nonetheless significantly exceed the modern categories that dominate rights claims. If these assertions are made in cultural terms, it may be because the area of cultural rights is the least interpreted of the human rights fields and thus most amenable to claims that combine but go well beyond our modern understandings of the political, the economic, the social, and the cultural. The specific paradigms of Western modernity and rationality that govern human rights laws are arguably too narrow to encompass the aspirations for social justice expressed by the world's poor in their resistance to the violence of modernization and the destruction wrought by state and capitalist development projects." Coombe, "Legal Claims to Culture" *supra* note 141, 32-55.

[1003] UNDP, *Making Trade Work, supra* note 747 at 222, emphasis added.

[1004] See Article 28 of the UNDHR, *supra* note 777.

[1005] See UN Global Compact, online: <http://www.unglobalcompact.org/Portal/>.

rights principles with trade objectives, honouring the sage message inscribed on the plaque outside the founding stone of the WTO: "if you seek peace, cultivate justice."[1006]

[1006] *Si vas pacem cole justitiam* cited in Adelle Blackett, "Whither Social Clause? Human Rights, Trade Theory and Treaty Interpretation" (1999) 31 Colum. H.R.L. Rev. 1at 5 and n. 5.

Chapter Six

Reconciling Competing International Obligations: *The Equitable Conduct Defence and the Stewardship of the WTO*

> We can sit down and look at the realistic possibility of making the WTO work for the whole world. We should be realistic. We shouldn't be kidding ourselves that the WTO is all right at the moment. It's not all right.[1007]
>
> The purpose of the law is to prevent the strong from always having their way.
> - Ovid

6.1 Introduction

This chapter provides the second of the two-pronged normative prescriptions advanced in this dissertation for appropriate state response to competing international obligations in the context of patenting life. Given the significant tensions between IPRs and HR reviewed in the last chapter, and the imperative for state agency, my concern in this chapter is to "cultivate justice" by re-uniting markets with universal principles and advocating for a human rights approach to dispute settlement. In addition to its 2006 country specific HR Committee review of its ESCRs commitments, Canada is precariously listed on the Special 301 watch list of the United States for failing to adopt stricter IPR standards. To review, the first branch of my bifurcated approach set out in chapters three and four would address the domestic need for improving patent system efficiency and efficacy, achieving cross-policy co-ordination to better meet the public's interest, and provide a means of reconciling international obligations with domestic law. Nevertheless, a Member may become party to a complaint contesting its measure(s) as a violation of TRIPS. This chapter considers what a state can do to defend the regulatory choices it makes to balance patents and public health or any of the other key trade-human

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[1007] Supachai Panitchpakdi (WTO Director-General as of September 2002), "Keynote Address: The Evolving Multilateral Trade System in the New Millennium" (2001) 33 Geo. Wash. L. Rev. 419 at 432.

rights issues raised at the nexus of biopatenting should the matter proceed to dispute settlement at the WTO. If the normative prescriptions advanced in this dissertation are to exist as more than a hortatory homily, they will have to be supported by collective individual and institutional action because the issues surrounding the patenting of life forms are complex and need to be mediated between governments and their respective publics. Until instrumental change is affected in trade agreements, the jurists comprising decision making bodies of the WTO remain charged with the task of interpreting trade obligations in a harmonious way with HR commitments[1008] because the absence of a supra-government has meant that social welfare, measured by consumer benefits under trade, has come with the compromise of individual rights which guarantee the just *distribution* of these welfare gains. This lack of a world government need not become determinative of social justice- an ongoing concern expressed in criticisms of the WTO.

Economist and Nobel laureate Amartya Sen finds the "compelling need in the contemporary world is to ask questions not only about the economics and politics of globalization, but also about the values and ethics that shape our conception of the global world."[1009] Trade liberalization and economic integration offer welfare gains for world citizens but "the greatest challenge facing the WTO today is also the greatest challenge facing the world. That challenge is the ever-increasing inequality that characterizes the division of income and assets on our planet."[1010] Some scholars believe that the division between and within nations is growing and is exacerbated by trade

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[1008] This is consistent with the UN High Commission's recommendations for a HR approach to trade and IPRs, discussed in text *supra* 321 and accompanying notes.
[1009] See Amartya Sen, *Globalization: Value and Ethics*, Talk given at Falcone Foundation, May 23, 2001, online, <http://www.fondazionefalcone.it/sen.html>.
[1010] Buckley, *Changing Face, supra* note 602 at 3.

liberalization;[1011] this view is increasingly shared by many NGOs. Mendes and Mehmet write,

> [t]he technical responsiveness to the changing picture of global trade shown in the establishment of the WTO is not matched by a sensitivity to existing and emerging trends in the social dimensions of trade, including labor, the environment, and human rights....[M]any have argued that the impressive responsiveness to the growing importance of services and intellectual property by the trade experts has ignored the possible conflict between the rules of these new trade areas and certain categories of human rights.[1012]

The treatment of economic liberalization as an *ends* instead of a *means* has raised tremendous concerns for civil society. The Report of the Canada Standing Committee on Foreign Affairs and International Trade captures these concerns cogently:

> For example, health, consumer, student and other social advocacy groups raised issues with respect to: the right of entry, establishment and "national treatment" for private health and educational services corporations; the extensions of patent rights for pharmaceutical drug companies; trademark rights in relation to cigarette packaging; the patenting by large transnational enterprises of genetically modified organisms and other life forms. Whose rights need to be protected in the public interest? What is consistent with international human rights norms?[1013]

As a result, the WTO must find a means to

> manage globalization in such a way that its benefits are shared far more equally among individuals than is today the case...not merely desirable on grounds of fairness or ethics, though it is utterly defensible on those grounds, [but]...is essential if we are not to slide backwards into a less interdependent, and far poorer world.[1014]

[1011] "The richest 1 per cent of people in the world earn as much as the bottom 57 per cent; in other words, less than 50 million of the richest people earn as much as the 2,700 million poorest people...If we look at assets rather than incomes, the richest 20 per cent of humanity owned 60 times as much as the poorest 20 per cent in 1990 and 74 times as much in 2000, and three men, the two founders of Microsoft, Bill Gates and Paul Allen, and the investor Warren Buffet, own as much as the 600 million people in the world's 48 least developed countries." Buckley, *ibid.* at 3-4 [footnotes omitted]. See also Branko Milanovic, Development Research Group, World Bank (taking into account income disparities within each country as well as between in 'True World Income Distribution, 1988 and 1993: First Calculations Based on Household Surveys Alone' (2002) 112 *Economic Journal* 51 and his new treatise, *Worlds Apart: Measuring International and Global Inequality* (New Jersey: Princeton University Press, 2005); for trends in global inequality, see "World Inequality," *BBC News,* 18 July 2001, online www.news.bbc.co.uk.

[1012] Mendes & Mehmet, *supra* note 598 at 72.

[1013] Report of the Standing Committee on Foreign Affairs and International Trade: Canada and the Future of the World Trade Organization, Advancing a Millennium Agenda in the Public Interest (Cndn Millennium Report), Chair Bill Graham, MP. (Ottawa: House of Commons, Canada, 1999) at 11-7. [CHECK]

[1014] Buckley, *supra* note 602.

Issues at the intersection of trade and human rights typically are concerned with the propriety of a domestic trade-impacting measure.[1015] Trade purists believe the system should remain insulated from extraneous considerations and that balancing policy concerns (the so-called 'social dimensions') is not within the WTO's mandate or jurisdiction. Critics conversely argue that fairness demands a purposive interpretation to be given to State obligations in order to integrate the international trade system into a *cohesive* and *coherent* system of public international law.[1016] Debate about a 'social clause', justice, and equity, and the burgeoning so-called "trade-and___" scholarly literature are testaments to the challenges of uncertainty the WTO faces. The institutional deficit for welfare maintaining mechanisms and constitutional protections coupled with the effective trade compliance-enforcing dispute settlement procedures has embroiled the WTO in controversy and myopically- rendered it "'public enemy number one' on the anti-globalist agenda."[1017] Matsushita *et al.*, identify some of the charges:

> 1. The WTO serves the interests of transnational corporation to the detriment of developing nations and the poor.
> 2. The WTO is anti-democratic and violates national sovereignty.
> 3. The WTO elevates property interests over human rights and health. It particularly "enshrines" intellectual property rights.
> 4. The WTO is hostile to protection of the environment, workers' rights, agriculture, food safety, and social welfare generally because it strikes down protection of such interests as trade barriers.
> In summary, to some, the WTO and globalization are forces for oppression, exploitation, and injustice.[1018]

[1015] The trade-human rights nexus is discussed in a variety of specific contexts. See *e.g.* Blackett, *supra* note 1006 focusing on trade and labour standards; McDonald, *supra* note 688 on trade and the environment; see generally Stephan Bottomley & David Kinley, eds., *Commercial Law and Human Rights* (USA: Dartmouth Publishing Company, 2002) arguing commerce and HR are not mutually exclusive.

[1016] Just as this principle has been used liberally within patent law to provide significant latitude but instead to property holders by interpreting, for example, perpendicular to mean more or less so. Public international law refers to the body of law traditionally governing state relations while private international law ("conflict of laws") is the corpus of domestic law governing relations with foreign law.

[1017] See generally Matsushita *et al.*, *World Trade Organization: Law, Practice, and Policy* (Oxford: Oxford University Press, 2003). The entire text is devoted to negating this judgment of the WTO by explaining the law, institution and function of the WTO and the ways in which it can be improved, on its own terms to address social concerns. See also the rejoinder to these charges offered by Trebilcock, "Critiquing the Critics of Economic Globalization", *supra* note 991.

[1018] *Ibid.* at vii.

All of these complaints, in fact, also dominate the discourse surrounding patenting life forms. The fields of biology, medicine, and life sciences have experienced substantial growth due to advancements in biotechnology and nanotechnology that allow for the manipulation of living matter at a genetic and atomic level and open newfound opportunities in the health and food sectors that *are* human rights promoting technologies but because of profound profitability, they are "fenced off" with exclusive property rights and thereby raise human rights issues.

External liberalization has entrenched itself in the international community with agreed upon economic obligations becoming binding and enforceable through new dispute mechanisms developed to ensure compliance under the auspices of the WTO. Yet the effective means of acquiring and enforcing constitutional-like rights that are germane, by liberal democratic ideals, to the development and operation of any nation state and the dignity of its peoples are notably absent in our global institutions. Trade agreements are no longer confined to ensuring trade 'free from discrimination' but have expansively encroached through language, law, and ideology, into the sovereignty of members with a new monolithic mantra of trade essentially free from regulatory burden.[1019] As our preceding discussion has established, since the state is the purveyor of IPRs, the state's role is central to the realization, or alternatively the violation, of human rights obligations. Yet governments may legitimately believe that any derogation from patent rights would attract potential liability under TRIPS in terms of trade sanctions. Does the TRIPs text allow for concurrent compliance of Members with HR instruments? Or will the global economy continue to be dictated by the coercive suasion of its political

[1019] D. Driesen, "'What is Free Trade?' The Real Issue Lurking Behind the Trade and Environment Debate" (2001) 41 Va. J. Int'l L. 279, cited in McDonald, *supra* note 640 at 145, n. 1.

economy with the private power of corporations the puppeteer of public law? This is the question occupying NGOs,[1020] public interest advocates, special interest groups,[1021] academics,[1022] government advisory committees and other institutional players analyzing issues surrounding a fundamental question of whether the rights to life can be owned.

TRIPS obligations are not necessarily *antithetical* to human rights,[1023] though they provide a position of privilege through the power of an exclusive grant of monopoly. The provisions require further consideration in terms of the obligations they impose on the rights holder and the *justifications* allowed for divergence in certain contexts in order to account for the human rights of individuals and state obligations for their realization.[1024] Sovereignty and self-determination require discretion to regulate on the patenting of life domestically without threat of trade-related interference as much as the substantive intersecting rights such as health, food, and the right to benefit from scientific progress independently oblige the state (even if in terms of a negative right to be free from harmful government intrusion). While WTO literature analyzes globalization's impact,[1025] the

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[1020] For strong advocacy in this area, see Rural Advancement Foundation International http://www.rafi.org/, Third World Network (TWN) at http://www.twnside.org.sg/, and Genetic Resources Action International (GRAIN) at http://www.grain.org/publications/it-november-2001.cfm.

[1021] For the concerns of the indigenous community, see Debra Harry, Indigenous People's Council on Biocolonialism, online: <http://www.ipcb.org/pub/>.

[1022] See Amani and Coombe, *supra* note 49. See also Marjorie Cohn, "The World Trade Organization: Elevating Property Interests Above Human Rights", 29:3 *Georgia Journal of International and Comparative Law*, (2001) 427-441.

[1023] Industry competition ensures that medical/technological advancements will be sooner made and theoretically sooner enjoyed by society consistent with long-term health policy.

[1024] When the interests are characterized as HR, they may be distinct in their persuasiveness and contribution to the international dialogue from traditional moral and ethical arguments. As human rights, they have a separate line of authority as customary law and can provide for a different form of accountability, attaching to varied subjects. See *e.g.* Ryan Goodman and Derek Jinks, "Measuring the Effects of Human Rights Treaties" (2003) 14.1 EJIL, 171-183.

[1025] See Robert McCorquodale and Richard Fairbrother, "Globalization and Human Rights", 21 Hum. Rts. Q. (1999) 735-766. For a defense of globalization, see "A Survey of Globalization" *supra* note 621. For an alternate view, on how globalization is resulting in increased income inequality and poverty and challenging the view that poverty is best reduced through growth oriented, rather than distributive policies, see Giovanni Andrea Cornia, "Liberalization, Globalization and Income Distribution", Working Papers No.

consequences of economic integration,[1026] and the protection of human rights in a trade regime,[1027] often the focus is on the potential use of restrictive border measures on imports, such as quotas or tariffs,[1028] to offensively elicit human rights compliance in another *exporting* nation.[1029] What this chapter seeks to do is to contour the conceptual framework for global co-operation and relate the objective of this framework to how a dispute settlement body should proceed to "adjudicate" measures taken to protect domestic human rights in alleged violation of TRIPS, given the theoretical, historical, institutional, and instrumental development of our global governance institutions in a manner that moves beyond charity towards justice as a means of promoting development and dignity. State discretion to prioritize HR should be re-imagined as a contribution to the co-operation paradigm in terms of promoting 'self-help' by the state, so long as the trade contested measure is adopted on a non-discriminatory basis. Because no external threat exists under UN HR instruments where sovereign discretion is exercised to give

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157, March 1999, The United Nations University World Institute for Development Economics Research, at http://www.wider.unu.edu/publications/wp157.pdf.

[1026] See Trebilcock, "A Qualified Defense", *supra* note 616, 319-329.

[1027] See *e.g.* Hoe Lim, "Trade and Human Rights: What's at Issue?" 35(2) J. of World Trade, (2001), 275.

[1028] Non-Discrimination and reducing quantitative restrictions are the two main pillars of the multilateral trade system. Tariffs (import duties) are a barrier to trade because they add costs to consumer purchase prices and thereby make foreign exported producers less competitive with domestic producers who are not subjected to this additional cost of doing business. If quotas were not reduced or eliminated, quantitative restrictions would simply substitute for tariffs (See GATT Article XI prohibiting quotas).

[1029] Most of the literature has traditionally focused on debates around the legitimacy and ability to use trade sanctions to affect foreign policy objectives. See *e.g.* Michael Trebilcock, "Trade Policy and Labour Standards: Objectives, Instruments, and Institutions" (2001) University of Toronto Research Paper No. 02-01, online http://ssrn.com/abstract/_id=307219; Sarah Cleveland, "Human Rights Sanctions and International Trade: A Theory of Compatibility" (2002) 5(1) J. Int'l Econ. L. 133; Robert Howse, "India's WTO Challenge to Drug Enforcement Conditions in the European Community Generalized System of Preferences: A little known Case with Major Repercussions for 'Political' Conditionality in US Trade Policy" (2003) 4 Chicago J. Int'l L. 385-405. See generally Vazquez, *supra* note 768 wherein the bluntness of economic sanctions as a mechanism for coercing HR compliance in trading partners is commented on with consideration to the potential ramifications of sanctions and withdrawal of economic engagement as potentially penalizing not the elite decision makers or governments but rather 'devastating an already much abused populace.' Of course, that is the intention since an unhappy constituency will bring greater pressure for political change. See *e.g.* Craig Forcese, Globalizing Decency: Responsible Engagement in an Era of Economic Integration" (2002) Yale Human Rts. & Dev. L.J. 1for an informative analysis of "smart sanctions" and the desirability of responsible engagement with repressive regimes.

trade policy priority, this chapter is concerned with developing an international response to neutralize the disincentive to domestically prioritize HR under fear of complaint and possible countermeasures by way of trade sanctions. By addressing the legal implication of policy preferences, it is hoped that citizens can more transparently target their governments to hold them accountable for the political influences affecting regulatory outcomes.

In this chapter, I review state commitments to distributive justice under both trade and human rights instruments and the Millennium Goals to support the assertion that human rights (HR) and human development (HD) are necessary correlatives for a coherent international system. On this basis, I argue that a HR/HD approach is what is needed to restore the legitimacy of the WTO and to achieve (distributive) justice through its dispute settlement mechanism. This perspective informs the development of my second branch of the prescribed framework for state response to competing obligations. After examining the jurisdiction of the WTO by review of key provisions, the location of conflict with other international law, and the legal arguments for treaty interpretation, this chapter posits that any complaint raised under TRIPS intersecting with legitimate health or other HR obligations be interpreted in a conciliatory rather than a conflicting manner to promote state rights and remedy unjust institutional arrangements. Failing this, WTO panels and the Appellate Body, in their juridical capacity should recognize an "equitable conduct defence" based on the language of the TRIPS text that respects state discretion to domestically prioritize human rights obligations; this defense would be open to the entire WTO membership. By corollary, an important ideological and legal question is raised: What ought to be the jurisdiction of the WTO? Helleiner asks rhetorically,

> What sort of World *Trade* Organization is it, after all, that doesn't seriously concern itself with trends and fluctuations in its members' terms of trade particularly those of its weakest and most vulnerable members? Or with "burdensome surpluses" (as the ITO charter called them) in primary commodity markets? Or with restrictive business practices and abuse of dominant power in international goods and services markets? While it has so far paid scant attention to such obvious *trading* issues it has moved deeply into such *domestic* policy issues as intellectual property regimes, domestic investment and subsidy policies and some would even push it into labour standards and environmental practice, all of which may or may not, in fact, be "trade-related"? On the basis of current practice it might better be called the World Market Harmonization Organization. [1030]

These comments are accurate and should galvanize movements towards a WTO that more effectively achieves a balanced interpretation of texts and dispute settlement and reconciles trade with its social dimension. I am optimistic that potential conflicts between trade and human rights related to patenting life are, accordingly, resolvable if not through reconciliation then by defensible regulatory diversity at the WTO.

6.2 A Global Co-operation Ethic & Renewed Commitments to "Development"

The last chapter demonstrated how trade law, like human rights law, emerged to promote friendly relations through economic interdependence and to facilitate and expedite development in poorer countries on the rationale that the world as a whole would be a more secure and prosperous place if its constituent nations and peoples within nations were secure and prosperous. With the rise of the welfare state, social welfare maximization objectives created a responsibility on the individual to act, to some extent, as his 'brother's keeper' (through tax-subsidized state-run welfare programs). By extension, richer developed countries were commonly recognized to owe a similar duty, in accordance with the same political ideals, to assist poorer countries.[1031] This sense of responsibility may have significantly impacted the changing face of international law over the last 50 years since the inception of the UN, from one based on state to state

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[1030] Helleiner, *supra* note 719 at 12.
[1031] See Rawls, *supra* note 20, item five on his list.

interaction to a more comprehensive global legal order, transcending state boundaries for the 'common good'. The accompanying intrusion of international trade law on state sovereignty is considered justified *because* of the recognized *duty* of wealthier nations to assist poorer countries to become *developed.* John Ruggie characterizes this as "embedded liberalism" which helped garner initial political support (as a projection of dominant national and philosophical trends primarily in the United States at the time) for a multinational trading regime tolerant of domestic regulatory variance emerging out of Bretton Woods.[1032] Trade liberalization "was embedded within a *political* commitment," writes Howse, that was

> broadly shared among the major players in the trading system of that era, to the progressive, interventionist welfare state; in other words, to a *particular* political and social vision, including at the same time respect for diverse ways of implementing this vision...[1033]

With time, "[a]t the hands of this trade policy elite, "embedded liberalism" came to be recast as *economics, and economics became ideology, the ideology of free trade*"[1034] such that the contingent nature of the bargain underlying the political foundation for free trade and the welfare state soon became forgotten[1035] and trade policies shifted from eliminating tariff barriers and border restrictions to the trade impact of non-tariff barriers including domestic regulatory and policy interventions.

[1032] Nicolaidis and Howse explain this as "a conception of the complementarity between bargained trade liberalization, on the one hand, and the evolution of the domestic welfare and regulatory state, on the other. This outlook tolerated significant national differences in the manner of delivering the social welfare function [which]...did not need to threaten increasingly liberal co-operative equilibria in the trading regime." See *supra* note 600 at 775.

[1033] Howse, "Technocracy", *supra* note 603 at 97. See Also Anne-Marie Slaughter, "Regulating the World: Multilateralism, International Law, and the Projection of the New Deal Regulatory State" in Robert Howse (ed.) *The World Trading System: Critical Perspectives on the World Economy* 50 (1988) reprinted in John Gerard Ruggie, *Multilateralism Matters* (New York, Columbia University Press, 1993) at 125.

[1034] Howse, "Technocracy", *supra* note 603 at 99.

[1035] Howse goes on to criticize the result, however: "The very success of the embedded liberalism bargain, along with other phenomena, led to forgetfulness or amnesia concerning the political foundation of the postwar trading regime, its character as a specific and contingent bargain about the interaction between freer trade and the welfare state." *Ibid,* at 98. See also Dani Rodrik, *Has Globalization Gone Too Far?* (Washington, D.C.: Institute for International Economics, 1997).

Trade and HR objectives are not inherently inconsistent, however. Economic prosperity facilitates, though it does not ensure for distributive reasons, the realization of all human rights (economic, social, civil, and political) and the improvement of aggregate world social welfare. Increasing global welfare should have the results of increasing human rights which are "income elastic"- meaning that demands for these will increase with the wealth of a society since HR require infrastructure and credible legal systems which in turn are costly to administer.[1036] Nevertheless, even in liberal democracies committed to the greatest good for the greatest number, such utility is always subjected and *subjugated* to the rights of the individual. Therefore, values that compete with trade norms, Pauwelyn asserts,

> [w]hen genuinely pursued, that is, when not abused as disguised restrictions on trade, such goals must trump the instrument of trade, even if they are not set out in the WTO treaty itself. This should be particularly so in case these goals have been defined in other, non-WTO rules of international law as between WTO members that have agreed to those rules.[1037]

Steve Charnovitz studies the interstices of global governance, advocating that international trade law should not be isolated from the other dimensions and spheres of international law because, as vital as trade is to economic *and human development*, it is not solitary in its contribution to these ends and may justify restriction in circumstances for the achievement of *other social goals*.[1038]

Under the UN Millennium Development Declaration (MDD) a list of Millennium Development Goals (MDGs) were articulated to galvanize world nations to co-operate towards their achievement. The MDD, adopted in 2000 at the largest ever gathering by

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[1036] Alan O. Sykes, "International Trade and Human Rights: An Economic Perspective", (2003) U. Chicago Law & Economics, Olin Working Paper Series John M. Olin Law and Economics Working Paper No. 188, The Chicago Working Paper Series, http://www.law.uchicago.edu/Lawecon/WkngPprs_176-200/188.aos.human-rights.pdf. , now published in Thomas Cottier, (ed.,) *International Trade and Human Rights: Foundations and Conceptual Issues,* (USA: University of Michigan Press, 2006), 29-40.
[1037] Pauwelyn, *Conflict of Norms, supra* note 12 at Preface xi.
[1038] See Charnovitz, *supra* note 645.

heads of State, revitalizes the political commitment to improving the human condition worldwide by making a compact to meet concrete *targets* set for advancing development and reducing poverty by 2015.[1039] The MDGs also reinforce national commitments to ECSRs by providing further positive state undertakings in relation to wealth distribution and the realization of welfare rights which were also being pursued by DCs and LDCs in the Doha Development Round of trade negotiations. To deny these goals would be to deny the significant commitment made in the first half of the 20th century to the institutions for governing international relations and the normative justification for their existence. The commitment pledged by 191 UN Member States is to meet eight stated goals which strive to achieve at a global population level the protection of individual rights articulated in the ICESCR: 1) the eradication of extreme poverty and hunger; 2) the attainment of universal primary education 3) the promotion of gender equality and female empowerment; 4) the reduction of child mortality; 5) the improvement of maternal health; 6) combat HIV/Aids, malaria and other diseases; 7) ensure environmental sustainability; and 8) develop a global partnership for development.[1040]

Patented seeds and GM plants impact the eradication of poverty and hunger, affecting access to food and farmer's rights; genomic, proteomic, and life patents extending to diagnostics and the genetic makeup of viruses and bacteria impede population based improvements to maternal health, child mortality, and eradication of diseases such as malaria and AIDS, and the widespread economical use of (plant derived) vaccines; and, environmental sustainability and cultural diversity are impaired by the

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[1039] See *Millennium Development Goals: An Overview setting out universal primary education as the second Millennium Development Goal*, online: <http://hdr.undp.org/reports/global/2003/pdf/hdr03_overview.pdf>.

[1040] UN Millennium Development Goals, online: United Nations, <http://www.un.org/millenniumgoals/#>.

privatization of traditional (cultural) knowledge. Strong uniform standards of IPRs will adversely affect the realization of several of these, most importantly, a *global partnership for development,* for its potential to subsume all of the other substantive goals.

Committing to partner towards development targets to deal with developing countries "special needs" would include a commitment to reducing their "debt". It might also include, with private sector co-operation, making essential medicines available and might even extend to "[d]evelop further an open trading and financial system that is rule-based, predictable and non-discriminatory, includes a commitment to good governance, development and poverty reduction-nationally and internationally."[1041] Since development and rights are linked, it would mark an equal commitment to human rights. Discretion over domestic regulation is a manifestation of self-determination of protections needed to preserve biodiversity, cultural diversity, and cultural knowledge, simultaneously serving both MDGs and ICESCR obligations.[1042] The MDGs transplant to the global community the premise of the welfare state and aim to further the attainment of social welfare and distributive justice simultaneously as part of the economic growth maximization mandate central to efforts for reducing trade barriers. These Goals are consistent with the embedded political liberalism of states that helped usher in the UN and multilateral trade system in a post-war era and reaffirm our moral role as 'our

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[1041] *Ibid.*

[1042] See generally Coombe, "IP, HR, & Sovereignty", *supra* note 54 94 writes "[T]he value of cultural diversity and its relevance to conserving biological resources warrant an effort to address the loss of cultural knowledge...[C]ultural knowledge can only be conserved by keeping it alive and in use....Turning public goods into private property is now heavily promoted for conservation purposes. Unfortunately, this is also a high-risk method for societies and cultures that have long been subordinated. Privatization of biological resources could result in greater poverty and exploitation without achieving conservation or equity."

brother's keeper.'[1043] With the MDGs, the duties corresponding to the ESC rights have been *formally* extended beyond individual states in relation to their citizens to the international community.

Co-operation for the purpose of *development* under the MDGs (and the Doha Round) confirms the overarching commitment of nations and fosters new optimism for a coherent international legal system which safeguards UN objectives while reconciling them with the complementary *means* that multilateral trade offers to achieve these *ends*. Alternative means should also be reflected upon because,

> [t]here is no technical reason, for example, why hunger and poverty should not be eradicated. Nor is there any technical reason why remarkable advances in medical science should not greatly improve the health and well-being of people around the world. Economic and political obstacles to realizing these goals are legion...This is a time for questioning—questioning the assumptions underlying current models of development, the concepts used to construct these models, and the methodologies that have been chosen to generate basic social and economic information. It is a time for constructing alternative scenarios.[1044]

Economist Jeffery Sachs, Director of the Millennium Project and special advisor to former UN Chief Secretary General Kofi Annan, argues that the goal to halve poverty by 2015 can be met by increasing annual foreign aid to .7% of Gross National Product (GNP) starting with an extra $70 billion per year as of 2006.[1045] His comprehensive "clinical economics" approach to solving wealth distribution accounts for the web of inter-related problems that perpetuate poverty and hunger. Sachs strongly advocates increasing foreign aid but explains the reality of how the money is spent:

> From the world as a whole, the amount of aid per African per year is really very small, just $30 per sub-Saharan African in 2002. Of that modest amount, almost $5 was actually for consultants from the donor countries, more than $3 was for emergency aid, about $4 went for servicing Africa's debts and 4% was for debt-relief operations. The rest, about $12 went to Africa. Since the "money down the drain" [that giving makes no difference] argument is heard most frequently

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[1043] David Kelley observes that "[t]he welfare state...rests on an idea. The thinkers and activists who built it insisted that the social provision of goods be treated as a right possessed by all people as citizens, rather than as an act of charity or noblesse oblige, a gift from some to others..." *Supra* note 783 at 257.
[1044] See the UN Research Institute for Social Development (UNRISD), http://www.unrisd.org.
[1045] Helleiner, *supra* note 719.

> in the U.S., it's worth looking at the same calculations for U.S. aid alone. In 2002, the U.S. gave $3 per sub-Saharan African. Taking out the parts for U.S. consultants and technical cooperation, food and other emergency aid, administrative costs and debt relief, the aid per African came to the grand total of perhaps 6¢.[1046]

The normative Rawlsian claim of a duty to assist[1047] is confirmed in global agreements like the MDGs, the Monterrey Consensus of 2002, and renewed commitment to both at the 2005 World Summit[1048] where the United States promised to give a larger proportion of its annual output (up to .7% of GNP) to official development assistance. But relying on aid alone is problematic since signatories such as the U.S.A. have failed to deliver on aid promises; "failure to follow through has no political fallout domestically, of course because not one in a million U.S. citizens even knows of statements like the Monterrey Consensus."[1049] Global political leadership necessary to allay distributional disparities cannot be sought from the "world's one super-power."[1050]

An important criticism of the "duty to assist" is that it manifests a paternal ideology reinforcing hierarchy and privilege in the world order by perpetuating a relationship of dependency by poorer countries rather than fostering *homegrown development.* A moral and often legal debt, in addition to the economic one, may be

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[1046] Jeffrey D, Sachs, *The End of Poverty* (USA: Penguin Press, 2005) and excerpt of his book in *Time* March 14, 2005, 32 at 44 [citation is to the Time article].
[1047] See Chapter One of this dissertation, footnote 20.
[1048] Official website, <http://www.un.org/summit2005>. For the U.S. agreement to the Monterrey Consensus, visit the U.S. Department of State official website, http://www.state.gov/e/eb/rls/fs/53133.htm. See also the UN General Assembly meeting on Financing for Development (Sept. 14) at the 2005 World Summit, at http://daccessdds.un.org/doc/UNDOC/LTD/N05/511/30/PDF/N0551130.pdf?OpenElement.
[1049] Sachs, *supra* note 1046 at 44.
[1050] Helleiner, *supra* 719 at 8 adds, "[t]he world's one super-power...seems to have little interest in multilateral organizations unless they can be used as instruments of its own fairly short-term interests... [O]ne cannot expect leadership towards the kinds of global economic processes and institutions that the world increasingly requires from this source- a country that, despite its wealth, has the weakest aid performance record in the OECD (.1 of GNP of which 30% goes to the Middle East); remains in serious arrears in its financial obligations to the United Nations; is so jealous of its sovereignty that it fails to ratify even some of the most obvious of international conventions relating to the world's most vulnerable (including those relating to the rights of the child; economic, cultural and civil rights; discrimination against women; forced labour; freedom for collective bargaining; and land mines) (UNDP, 2000); and continues to oppose effective international conventions on...the preservation of global diversity."

created where perhaps on a social psychological level, the message sent is that if you want our help, you must play by our rules, especially when funds are tied to specific (IMF or WB) conditionality. Additional monetary funds, debt relief, or other conditional initiatives to provide fiscal assistance through international financial institutions,[1051] is necessary but insufficient for global change.[1052] It can be criticized as yet another means of legitimizing cultural imperialism,[1053] making developing countries obliged beneficiaries for the conferred benevolence that monetary aid, debt forgiveness, and technology transfer provide, whilst external forces are credited with "civilizing" them. This, despite the concurrent economic and social gains garnered by the donors in ensuring peace and stability,[1054] in creating new markets for the export and consumption of their goods and new subjects from whom rent seeking is possible at first world prices. This debt is not one which the developed countries had to endure as part of their maturation where, without TRIPS like restrictions on their regulatory sovereignty, access to knowledge as a public good was determined by *domestic policies* that fostered development. The Uruguay Round's changes to the institutional, cultural, and regulatory mechanisms for international trade deprive the DCs and LDCs of this regulatory discretion and the developmental opportunities previously enjoyed by them.

[1051] See *e.g.* the discussion on the IMF and the conditionality of the Fund's commitment of resources in Ross Leckow, "Bringing the Disenfranchised to the Table- Lessons of Conditionality" in *The Measure of International Law: Effectiveness, Fairness and Validity,* Canadian Council on International Law 31st Annual Conference 2002 (Kluwer Law International: New York, 2004) 1-11.

[1052] For a discussion of the view that international aid is actually harmful, See William Easterly, *The White Man's Burden: Why the West's Efforts to Aid the Rest Have Done So Much Ill and So Little Good* (U.S.A.: The Penguin Press, 2006). For a thought-provoking review, see Amartya Sen, "The Man Without a Plan", Foreign Affairs, March/April 2006, online: http://www.foreignaffairs.org/20060301fareviewessay85214/amartya-sen/the-man-without-a-plan.html.

[1053] See Charles Gore, "The Least Developed Countries 2000 Report, "Aid, Private Capital Flows and External Debt: The Challenge of Financing Developments in the LDCs" (Geneva: UNCTAD 2000).

[1054] "[i]t is difficult to deny that increasing inequality fuels the bitterness and sense of alienation that underpin much terrorist activity." Buckley, *Changing Face, supra* note 602 at 5. See also D. Bell & M. Renner, 'The War on Terrorism Needs a Marshall Plan," online: <http://www.net-about-town.com.au/imaginepeace/articles/marshallplan.htm>.

Socially, we should minimize creating the antecedent conditions necessary for assistance by giving with one hand and taking with another through internationally mandated IPR protection. Must "trade liberalization," which in the case of IPRs reinforces private monopolies instead of free market competition, be purchased by domestic regulatory policies? The matter of balancing patent and health policy is in need of cautious reform to better accord with the public's interest integral to a 'bargain theory' of IPRs and a more efficient use of domestic resources as I have already argued. But also, the great inefficiencies in the allocation of *global* resources and the awesome (and woefully awful) distributive violence to international humanitarian relief efforts for the benefit of the private at the cost of the "public" needs to be addressed. From this perspective, the ostensible system of monetary aid to DCs and LDCs for health, food, and medicinal relief is fiscally inadequate and ethically bankrupt, creating an additional source of foreign subsidy to the developed countries' innovation-based patented export products by the poorer third world.[1055] Even if DCs and LDCs were able to shift domestic industries towards innovation, their innovators could hardly afford the costs of protecting their IPRs in developed countries.[1056] It is apparent then that "[i]t is justice, not charity

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[1055] Deardorff, *supra* note 998, argues that global aggregate welfare would be maximized if certain countries were completely exempted from requirements for IPP because the poorer countries' marginal increased rents to the patent holder are unlikely to be significant enough as incentives for further innovation but the losses of being forced out of their comparative advantage in imitation are greater, shift in productive resources to areas of less advantage, resulting in a reduction of global allocative efficiency. See also Keith Maskus, "Normative Concerns in the International Protection of Intellectual Property Rights" (1990) 13 *World Economy* 387. Allocative inefficiency is further compounded by directing foreign debt and aid to paying for patented inventions or the infrastructure for their enforcement instead of other institutional uses.

[1056] "[T]he inventors in poor countries find it tough to use patent systems in the rich world…[S]ecuring a patent from America's patent office costs at least $4,000. Defending it in court can cost millions. The commission identifies several ways in which countries could open their domestic IPR system, including discounted fees and subsidized technical assistance." See "Patently Problematic" *The Economist* (14 September 2002), online http://www.economist.com/science/displayStory.cfm?story_id=1325219; Report of the Commission on Intellectual Property Rights: Integrating Intellectual Property Rights and Development Policy, http://www.iprcommission.org/graphic/documents/final_report.htm.

that is wanting in the world"[1057] and in order to restore the WTO's legitimacy and promote development, international trade rules must be interpreted and implemented in a manner that allows Member states to meet their human rights obligations. Trade's instrumental operation must necessarily adapt to the shifting political and economic dynamic underlying the current context in which the UN and WTO continue to co-exist by becoming more inclusive of DCs and LDCs interests and offering them technical aid where needed[1058] without compromising the integrity of the *telos* to which their signatories subscribed and the next section explores.

6.3 Locating the Social Dimensions of the GATT/WTO:

A member state is the only juridical party with standing to bring a complaint before the WTO but the traders' purported interests protected by members under the multilateral trade regime are aligned with both national interests and those of individual citizens who comprise the "public" for whom the state is authorized to act. These are not merely consumers characterized by 'market citizenship' in this age of "market liberalism"[1059] but human beings – or in neoliberal terms, human "resources"- whose

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[1057] Mary Wollstonecraft, *A Vindication of the Rights of Women,* online, http://womenshistory.about.com/library/etext/bl_vindication000.htm. Wollstonecraft writes, "I have sighed when obliged to confess that either Nature has made a great difference between man and man, or that the civilization which has hitherto taken place in the world has been very partial." See also discussion commencing at page 263 of this dissertation.

[1058] The WTO Advisory Centre located in Geneva provides DCs with technical legal support on WTO law and dispute settlement as a response to their concerns over being marginalized by the multilateral trading system. See <http://www.ictsd.org/html/weekly/24-07-01/wtoinbrief.htm>. The Uruguay Round established a WTO Committee on Trade and Development to examine how global trade rules affect developing countries whose membership constitutes a majority.

[1059] Defined by its embrace of "a neoliberal political philosophy of limited government and strong property rights, coupled with what one might call a cultural exaltation of the market, both as a primary locus for individual growth and expression and as a dominant template for policy design and implementation in those few instances where public action is seen as necessary." Douglas A. Kysar, "Sustainable Development and Private Global Governance." (2005) 83 Tex. L. Rev. 1 at 8, online: <http://lsr.nellco.org/cgi/viewcontent.cgi?article=1030&context=cornell/lsrp>. See generally Kysar, "Preferences for Processes: The Process/Product Distinction and the Regulation of Consumer Choice" (2004) 118 Harv. L. Rev. 525 discussing "the effort by regulatory cost-benefit analysts to ground public policies on the values revealed by individuals acting in their roles as market actors."

existence and therefore potential for productivity and exploitation is shaped by a more complex (counter) narrative than that provided by any single neoliberal (trade) institution under any singular mandate. For textual analyses, this thesis has consistently referred to the preambles of various instruments because preambular language captures the spirit and intentions of any given agreement and provides interpretative insight.[1060] It does this by "setting the foundational constitutional principles of an entire legal text, be it a national constitution, an international treaty, or the charter of an international organization."[1061] GATT 1947's preamble provides that Contracting Parties (CP),

> Recognizing that their relations in the field of trade and economic endeavour should be conducted with a *view to raising standards of living, ensuring full employment and a large and steadily growing volume of real income* and effective demand, developing the *full use of resources* of the world and expanding the production and exchange of goods,
> Being desirous to contributing to these objectives by entering into *reciprocal and mutually advantageous arrangements* directed to the substantial reduction of tariffs and other barriers to trade and to the elimination of discriminatory treatment in international commerce,
> Have through their representatives agreed as follows:...

It is clear from the outset that the signatories in 1947 had made a commitment to trade liberalization as a *means* for attaining the goal of enhancing human welfare and development by facilitating what today are considered *social and economic rights* and by restricting monopolies ("full use of resources of the world"). That trade and human rights are linked *in situ* is less an argument about the proper jurisdiction of the multilateral trade system- which is the dimension commonly focused on in modern linkage debates- and more a testament to their indivisibility for the attainment of certain ultimate goals for the common good of humanity.[1062] However, reference to trade for the purpose of *raising*

[1060] The *Vienna Convention on the Law of Treaties (VCLT)* provides under Article 31.2 what is to be included in the *context for the purpose of the interpretation of a treaty* expressly including the preamble and annexes as part of a treaty text. Full text online: < http://www.un.org/law/ilc/texts/treaties.htm.>.
[1061] Mendes & Mehmet, *supra* note 598 at 74, with reference to the SCC's use of principles found in the preamble to the Constitution Act, 1867 when ruling on important constitutional issues.
[1062] *Ibid.* at 75. See generally Amartya Sen, *Development as Freedom* (New York: Oxford University Press 1999).

standards of living does more by filling the interstices of trade liberalization with a strong commitment to its social dimensions and thereby puts into perspective the remainder of the text as merely *facilitative*.[1063] More expressly, the preamble of the Marrakesh Agreement establishing the WTO states that the parties to the agreement recognize that

> [t]heir relations in the field of trade and economic endeavour should be conducted with a view to *raising standards of living*, ensuring full employment and a large and steadily growing volume of real income and effective demand, and expanding the production and trade in goods and services, while allowing for the optimal use of the world's resources in accordance with the objective of sustainable development...in a manner consistent with their respective needs and concerns at different levels of economic development,...that there is a need for positive efforts designed to ensure that developing countries, and especially the least developed among them, secure a share in the growth in international trade commensurate with the needs of their economic development.[1064]

An addition made in 1964-65 dealt with trade and development and emphasizes the social dimensions of trade by articulating principles and objectives consistent with the preambular ethos of both the WTO Agreement and its predecessor.[1065] Article XXXVI, for example, reiterates in clause (a) that the "basic objective of this Agreement include the *raising of standards of living* and the progressive development of the economies of all contracting parties...", that (d) "individual and *joint action is essential...*" and that (e)"...international trade as a *means* of achieving economic and social advancement". The Article reinforces the need to increase market access for the products of developing countries. The need for *co-operation* of members is also highlighted with trade liberalization as simply one manifestation.[1066]

[1063] See also Article XVIII.2: "The contracting parties recognize further that it may be necessary for those contracting parties, in order to implement programmes and policies of economic development designed to raise the general standard of living of their people, to take protective or other measures affecting imports, and that such measures are justified in so far as they facilitate the attainment of the[se] objectives...

[1064] *Supra* note 8.

[1065] Part IV of the GATT 1947 (Articles XXXVI –XXXVII),

[1066] Emphasis added. GATT 1947, Clauses XXXVI (a), (d), and (e). In fact, Article GATT 1947, Article XXXVI.8 provides that "[t]he developed contracting parties do not expect reciprocity for commitments made by them in trade negotiations to reduce or remove tariffs and other barriers to the trade of less-developed parties."

The Uruguay Round added "special and differential treatment extended to developing country Members under a number of the WTO agreements."[1067] The provisions recognize that the primary goal of trade liberalization - *to raise standards of living*- according to trade theory and as codified in the preamble requires some general exceptions from the general principles of non-discrimination and reduction of trade barriers on which the international trading regime is based.[1068] Most exceptions to members' general obligations provided under GATT 1947 are justifiable on the basis of conformity to the grundnorm of non-discrimination. The most significant are the general exceptions provided for under Article XX[1069] which support the conclusion that in 1947, it was intended that a sovereign realm of discretion free from trade obligations would be expressly preserved (as a complementary means to free trade) for furthering its welfare promoting and development objectives so long as these domestic measures were not "arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or a disguised restriction on international trade". The GATT vision of

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[1067] Thomas & Meyer, *supra* note 645 at 69. See also the "Decision on Measures in Favour of Least Developed Countries" and the "Decision on Measures Concerning the Possible Effects of the Reform Programme on Least-Developed and Net Food-Importing Developing Countries" referred to therein.

[1068] The cornerstone of trade liberalization is the principle of non-discrimination as referred to in the preamble to GATT 1947 and manifested in the doctrines of the Most Favoured Nation Treatment (Article 1 of the GATT) and National Treatment (Article III). Permissible regional trading blocks (Article XXIV) and grandfathering clauses provide certain exceptions to this principle but on the whole, the provision is effective in extending the benefit of negotiated concessions between two members to all other member states usually without the ability to extract further concessions with those members as a precondition to this extension. There is to be no playing favourites amongst foreign exporters. National Treatment goes further safeguarding against discrimination between domestic and foreign producers.

[1069] These allow members to take measures "necessary to protect public morals" (clause a), "necessary to protect human, animal or plant life or health" (clause b), and measures "necessary to secure compliance with laws or regulations which are not inconsistent with the provisions of the Agreement, including those relating to...the protection of patents, trademarks and copyrights, and the *prevention of deceptive practices"* (clause d) which could be used to curtail the growing number of questionable patents applied for and the resulting fraud on the public and crown. Article XX has been the subject of a number of contentious disputes and is considered as an affirmative defence below in text.

multilateral trade was founded on the ideals of mutuality, reciprocity, and non-discrimination and was expressly committed to its social, HR promoting, dimensions.

6.4 The Relationship between Human Rights & Human Development

Human development (HD)[1070] and Human rights (HR)[1071] share a common vision and purpose: "to secure the freedom, well-being and dignity of all people everywhere."[1072] Amongst other important shared goals, both desire to secure "freedom from want- to enjoy a decent standard of living; [and] freedom to develop and realize one's human potential."[1073] The interdependency of this relationship is expounded by the 2000 UNDP Report on HD that confirms that "when human development and human rights advance together, they reinforce one another- expanding people's capabilities and protecting their rights and fundamental freedoms."[1074] The report traces the historical parallel paths of the distinctly separate HR and HD agendas[1075] observing that there has been growing convergence of the two with newfound ways for each to complement the other.

First, HD agendas are enhanced by HR as the latter tends to draw attention to accountability for respecting, protecting, and fulfilling the HR of all people:

> The tradition of human rights brings legal tools and institutions- laws, the judiciary, and the process of litigation- as means to secure freedoms and human development. Rights also lend moral legitimacy and the principle of social justice to the objectives of human development. *The*

[1070] The UNDP HR/HD Report 2000, *supra* note 27 at 2, defines human development as "a process of enhancing human capabilities- to expand choices and opportunities so that each person can lead a life of respect and value." This reaffirms Sen's definition of development as freedom.
[1071] The UNDP HR/HD Report 2000, *ibid.,* defines human rights as "...claims to social arrangements that...secure the freedom for a life of dignity."
[1072] *Ibid.,* Overview. See also World Bank Report, *Development and Human Rights* 1998, online: <http://www.worldbank.org/html/extdr/rights/hrtext.pdf>, acknowledging that the protection and promotion of universally recognized human rights may be subsumed as part of the expansive principle of sustainable development.
[1073] UNDP HR/HD Report 2000, *supra* note 27 at 64.
[1074] *Ibid.* at 2.
[1075] "The one largely dominated by economists, social scientists and policy makers, the other by political activists, lawyers and philosophers" UNDP HR/HD Report 2000, *ibid.*

> *rights perspective helps shift the priority to the most deprived and excluded,* especially to deprivations because of discrimination.[1076]

Second, the attainment of HR has much to gain from the perspective of HD as HD initiatives offer a long-term perspective by directing attention to the socio-economic context for realizing or suppressing human rights:

> The concepts and tools of human development provide a systematic assessment of the economic and institutional constraints to the realization of rights- as well as the resources and policies available to overcome them.[1077]

"[T]he human rights approach", the report adds, "links the human development approach to the idea that others have duties to facilitate and enhance human development."[1078] The indivisibility of human rights and their contingent nature is increasingly recognized.

Development is polycentric and requires domestic conditions conducive to its objective of *freedom,*[1079] which in turn is integral to a life of *dignity.* While it may be difficult to establish conclusively a causal relation between development and freedom, a correlation is empirically supported. Michael Trebilcock posits that

> ...it is an observable fact that most of the relatively rich countries in the world are democracies, while most of the poorest countries are not. It is also true that most of the relatively rich countries in the world are market economies, and many of the poorest countries are not. Scully (1992) in an extensive empirical analysis of 115 economies over the period of 1960-1980, claims that societies with high levels of political liberty, civil liberty, and economic liberty grow at three times the rate and are two and one-half times as efficient in transforming inputs into national output as societies in which these rights are proscribed.[1080]

[1076] *Ibid.* at 1, emphasis added.
[1077] *Ibid.* at 2.
[1078] *Ibid.* at 21.
[1079] See *e.g.* Sen, *Development as Freedom, supra* note 1062 at 3 defines development as "a process of expanding the real freedoms that people enjoy. The focus on human freedoms contrasts with narrower views of development, such as identifying development with the growth of gross national produce, or with the rise in personal incomes, or with industrialization, or with technological advance, or with social modernization. Growth of GNP or of individual incomes can, of course, be very important as *means* to expanding the freedoms enjoyed by the members of the society. But freedoms depend also on other determinants, such as social and economic arrangements (for example, facilities for education and healthcare) as well as political and civil rights (for example, the liberty to participate in public discussion and scrutiny)...Viewing development in terms of expanding substantive freedoms directs attention to the ends that make development important rather than merely to some of the means that, *inter alia,* play a prominent part in the process."
[1080] See Michael Trebilcock, "What Makes Poor Countries Poor?: The Role of Institutional Capital in Economic Development", in E. Buscaglia *et al.*, eds., *The Law and Economics of Development* (Connecticut: JAI Press, 1997) 15 at 20. See also UNDP HR/HD Report 2000, *supra* note 27.

The various intergovernmental institutions (including the UN and its many agencies, the IMF, WB, GATT and WTO, in their collective mandates), also acknowledge the necessity of having facilitating domestic conditions and strive, to this end, to foster transformative modalities. Whether we call it *development, Democracy and free markets,* or simply, the desire to provide the means for "raising the standards of living" by respecting cultural diversity and the sovereign right to self-determination - without compromising individual rights- the objective is the same and it is meant to serve a *human* (rather than corporate) agenda as evinced by the historical, institutional, instrumental, theoretical, and operational examinations undertaken in this dissertation.

World Bank president James D. Wolfensohn, states that given the dire living conditions of most of the world's population, "progress is too slow."[1081] Wolfensohn asserts the need for a multifaceted and co-operative approach for development:

> I believe we have a better articulation of our role with the IMF. Broadly, our sister institution has the responsibility for macroeconomic stabilization for our client countries and for surveillance. We have the responsibility for the structural and social aspects of development. Obviously, these are not isolated roles and we work together very closely on a day-to-day basis.... [T]he two functions are like breathing in and breathing out. An appropriate macroeconomic framework is essential for our work, but the social, structural, and human agenda, which we share with the regional banks, members of the UN system, and other partners in development, is essential for the IMF which cannot and does not prescribe in a vacuum. Together we must serve the hopes and aspirations of the people in our client countries, or our clients will not achieve their objectives in peace and stability. And together, we must work with and support the work of the World Trade Organization which is so critical to the trading arrangements and future of our client countries.[1082]

The multilateral trade system provides the instruments for economic integration, growth, fiscal stability, and furthers co-operation towards development. Perhaps the failure of

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[1081] "With three billion people still living under $2 a day, with growing inequity between rich and poor, with forests being degraded at the rate of an acre a second, with 130 million children still not in school, with 1.5 billion people still not having access to clean water, and two billion people not having access to sewage we cannot be complacent...Two billion more souls must feed themselves by the year 2025, hampered by wars, with growing inequity, and with distortions of economies and politics as evidenced in crises....With the reduction in Overseas Development Assistance and current instability in the international financial markets, there is much to be concerned about." See James D. Wolfenshon, *A Proposal For a Comprehensive Development Framework (Discussion Draft)*, January 1999, online: Worldbank, <http://www.worldbank.org/cdf/cdf-text.htm>.

[1082] *Ibid.*

Members to overcome significant impasses leading to the collapse of the 9th Round of negotiations was due to the strong commitment that the majority of the WTO's membership made to secure significant gains in DCs and LDCs issues such as agriculture, textiles, and intellectual property[1083] and thereby further their development agendas within the multilateral trading regime. The Doha Declaration clearly shows this emphasis on free trade as a *tool* for economic growth and "sustainable development":[1084]

> International trade can play a major role in the promotion of economic development and the alleviation of poverty. We recognize the need for all people to benefit from the increased opportunities and welfare gains that the multilateral trading system generates...Recalling the Preamble to the Marrakesh Agreement, we shall continue to make positive efforts designed to ensure that developing countries, and especially the least-developed among them, secure a share in the growth of the world trade commensurate with the needs of their economic development.[1085]

A 2003 UNDP Report affirms: "the multilateral trade regime will be well governed if it is focused on the achievement of the Millennium Development Goals."[1086] Helleiner recommends that the WTO become a *development* focused agency connected to a

> vision of humane global governance, with celebration of humanity's diversity, promotion of democratic process, and social and economic justice and human rights for all. Such...[a] vision

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[1083] But see Jeffrey Schott, "Unlocking the Benefits of Free Trade" Special Report, *The Economist*, (1 November 2003) at 67, online: http://www.petersoninstitute.org/publications/print.cfm?doc=pub&ResearchID=27. Schott believes the promises made to DCs were actually self promoting "rhetoric" to which some of the failure of the Doha Round, at the Ministerial meeting in Cancun, can be attributed: "The emphasis on development inspired many [DC] to justify their demands for new concessions by arguing that they paid too much in the previous trade talks (the Uruguay Round) and got nothing in return- and now it was pay back time. Those countries seemingly believed their own rhetoric and expected Cancun to be a donor conference rather than a trade negotiation." Compare, Heather Stewart, "Mandelson: US Greed caused the Doha Collapse" *The Observer*, July 20, 2006, referencing the EU Trade Commissioner's view that the US was wrong to expect to be recompensed "dollar for dollar" for every reduction to farm subsidies and that Washington should have made some concessions against its farmers in exchange for gains in manufacturing and service. Online: http://politics.guardian.co.uk/development/story/0,,1833208,00.html.

[1084] Defined by the OECD as "a development path along which the maximization of human well-being for today's generations does not lead to declines in future well-being." Online, http://www.oecd.org/glossary.

[1085] "[E]nhanced market access, balanced rules, and well targeted, sustainably financed technical assistance and capacity-building programmes have important roles to play." Doha Declaration, *supra* note 12 para. 2.

[1086] UNDP, *Making Trade Work*, *supra* note 747. See also Dani Rodrik, "Global Governance of Trade as if Development Really Mattered" Report Submitted to the UNDP 2001, criticizing the substitution of trade liberalization for development ("confounding the ends and means") and questioning the centrality of trade and trade policy over "the critical role of domestic institutional innovations that often depart from prevailing orthodoxy."

> will see trade, financial flows and macroeconomic stability as no more than instruments of its objectives rather than as ends in themselves.[1087]

HR and HD have a simultaneously dialectic and mutually reciprocal relationship despite their apparent insularity. Trade liberalization furthers human rights objectives by facilitating development. A human rights framework for trade dispute resolution is not inconsistent with the original mandates of the two regimes and would create a coherent international order because diverse instruments and interpretive practices need to be reconciled into a single trajectory whose post war evolution speaks to the future realization of a better world measured by improvements to *both* HR and HD.[1088]

6.5 A Human Rights Framework for WTO Dispute Settlement: Human Rights as a Shield

"Markets", economist Helleiner writes, have never been the "primary basis for human interaction" and globalized markets "operate within politically defined rules and governance institutions."[1089] The 2001 "Nightmare Report" of the Expert Group of the UN Subcommission on Human Rights qualified the WTO as the "nightmare" of human rights.[1090] TRIPS clearly demonstrates that the relationship between the national and international is not apolitical.[1091] The ambition towards homogeneity and harmony with

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[1087] Helleiner, *supra* note 719 at 17.

[1088] Richard B. Brandt, *A Theory of The Good and The Right* (USA: Prometheus Books, 1998) argues: "fully rational persons will support roughly that moral system which will maximize expectable welfare in some sense of 'welfare,' for some group of individuals."

[1089] *Ibid,* at 3 and 16.

[1090] See Preliminary Report, by J. Oloka-Onyango and Deepika Udagama, submitted to the UN Sub-Commission on the Promotion and Protection of Human Rights, June 15, 2000 in accordance with Sub-Commission Resolution 1999/8 and UN Press Release, "Globalization and Its Impact on the Full Enjoyment of Human Rights, E/CN.4/Sub.2/2000/13.

[1091] For further discussion of the relationship between TRIPS and human rights, see Sol Picciotto, "The WTO As a Node of Global Governance: Economic Regulation and Human Rights Discourses" Working Paper, Conference on Human Rights & Global Justice, University of Warwick, March 29-31, 2006 online: http://www2.warwick.ac.uk/fac/soc/law/events/past/2006/rightsandjustice/participants/papers/picciotto.doc. For a general comment, see Cheyfitz, *supra* note 755 at 4-5. Cheyfitz explains: "The relationship between the domestic and the foreign is at once literal and figurative, that is to say, material and ideological....[T]he material and the ideological are always already figures of one another...they are always already translations of one another...Nevertheless, we must recognize a progressive strain in this imperial foreign policy, one that apparently welcomes homogenization, but-and here homogeneity harmonizes itself with hierarchy-

New World (American) standards and the ensuing and enduring international struggle for voice in this process is well rooted in the imperialist foreign policy traditions of both trade and human rights.[1092] Respect for diversity, however, is now more than ever necessary to ensure that strict rule orthodoxy in TRIPS' interpretation does not dictate how governments can and should interact with the new global economy,[1093] nor undermine core human values discussed in the last chapter.

Although jurisdiction over some IP related matters would seem to fall under the auspices of WIPO, the contentious issues tend to arise in tension with trade obligations, and despite current attempts to strengthen the role of the United Nations,[1094] because of its formalized dispute settlement mechanism, the existing jurisdiction of WTO panels in this field, and the first mover advantage enjoyed in resolving trade related IP disputes, the WTO remains charged with such issues and less modestly will remain the preferred forum for disputants. Considering that the WTO membership of approximately 150 states is represented by more than two-thirds DCs and LDCs,[1095] the disproportionately

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only in the terms of the policy maker, who writes a script in which the *other*, in order to be heard, must say: "for your sake I have become a civilized man...for your sake I will be whatever you will me to be."

[1092] International law can be traced to the original formation and ascendancy of the nation state in the 16th and 17th centuries, with Europe as its birthplace. Accordingly, international law "has been infused with European social and political cultures and values." Kindred *et al.*, *supra* note 792 at 1.

[1093] See Helleiner, *supra* note 719 at 3.

[1094] See "Revised draft outcome document of the high-level plenary meeting of the General Assembly of September 2005 submitted by the President of the General Assembly, 10 August 2005, Fifty-ninth session, Agenda items 45 and 55, Integrated and co-coordinated implementation of and follow-up to the outcomes of the major United Nations conferences and summits in the economic, social and related fields. Revised Draft Outcome Document (10 August 2005) [A/59/HLPM/CRP.1/Rev.2], in particular para. 14 (Values and Principles), online: < http://www.un.org/summit2005/documents.html>, which states: "We pledge to make the United Nations more relevant, more effective, more efficient, more accountable and more credible..." (para. 125) "...to strengthen the United nations with a view to enhancing its authority and efficiency, as well as its capacity to address effectively the full range of the challenges of our time...."; (para. 103): "We resolve to strengthen the United Nations human rights machinery with the aim of ensuring effective enjoyment by all of the human rights, civil, political, economic, social and cultural rights, including...to development."

[1095] The WTO, Overview, online: <http://www.wto.org/english/thewto_e/whatis_e/tif_e/dev1_e.htm>. Although there are no WTO definitions for "developed" and "developing countries" (DCs) and DCs status is designated on the basis of self-selection subject to acceptance by WTO bodies.

large population of these countries, notably that of India and China,[1096] and the disproportionately large population of poor within these populations,[1097] the future trade governance of the WTO is indeed fragile (reflected in the apparent collapse of the Doha Round); in this case the whole is critically dependent on the participation of its parts which can only be assured by assuaging some of the main institutional criticisms, not all of which relate to legitimacy, process, and architecture but to the content and relationship of international norms.[1098]

HR *compete* but do not necessarily *conflict* with trade obligations. By definition, "conflict" requires that the norms be mutually exclusive. The obligations arising under HR instruments that may *appear* to conflict actually will *not conflict* for several reasons. First, though binding as treaty obligations, the substance and justiciability of HR obligations are still a contentious issue and in relation to social and economic rights may be without the precisely defined content necessary as a substantive norm for the creation of conflict between international instruments but can clearly lead to conflict between a state's implementation and operationalization of HR norms domestically and its international trade obligations (vertical conflict) – something, if contested, the equitable conduct defence (ECD) I have devised would remedy in relation to patenting life.

[1096] "By 2001, India had 1,033m people against China's 1,272m. But China's national income per head, according to the World Bank, was $8F90, nearly double India's $450. Adjusted for purchasing power, the Chinese were still 70% wealthier than Indians were. In the ten years from 1992, India's GDP per head grew at 4.3% a year, China's twice as fast. Some 5% of Chinese now live below the national poverty line compared with 29% of Indians. Economic strength begets strategic clout. An accident of history made China one of five permanent, veto-wielding members of the United Nations Security Council, but that seat now seems to belong to it as of right." Special Report India and China: A tiger, falling behind a dragon" *The Economist* (21 June 2003) at 21-23. See also "India and China oppose attempts by some developed countries to "divide" developing nations as WTO negotiations" *India Daily* July 12, 2005, online: <http://www.indiadaily.com/editorial/3553.asp>.

[1097] See Jeffrey D, Sachs, "The End of Poverty" *Time,* March 14, 2005, 32-39.

[1098] *Supra* note 1090. For a thoughtful discussion of the two distinct approaches to the IP-HR interface (one positing a fundamental conflict, and the other advancing co-existence of the two legal fields for a common end), see Laurence Helfer, "Human Rights and Intellectual Property: Conflict or Co-existance" (2003) 5 Minn. Intell. Prop. Rev. 47, online: <http://mipr.umn.edu/archive/v5n1/Helfer.pdf>.

Furthermore, there should be no conflict if proper interpretation is given to TRIPS provisions in a conciliatory manner. At most, these obligations *compete* in the sense that there may be less *market* force or political pressure for states to give priority to the ethical issues and HR consequences of trading than there will be to respond compliantly to trade obligations because of costs associated with WTO complaints and their enforcement (trade sanctions), even if a state may be liable for HR obligations in domestic law (the extent of which would be significantly less costly). By necessity, the WTO must account for the human rights impact of trade. Finally, these rights will not conflict because HR should always *trump* trade values, either on the basis of having achieved the status of customary law or because of their normative moral force.[1099] Both human rights and trade obligations derogate from the full unfettered sovereignty of a state but whereas human rights instruments can be interpreted as articulations of *existing* rights (and simultaneously universal *ends*)[1100] trade obligations are appropriately characterized as enabling *means* to those rights and may therefore have to surrender to better, non-or less-human-rights impacting means (i.e. presumably by way of the domestic measure being contested). Despite convergence trends, diverse regulatory approaches are necessary for these objectives.

The HR community is ostensibly threatened by the international trade system according to Vazquez while the trade system seems not to suffer from the same insecurities. In March 2005, the UN General Assembly issued a Report of the Secretary

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[1099] The UN Sub-Commission on the Promotion and Protection of Human Rights argues for the primacy of HR over economic policies and agreements in order to avoid conflict at the intersection of IPRs, trade and HR, online < http://www.unhchr.ch/html/menu2/2/sc.htm>.
[1100] Hastrup, *supra* note 23.

General[1101] revitalizing human rights and the role of the UN in the new era. Some commentators argue that trade sanctions can and should be used to induce human rights compliance in trading partners. The position advanced in this thesis and in support of the Article 8 ECD is a more modest proposal of human rights as a *shield* against liability, not as a sword for intervention, in protecting interests arising from the issues related to patenting life forms. At a minimum, trade obligations should *not interfere* with the domestic realization of internationally recognized human rights obligations where a state gives these obligations priority in domestic policies. The threat of trade-related costs should not form a disincentive to states and representative governments in forming policies for meeting, and remaining accountable for their HR owed to their citizens.

The duty of national governments to their *own* citizens to ensure HR are met, or at least not interfered with at *home*, is of practical relevance as civil society attempts to *localize the global* in domestically contingent frameworks.[1102] It is hypocrisy not to mind one's own house when committing to these values *globally* through the MDGs and Monterrey Consensus. If each state governed by the ethos that domestic HR are the primary obligation of the nation state, the aggregate status of individual human rights protection worldwide would be vastly improved. My fundamental commitment to Article 2.7 of the UNC, which confirms the sovereignty of nations, underlies my use of HR

[1101] Report of the Secretary General, A/59/2005, <http://www.un.org/ga/59/hl60_plenarymeeting.html>.
[1102] There are growing attempts to operationalize internationally recognized HR through express constitutional protections i.e. the right to health is integral to the right to life and security of the person. See *e.g. Chaoulli*, *supra* note 841 and reference to prior decisions; see also Study on Canada's Human Rights Obligations,http://www.sen.parl.gc.ca/vpoy/english/Special_Interests/speeches/human_rights_report_response_300402.htm.

within the WTO as a shield to defend measures taken for the domestic realization of HR.[1103]

Robert Howse contends that (unilateral) trade sanctions can be used proactively to coerce HR compliance in trading partners.[1104] Howse and Makau Mutua have argued that violators of HR tend to be WTO rule violators.[1105] A more inclusive HR approach to trade advocated by some scholars, NGOs, and representatives of developed countries, as a *sword* to elicit compliance in a trading partner through trade sanctions, however, would graft the hegemony of trade values onto HR norms and thereby supplant the role and importance of the UN system.[1106] Concessions conferred *ex gratia* (such as the GSP) can, nevertheless, currently be unilaterally withdrawn even in the absence of violation of international human rights law.[1107] But, to impose trade sanctions or refuse trade with a partner for human rights violating production methods of a product for export, for example, which renders these products not "like" products for the purposes of a GATT dispute, although laudable in its objective of reducing HR violations is paternalistic and invasive of a Member's sovereignty. It is more amenable to abuse as disguised

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[1103] "[n]othing contained in the present Charter shall authorize the United Nations to intervene in matters which are essentially within the domestic jurisdiction of any state or shall require the Members to submit such matters to settlement under the present Charter..." UNC, *supra* note 11.

[1104] See also Vazquez, *supra* note 768 for using trade to sanction HR in other countries and Gabrielle Marceau, "WTO Dispute Settlement and Human Rights" 13.4 E.J.I.L 753.

[1105] Robert Howse and Makau Mutua, "Protecting Human Rights in a Global Economy: Challenges for the world Trade Organization" (2002), online http://www.dd-rd.ca/site/publications/. Compare this with Jose Alvarez's reply, "Trade and the Environment: Implications for Global Governance 7 Widener Law Symposium Journal (2001) 1 that "many HR violators will routinely comply with international economic agreements and many prominent defenders of human rights, including the United States, have trouble adhering to and complying with some international agreements."

[1106] Historically, trade sanctions or the suspensions of concessions replaced the use of force as a legitimate means of coercing compliance with international obligations owed to the nationals of another state. Such sanctions can now only legitimately be imposed by the UN's Security Council as a form of coercing HR compliance. In the multilateral trade regime, sanctions for enforcing a decision are to equal the amount of lost trade related to the impugning measure. The UN continues to play an important role in many respects, one of which is in interpreting the ICESCR and thereby serving in an influential institutional advisory capacity for a human rights approach to IPRs and trade. See *e.g.* discussion in footnote 814 and 822 *supra*.

[1107] But, if the concession was conferred by a treaty, it could only be withdrawn in accordance to that treaty on the basis of a violation of it or some other norm (as a countermeasure), Vazquez *supra* note 768 at 799.

protectionism. Moreover, it creates compounding HR complications because sanctions may lead to graver subverted forms of HR violations as internal industries shift violations to domestic supply industries.[1108] In the end, Sir Anthony Mason argues, "[t]he correct balance between efficient economic outcomes and respect for human rights may depend upon the stage of development that a particular country may have reached. In the developed countries of the world, human rights are an established culture, centred upon judicially enforced human rights which are either entrenched or statute based."[1109]

The legal justification and authority derived from the Equitable Conduct Defence (ECD) I advocate is a healthy compromise in preserving the sovereign discretion to give human rights priority within a limited domestic context despite its impact on trade, without *requiring* this priority within a multilateral trade setting which, some may argue, is *ultra vires* the WTO. Most important is that the foundational pillars of the trading system, the tenets of non-discrimination, non-unilateralism and the preservation of co-operation and conformity to the rule of law, are retained. This is the only qualification to my proposed ECD. Using HR as a shield against the complaints of another member requires that the trade-contested measure be applied in a non-discriminatory manner.

[1108] For example a ban (quantitative restriction) might be imposed on imported products made by child labour on the basis that these are not "like products". However, such a measure might shift domestic child labour away from export oriented industries (i.e. rug weaving) towards domestic service industries such as the child sex trade. Although this is a gross oversimplification, has the measure been effective in curtailing child labour or simply compounded it by adding another dimension that drives it further underground? Is a country taking such a measure obliged to cease trade with *all* other trading partners who continue to do trade with the human rights violating Member on the basis of non-discrimination? But see Bottomly & Kinley, "Human Rights as Legally Binding or Merely Relevant" in Bottomley and Kinley, *supra* note 1015, where it is argued that sanctions help create pressure for a corporate culture sensitive to HR.

[1109] Sir Anthony Mason, "Comment on Papers presented at the Commercial Law and Human Rights Conference" in Bottomley & Kinley, *ibid.* at 6.

This is actually more important than deciding whether human rights have any formal role to play in the multilateral trade system. Robert Howse suggests:[1110]

> [r]ather than attempt once again to decide what is 'in' or 'out' of the WTO, we should try to mould the rules and their interpretation to structure the *interaction* of the trading regime with other powers and authorities, both domestic and international, in a legitimate manner.[1111]

International law should be a process- a dialogue- of different but equal sovereign voices in choral tandem; recognizing it as such would reduce some of the current politics that detract from the legitimate role and function of the WTO. DCs have made significant strides in revisiting the issue of patents and public health, and revitalizing the discussion on trade and agriculture, but at the point where health and agriculture merge, with the patenting of life, bilateral and regional arrangements continue to erode TRIPS protections, suggesting that the industry lobby in the North will continue to push for the removal of sovereign discretion and narrow interpretation of Member rights under TRIPS until they are completely eliminated. States should not assist such efforts by voluntarily surrendering these rights through their common law, by failing to exercise the scope of their TRIPS rights, or by committing to TRIPS-Plus agreements. The proliferation of such agreements adds to the sites of potential conflict. A more comprehensive agenda to revisit the equal participation by members in trade negotiations to ensure justice in mediated outcomes is underway[1112] but requires a concurrent complementary framework for conflict resolution.

[1110] Helleiner argues for increased democratic participation in the global governance institutions, political gains of co-operation amongst the weaker and poorer WTO member states, and is eloquent in expressing concern over equity and redistributive justice. *Supra* note 719.

[1111] Howse, "Technocracy", *supra* note 603 at 112.

[1112] The Director General of the WTO, Supachai Panitchpakdi, in his address, *Prospects for the Millennium Round*, online: <http://www.moc.go.th/thai/dbe/global10.html>, states: "The top priority facing the WTO today is first to identify and then redress many of its shortcomings. Furthermore, we need to strengthen the organization and rebuild confidence among its Members after the Seattle Ministerial Conference. To this end, the WTO is currently working on the confidence-building measures as agreed to recently in Geneva. They include: ...increasing technical assistance to developing countries and LDCs, addressing the

6.6 Regime Shift or the Desire for Conflict?

The state as "subject" of international law[1113] has given way to a plurality of subjects matched by a parallel pluralism in the *sources* of the law,[1114] precipitating concerns over a "disaggregated" if not "dissolving" state given the fragmentation of international law."[1115] According to the International Chamber of Commerce (ICC), "[a] total of 162 regional trade agreements notified under the GATT and the WTO are in force

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implementation concerns, and improving transparency in decision-making process...*Most developing countries are facing the lack of human, financial, and institutional resources, and this inadequacy has hindered them from realizing the full benefits of the negotiating process.*"

[1113] Art. 38(1) in *The Statute of the International Court of Justice* (ICJ) asserts the state as subject and sets out valid sources of law. Non-states have acquired some international personality and can maintain legal relations, enjoy rights, or assume prescribed obligation. See *e.g. Kindred* et al., *supra* note 792 at 11-91.

[1114] See Anne-Marie Slaughter, "Breaking Out: The Proliferation of Actors in the International System" [Breaking Out] in Dezalay & Garth, *Global Prescriptions*, *supra* note 714 at 12-36 argues that with the proliferation of actors and legal norms, international law can no longer be limited in application to the monolithic sovereign state- itself disaggregating into its components of courts, regulatory agencies, and legislatures. Law is the key discourse of these subjects for legitimating the system and provides for a set of legitimate actors who can *produce* the law. But see Linda Weiss, *The Myth of the Powerless State* (New York: Cornell University Press, 1998) wherein she argues that state capacities for domestic transformative strategies provide a competitive advantage by offering state-embedded institutions for economic governance which will determine the extent and effect of external economic pressures.

[1115] The International Law Commission (ILC) established a Study Group on "Fragmentation of international law" chaired by Professor Bruno Simma on May 9, 2002. See Daily Bulletin, 54th session of the ILC, at http://www.un.org/law/ilc/sessopms/54/jourchr.htm. See also Gerhard Hafner, "Risk Ensuing from Fragmentation of International Law," ILC, Annex to Report on the Work of the 52nd session, General Assembly Official Records, 56th session, Supplement No. 10 (A/55/10), 321-339 at http://www.un.org/law/ilc/reports/2000/english/annexe.pdf. There is a parallel need to reclaim politics in the face of equal fragmentation occurring to international politics. David Kennedy, "The Forgotten Politics of International Governance" (2001) 2 E. H.R.L. Rev. 117-125, suggests that "the resignation about the demobilization of a vigorous public policy indicates that even as welfare states erode, the notion of public policy they exemplified is alive and well: pubic policy is territorial intervention by "public authorities against a background of apolitical private initiative. This resignation refuses to treat as political, as public, as open to contestation, the institutions and norms which structure background market. If we think of the private domain as political, it is not at all obvious that the current situations is one of fragmentation rather than concentration...Where factors of production are relatively immobile, a locality or private actor may have more capacity to conduct global public policy than either the welfare state or the institutions of international economic law. The question, in other words, is not whether politics or where politics, but what politics. Internationalists should care less about whether the State is empowered or eroded than about the distribution of political power and wealth in global society....Technocratic governance, a displacement of public by private, of political alignments by economic rivalries, the unbundling of sovereignty into myriad rights and obligations scattered across a global civil society-all this has transformed international affairs....The result is an intellectual class unable to develop viable political strategies for the world it has applauded into existence, ratifying the political choices that result from the arrangements of private power to which the State has handed its authority, while still celebrating the expansion of participation in an emasculated public policy process" (Kennedy, *ibid.* at 120).

today. Between 100 and 200 new regional trade formations are anticipated by 2005"[1116] International law specialist Joost Pauwelyn, a former Legal Affairs Officer for the WTO and now professor of law explains:

> [m]odern international law, is indeed, composed increasingly of treaty-based sub-systems (such as that of the WTO...or the World Intellectual Property Organization)...said to have their own sector-specific 'international law', law-maker and law-enforcement mechanism. Like national laws within the discipline of 'conflict of laws,' these sub-systems of public international law interact and may give rise to conflict...[T]o talk of these sub-regimes as being separate 'international laws' which may 'conflict' would give the wrong signal. First, it would lose sight of *general* international law in creating the impression that these sub-regimes are 'self-contained regimes' to be evaluated exclusively with reference to norms created *within* the particular sub-regime. Second, it could be understood by some as elevating what are basically treaty norms (say, WTO provisions) of a *contractual* nature to the status of "law" in the strict domestic law sense of norms imposed by an independent 'legislator' on all subjects (i.e. states) of the sub-regime independently of their will.[1117]

And, "for foreign policy", according to Louis Henkin, "perhaps the most important legal mechanism is the international agreement, and the most important principle of international law is *pacta sunt servanda*: agreements shall be observed. This principle makes international relations possible."[1118] Adhering to *pacta sunt servanda* grows more difficult the greater the number of international, transnational, multi-national, and bilateral agreements imposing diverse obligations. A state may face conflict with disparities between *domestic laws* in a national legal system and the norms provided in treaty based sub-systems (vertical conflict) or as between different international instruments (horizontal conflict). This neo-liberal narrative has gradually given rise to a counter hegemonic narrative which Laurence Helfer describes as a post-TRIPS regime

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[1116] ICC Policy Statements (2002). For a discussion of potential negative effects of regional trade agreements on trade distortion and the relationship with Articles XXIV and V of the GATT, see The International Chamber of Commerce, "Regional Trade Agreements and the Multilateral Trade System" prepare by the Commission on Trade and Investment Policy, November 2002, online: http://www.iccwbo.org/home/statements_rules/statements/2002/Regional%20trade%20agreements_multilateral%20trading%20system.asp.

[1117] Pauwelyn, "Conflict of Norms", *supra* note 12 at 9. However, international law is *not* merely positive contractual law. For criticism of "voluntarist" or "auto-limitation theories", and their inability to adequately address *custom* derived norms and why, as a "genre" they are binding, see R. Higgins, *Problems and Process: International Law and How We Use It* (1994) at 15. Higgins' own view is that international law is "decision-making by authorized decision-makers, when authority and power coincide."

[1118] Henkin, *supra* note 993 at 19.

shift that strives to (re)locate international IPR governance to a more compatible space for the interests of DCs and LDCs:

> Intellectual property issues are now at or near the top of the agenda in intergovernmental organizations such as the World Health Organization and the Food and Agriculture Organization, in international negotiating fora such as the Convention on Biological Diversity's Conference of the Parties and the Commission on Genetic Resources for Food and Agriculture, and in expert and political bodies such as the United Nations Commission on Human Rights and its Sub-Commission on the Promotion and Protection of Human Rights. In some of these venues, "intellectual property lawmaking" involves the negotiation of new treaties; in others, such lawmaking occurs through the re-interpretation of existing agreements and the creation of new nonbinding declarations, guidelines, recommendations, and other forms of "soft law."[1119]

Helfer's delineation of a regime shift of IPR governance and "lawmaking from "WIPO to GATT to TRIPS"[1120] and the subsequent post-TRIPS regime shifting *out* of the WTO into other international fora with non-binding soft law instruments can better be understood simply as a further *decentralization* and fragmentation of international law rather than a portent of a total regime *shift* per se. Helfer concedes this point despite his broader argument that orchestrated efforts by developing states and NGOs are deliberately taken to create IP norms that supplement, modify, or supplant TRIPS norms:

> But regime shifting may also spawn inefficient rivalries among actors or attenuate mechanisms for holding international institutions accountable to affected constituencies. And it increases the likelihood of conflicting or incoherent legal obligations for states and private parties- an especially grave concern for an international system with few hierarchical rules for resolving such inconsistencies.[1121]

In the first decade of the WTO, civil society has assumed a critical role in influencing negotiated outcomes in IP protection.[1122] It may be argued that the shifting is still

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[1119] Laurence Helfer, "Regime Shifting: The TRIPS Agreement and New Dynamics of International Intellectual Property Lawmaking" (2004) 29.1 Yale J. of Int'l L. at 6 and footnote 20: "International law and international relations scholars have recently emphasized the importance of non-binding norms, or soft law, as a method to promote international co-operation and alter state behaviour."

[1120] *Ibid* at 7. Helfer proceeds to explain how various actors use regime shifting "to maximize desired policy outcomes, to relieve pressure for action in other international venues, to create treaties and soft law in tension with TRIPs and to lay the political groundwork needed to integrate new principles, norms, and rules of intellectual property protection into the WTO and WIPO."

[1121] *Ibid* at 81.

[1122] See *e.g.* Sell, *Private Power, supra* note 613 at 121-62 and the role of civil society in negotiation of the Doha Declarations on TRIPS and Public Health, *supra* note 918. See also Amani and Coombe, *supra* note 49 and the role of civil society in undermining the discriminatory objective of genomics mapping and the

occurring such that the transition of international IP out of the WTO and into subaltern "international regimes concerning biodiversity, plant genetic resources, public health, and human rights"[1123] is still incomplete. But considering the binding nature, political clout, and normative force of the TRIPS, as well as the developed world's attraction to the juridical quality of the WTO as a dispute settlement mechanism, developed countries would be reluctant to allow the shift to be completed. They enjoy a comparative advantage in information capital and domestic legal systems which allows them to dominate and succeed in the WTO's judicial-like setting.[1124] A regime shift may *never* transpire. Helfer explains that the norms, principles, and rules generated outside of TRIPS are, nevertheless, functional in creating tension with TRIPS norms:[1125]

> Regime shifting allows state and nonstate actors, particularly those that have been ignored or marginalized in other international regimes, to experiment with alternative ways to achieve desired policy outcomes.—such as different institutions, different decision-making procedures, and different compositions for actors with different types of subject matter or functional expertise. For NGOs, particularly those shut out of a forum by state-only access rules, regime shifting also offers the obvious advantage of greater access to lawmaking processes.[1126]

Most UN reports released on this subject are critical of TRIPS' uniform standards and urge re-examination for DCs, LDCs, and development agendas.[1127] Participation in norm generation in other legal fora has been successful but short of abandoning TRIPS or

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resulting *Indigenous Research Protection Act (IRPA)* of 2000 and UNESCO's 2003 adoption of the International Declaration on Human Genetic Data. See also Rosemary Coombe, "The Recognition of Indigenous Peoples and Community Traditional Knowledge in International Law" 14 ST. Thomas Law Review 275-85.

[1123] Helfer, *supra* note 1119 at 81.

[1124] Conversely, for some countries' legal systems may have a constraining effect on the actions of governments and the ability to bring forth successful complaints to the DSU. See Christina R. Sevilla, "The Political Economy Model of GATT/WTO Trade Complaints" (1997) Jean Monnet Working Paper Series No. 5, online http://www.jeanmonnetprogram.org/papers/97/97-05.rtf.

[1125] Helfer, supra note 1052 at 9.

[1126] *Ibid.* at 55.

[1127] See *e.g.* UNDP, *Making Trade Work, supra* note 747 at 221-222; Commission on Intellectual Property Rights, Integrating Intellectual Property Rights and Development Policy (2002), online: IPR Commission, <http://www.iprcommission.org/graphic/documents/final_report.htm>,

waiting for further amendments to take force,[1128] it is doubtful whether individuals will become any greater beneficiaries of a de facto shift for the very reason that international IP governance under WIPO was unsuccessful: these other fora simply lack teeth. That is not to say that efforts undertaken to amend TRIPS are not worthwhile[1129] but merely shifting the problems related to IP governance *outside* of the multilateral trading regime by creating *new* norms will not necessarily help solve them.

Professor Dunoff offers a different insight into the rationale behind Helfer's observations of a regime shift.[1130] He contends that state and non-state actions in these other international venues are really about *creating* conflict in recognition and in protest at the binding yet flawed existence of TRIPS and the WTO's faulty 'regime architecture'. Effectively, the impetus for shifting is conflict creation (*within* the WTO and domestic contexts) as a means to demand change:

> That is, one significant component of civil society's response to the frustration resulting from WTO litigation is agitation in other international fora. How should we understand this response? Maybe it is simply forum shopping. But maybe something more significant is at stake. Perhaps

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[1128] For an important discussion on this point and the impediment TRIPS has created for development, see the UNDP Report criticizing TRIPS for the developing world and encouraging these countries to "begin dialogues to replace TRIPS...with alternate intellectual property paradigms" and in the interim to "modif[y]...the way the agreement is interpreted and implemented." Also, there seems to be no indication that TRIPS is being implemented appropriately with inherent balance in mind. *Making Trade Work*, *supra* note 747 at 221, 222.

[1129] Daniel Gervais argues that TRIPS may be the appropriate means for *extending* substantive IP protection to new fields in the interest of developing and LDCs. In relation to prescribing protection for traditional knowledge he warns of some potential problems: "First, while one is perfectly free to criticize TRIPS or suggest that it be amended, the prospect and extent of any such modifications are unknown and difficult to predict. In addition, if amendments do happen, they are likely to require several years to negotiate and enter into force. Third, one would have to be an extreme optimist to think that TRIPS will be amended in ways that respond to every need and concern of holders of traditional knowledge. For these reasons, finding solutions within the confines of the *current TRIPS* text seems a rational way to proceed- which does not mean that work on rewriting TRIPS is ill conceived. Both approaches are complementary." Daniel Gervais, "Traditional Knowledge & Intellectual Property: A TRIPS-Compatible Approach" (2005) Spring Issue 1 *Mich. St. L. Rev.* 137 at 139, footnotes omitted, emphasis added.

[1130] In addition to forum shifting as a means of forum shopping, and providing the opportunity for broader participation by state and nonstate actors (an opportunity to have 'a voice'), Helfer outlines how IP norm creation outside of TRIPS serves as a kind of pressure valve that allows industrialized states that hope to defeat developing countries' proposals to amend TRIPS to resort to the WIPO or other soft law "to shunt issues away from the WTO and thereby reduce pressure from developing countries to address those issues in the WTO." Helfer, *supra* note 1119 at 79.

> civil society, unable to obtain a voice at the WTO, has embarked on a form of exit, in a way that constitutes a deliberate attempt to create conflicts with TRIPS norms. The resulting legal inconsistencies create pressures on states to try to address these conflicts, hopefully in a way more amenable to developing state interests. From this perspective, forum shifting represents a strategic exit and an effort to create strategic legal inconsistency, as part of a larger effort to force change by generating rules in one regime that are at least arguably inconsistent with those in another.[1131]

Dunoff relates this "forum shifting" as a means of contributing to the legitimacy crisis of the WTO in order to rouse support for increasing equity, fairness and civil participation, improving regime architecture and inducing future TRIPS amendments. In the interim we are left with the task of resolving disputes in an era when the potential for disputes has veritably increased and the power for enforcement is disparate.

Still, the creation of conflict creates the imperative for resolution in three noteworthy ways by 1) articulating the conflict in concrete terms and thereby making the conflict more pronounced; 2) creating a more immediate need for resolution; 3) forging a basis for resorting to procedural principles of custom and law for treaty interpretation which effectively facilitate giving preference to substantive content articulated in subsequent instruments.[1132] The critical need to develop a framework for working through contested operability and juridical interaction between hard and soft law[1133] within the WTO, as well as different sub-regime obligations becomes a pragmatic issue as much as a social and redistributive justice one, calling on established rules of treaty interpretation for guidance.

6.6.1 Conflict of Norms: The Matrix of Conflict

A conflict of norms arises when

[1131] Dunoff, supra note 604 at 967. Dunoff adds, "[i]n short, it seems that a diverse group of participants, including grassroots activists, farmers' groups, environmentalists, development groups, human rights groups, consumer organizations- in a phrase, civil society- is the engine here. So after finding little or no voice at the WTO, it seems that civil society groups have started to agitate in other international regimes where they are finding that they can have a meaningful voice." At 968.

[1132] See discussion of the Vienna Convention, *supra* note 1012.

[1133] See Helfer, *supra* note 1119 at 77-79. These conflicts are not the subject of this analysis.

> *it is impossible to comply with all requirements of two norms.* The impossibility of complying with two norms implies that the norms are mutually exclusive; they cannot coexist in a legal order. Compliance with one norm entails non-compliance with the other.[1134]

Some norms are mandatory and impose firm obligations on a party to do something (obligatory norms) or refrain from doing something (prohibitive norms) - identified by "shall" in the norm. Some norms are permissive with discretion/freedom provided to do or refrain from doing something,[1135] using the language "may". Technically, "compliance" can only be required by mandatory norms but may extend to include the permissive exercise of discretion, recognizing that "two norms are reconcilable if there is at least one way of complying with both of them."[1136] Reconcilable "conflict" means that the norms compete until the preferred reading (compliance) is achieved; if there is only one means of reconciliation, it effectively transforms the permissive norm into a mandatory one.

Conflict is "inherent in a system of law" because it is impossible to comprehensively foresee and anticipate the interaction of a norm with existing norms and future norms. In addition, to remain adaptable (and in international law, to be acceptable to the range of parties), norms are phrased in general and vague language.[1137]

Joost Pauwelyn provides a detailed study of conflict of norms,[1138] offering taxonomy of rights and obligations, a framework of how the different norms of international law interact, and a hierarchy with WTO norms. His classification of norms has two notable distinctions. First, he considers the mandatory norms to create

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[1134] Seyed Ali Sadat-Akhavi, "Methods of Resolving Conflicts Between Treaties" (Boston: Brill Academic Publishers, 2003) at 5. Sadet-Akhavi outlines the sources of treaty law, the basis of real and false conflicts, and the resolution of conflict under international laws.

[1135] This is permission *stricto sensu* and is the meaning intended by the use of the term in this chapter. However, another possible use of the term "permission" may be *lato sensu* which means that the act is not forbidden; that is, it is permitted. See discussion and ensuing footnotes in Ali Sadat-Akhavi, *ibid.* at 6.

[1136] *Ibid.* at 42

[1137] Pauwelyn, Conflict of Norms, *supra* note 12 at 12.

[1138] *Ibid.*

obligations: the obligation to do something (a prescriptive norm") imposes a positive obligation and is a "Command"; the obligation to refrain from doing something (a prohibitive norm) imposes a negative obligation and is a "Prohibition". The intricate system of regimes and sub-regimes are also *rights* creating. Discretionary norms create rights: the right not to do something is an "Exemption"; the right to do something is "Permission."[1139] This distinction between rights and obligations is insightful and sufficiently nuanced to bring balance to various interests under TRIPS and the WTO Agreements. That TRIPS contains both *rights* and *obligations* may create intra-textual contestation "not only between two contradictory obligations but also as between an obligation and an explicit right....[I]n practice a conflict of norms will always boil down to a conflict of *rights* and/or *obligations* resting on one or several states"[1140]

Using Pauwelyn's structural conflict taxonomy, we may discern three primary (meta) forms of relational conflict: what I call *Inter-conflict, Intra-Conflict, and Apparent Conflict (Reconcilable* norms). Inter-conflict refers to competing norms found under different regimes or sub-regimes such as, for example, a potential conflict between the CBD and TRIPS Agreement or between TRIPS and human rights instruments, customary international law, or the concept of *jus cogens* which are peremptory norms of general international law governing state behaviour. An intra-conflict of norms is those internal to the system and might exist between *rights* and *obligations* within a single WTO text such as TRIPS or within different WTO agreements such as GATT Article XX and

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[1139] See Pauwelyn, *supra* note 12 at 158. Two additional norms he identifies are those which empower an organ, institution or individual (other than states) with legal capacity under international law, such as Article 2.1 of the DSU which establishes the DSB or WTO committee decisions appointing a committee chairman and norms that regulate other norms by addressing the creation, application, interplay, suspension, termination, breach or enforcement of other norms of international law regardless of whether they additionally impose obligations on states or grant them rights (secondary norms). The norms under the Vienna Convention would fall into this category.

[1140] *Ibid.* at 10.

TRIPS. Both of these two categories raise issues of priority or hierarchy within conflicting norms. Most conflicts under these two categories are merely apparent, however, in that the norms may compete for priority but do not actually conflict since they can be reconciled. Upon further scrutiny the relationship of these norms would better be classified under a third category: Apparent but Reconcilable Conflict for conflicts that can in fact be avoided. Avoidance can take many forms: recourse to treaty interpretation principles and reference to the Vienna Convention on the Law of Treaties (VCLT),[1141] further examination and liberal interpretation of the language giving rise to the perceived conflict including any explicit exclusions ("this provision does not apply to"), permissions ("Members may"), special provisions (such as transition periods or the allowance of regional arrangements which would appear in conflict with the non-discrimination/MFN principles of the WTO), "statutory" (treaty based) defences (such as Article XX of GATT or Article 8 of TRIPS), an equitable defence similar in principle to those in western domestic legal systems, or any combination of these- for example where a text provision has gained international recognition and currency as a customary norm *erga omnes,* that is, in relation to the international community as a whole and is closely linked with - and often derivative of- *jus cogens*; the right to self-determination for example is one in which all states have a legal interest. These examples are merely illustrative and not intended to be exhaustive; they will are examined in the following sections.

6.7 TRIPS Conflicts with Other Instruments: Inter-Conflict with the CBD

The BRCA1 example demonstrates that a state, in attempting to comply with one set of international obligations through domestic implementation (i.e. the right to health),

[1141] *Supra* note 1060. Full text, online: United Nations, <http://www.un.org/law/ilc/texts/treaties.htm>.

may find it has a vertical conflict with a different set of internationally prescribed norms (i.e. TRIPS patent rights) whether or not a concurrent horizontal conflict between the competing international norms exists. Some key international HR obligations creating potential vertical conflict were discussed in the last chapter and are important in the relationship of the state and its citizens. In this section, I will consider the relationship between two international texts and whether there is horizontal conflict between TRIPS and *the* primary international agreement to specifically address biopatenting.

The patenting of genetic material was debated in the biodiversity field well before TRIPS, resulting in the 1992 United Nations Convention on Biological Diversity (CBD) concluded at the Earth Summit in Rio de Janeiro.[1142] The CBD was ratified by over 180 nation states, displaying a significant level of commitment by its signatories. It became an important locus for negotiations by developing countries and international NGOs seeking to offset the corporate lobby to extend patent provisions to life within the multilateral trade regime during the Uruguay Round.[1143] The CBD has three main objectives set out in Article 1: "...[t]he conservation of biological diversity,[1144] the

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[1142] United Nations Convention on Biological Diversity, June 5, 1992, S. Treaty DOC. No. 103-20 (1993) [hereinafter *CBD, Convention, or Treaty*] at http://www.biodiv.org/convention/articles.asp?lg=0&a=cbd-08. The Convention came into force on December 29, 1993 – 90 days after the 50th ratification pursuant to Article 37. Canada was the first industrialized country to fulfill the requirement to also ratify the Convention through its domestic national system. Chairman of the Senate Foreign Relations Committee, Senator Jesse Helms, refused to present the Treaty for a vote and therefore the United States has signed but not yet ratified the Treaty (it requires a majority vote by the US Senate).

[1143] The tension between the CBD and TRIPS has continued since that time. See generally N.S. Gopalakrishnan, "TRIPS and Protection of Traditional Knowledge of Genetic Resources: New Challenges to the Patent System" [2005] EIPR 11-18. There is a strong push from NGOs, DCs and LDCs for another TRIPS amendment to ensure proper disclosure, proof of consent, and benefit sharing of TK.

[1144] "'Biological diversity' means the variability among living organism from all sources including, *inter alia*, terrestrial, marine and other aquatic ecosystems and the ecological complexes of which they are part; this includes diversity within species, between species and of ecosystems." Article 2, CBD.

sustainable use[1145] of its components and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources including by appropriate access to genetic resources and by appropriate transfer of relevant technologies..." The CBD acknowledges and confirms that the UN Charter recognizes a sovereign right of states to exploit their own resources under domestic environmental policies (echoed also under Article XX(g) of GATT 1947).[1146] States also have a duty to ensure the activities within their jurisdiction or control do not cause environmental damage "beyond the limits of national jurisdiction."[1147]

The Parties undertake to co-operate to achieve the objectives of the Convention and are accordingly obligated to take general *national* measures for the conservation and sustainable use of biological diversity.[1148] Whether the TRIPS Agreement can protect biological and cultural diversity through its various IP provisions has been explored comprehensively by Graham Dutfield.[1149] Patenting life raises issues related to the

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[1145] Article 2 on the Use of Terms in the CBD defines this exhaustively to mean "the use of components of biological diversity in a way and at a rate that does not lead to the long-term decline of biological diversity, thereby maintaining its potential to meet the needs and aspirations of present and future generations."

[1146] "...nothing in this Agreement shall be construed to prevent the adoption or enforcement by any contracting party of measures...relating to the conservation of exhaustible natural resources if such measures are made effective in conjunction with restrictions on domestic production or consumption." It is worth noting that the provision applies to "exhaustible natural resources" and biological resources are finite- that is, if used continuously, will be exhausted leading in many cases to extinction.

[1147] Article 3 CBD. See also Article 4 for the scope of the CBD to protect biodiversity within national jurisdiction. Article 4(b) deals with *processes and activities*, within or beyond the limits of national jurisdiction *regardless of where their effects occur* [emphasis added].

[1148] Article 5 and Article 10 CBD. See also Article 8 for In-situ Conservation and Article 9 providing for Ex-situ Conservation obligations of the Parties For a discussion on the intersection between the CBD and the TRIPS Agreement, see Charles R. McManis, "The interface Between International Intellectual Property and Environmental Protection: Biodiversity and Biotechnology." (1998) 76 Washington University Law Quarterly 255-279.

[1149] Dutfield explores the potential use of trademarks for this purpose, including the possibility of certification marks; the potential extension of geographic indications to protect such cultural community based commodities such as Basmati rice cultivated in Northern India and Pakistan (a variety of which has controversially been patented by a foreign firm) will remain a contested issue according to Dutfield until the Parties to the CBD resolve the issue of genetic resources in *ex situ* collections which cannot be protected under plant variety protection where available because it is not a new variety. Trade secrets/undisclosed information protection provided for under TRIPS Article 2 on Unfair Competition can

degree of access and benefit sharing under the CBD that may be attainable with regard to non-human genetic resources (plant, animal, soil etc)[1150] and the availability of the *sui generis* option for plant varieties offered in Article 27.3(b) of TRIPS. In recognition that indigenous communities play a critical role in the preservation of biological diversity as guardians of traditional knowledge, Article 8(j) of the CBD provides:

> Each country *shall*, as far as possible and as appropriate...subject to its national legislation, respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovation and practices and encourage the *equitable sharing of the benefits arising from the utilization for such knowledge, innovations and practices;*[1151]

This *command* norm creates a potential inter-norm conflict with the monopolistic rights of patent holders that TRIPS prescribes (Article 28) which allow not only the non-sharing of the benefits arising from such knowledge but also the exclusion of the community from which the knowledge, innovation, and practice is derived. The "putative conflict between biodiversity and biotechnology", writes Jim Chen, "arises from a fundamental difference in factor endowments. The global north is rich in financial capital and industrial technology but poor in genetic resources. The global south is the precise

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be used to protect the knowledge or know-how of an individual or a whole community as long as it has commercial value and provides a competitive advantage. This would allow a share of profits to be obtained from a company that misappropriates the information. See generally Graham Dutfield, *Can the TRIPS Agreement Protect Biological and Cultural Diversity?* Biopolicy International Series No. 19. (Nairobi, Kenya: ACTS Press African Ctr. For Tech. Stud., 1997).

[1150] See generally Graham Dutfield (2002), "Sharing the Benefits of Biodiversity: Is there a Role for the Patent System?" 5(6) Journal of World Intellectual Property 899-931, reprinted in Keith Maskus, ed. *The WTO, Intellectual Property and the Knowledge Economy: Critical Perspectives on the Global Trading System and the WTO,* (USA: Edward ElgerPublishing Ltd, 2004) at 292. For a discussion of the politics behind these issues, see Rosemary Coombe, "Works in Progress: Traditional Knowledge, Biological Diversity, and Intellectual Property in a Neoliberal Era." In R. Perry and B. Maurer (eds.) *Globalization Under Construction: Governmentality, Law and Identity"* (Minneapolis: University of Minnesota Press, 2003). See also J.H. Vogel, "Know-how licenses: recognizing indigenous rights over collective knowledge" (1997) 4 Bulletin of the Working group on Traditional Resource Rights, 17-18.

[1151] CBD, *supra* note 1142, emphasis added.

opposite: biologically rich but economically poor."[1152] The issue is not, however, just about inputs and outputs in innovation. Rather, it equally pertains to the inclusiveness or exclusiveness of global IPR regimes and the disparate, culturally imperialist treatment given to traditional knowledge, oral culture, and ethnobiological know-how. Drahos and Braithwaite relate this to the accretion quality of knowledge:

> Because intellectual property relates to information and knowledge, and because information and knowledge is built up over time by many people, it is hard to work out just what any given individual is truly responsible for. Ideas are triggered by related ones. All ideas have fuzzy boundaries. Working out where the fence of intellectual property ownership should go is very difficult. In the world of commerce it is legal muscle more than moral entitlement that determines the fenceline.[1153]

Moreover, "indigenous communities tend not to enjoy legal property rights over their valuable (or potentially valuable) knowledge" writes Dutfield. "It would certainly help if they did," he adds, "though the fact that they do not is really a matter of social injustice rather than one of economic inefficiency."[1154]

6.7.1 The Turmeric Example

The conflict over the turmeric patent is an illustrative example. In March 1995, the US patent on "use of Turmeric in Wound Healing" was awarded to the University of Mississippi Medical Center[1155] despite the treatment forming part of the traditional knowledge of Indian communities. By 1996, the Council of Scientific and Industrial Research of India (CSIR) requested that the patent be revoked on the basis that it failed to meet the novelty and non-obviousness requirements for patentability. The patent

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[1152] See Jim Chen, "Intellectual Property and Biological Diversity: A Misunderstood Relation" online, http://www.law.ufl.edu/faculty/pdf/chen.pdf concluding that all stakeholders in the biodiversity and biotechnology debate have exaggerated the nature of their claim and that the commercial exploitation of genetic resources holds the key to biodiversity conservation as it may positively help overcome perverse incentives to consume scarce natural resources by fencing them off.

[1153] Drahos & Braithwaite, *supra* note 7 at 26.

[1154] Dutfield, "Sharing the Benefits of Biodiversity" *supra* note 1150 at 905.

[1155] Specifically, the claim was for "a method of promoting healing of a wound by administering turmeric to a patient afflicted with the wound" including surgical wounds and body ulcers. See Dutfield, *IPRS, Trade & Biodiversity*, *supra* note 22 at 40-74.

description listed other traditional uses for turmeric, derived from the plant *Curcurma longa*, some medicinal, but failed to disclose the prior knowledge of its wound healing properties for which the patent was sought. Nor did the patent disclose any real "invention" by strict standards, failing to provide a method of extracting the active therapeutic principle described. Instead, Dutfield writes, the patent simply declared that 'turmeric is a natural product that is readily available in the food store.' The patent was ultimately revoked on domestic patentability criteria but not on India's claim that it formed part of their traditional knowledge. That is, the US patent examiners are not required by law to accept the evidence of such knowledge held outside of the US as prior art unless it has been reported and *published* in scientific journals or databases or made available to the public in some tangible medium.[1156] Here the conflict was resolved at the state level through patent revocation[1157] without further recourse to international law, highlighting the importance of maintaining strict patentability standards, broad prior art

[1156] In fact, coordinated efforts are now taken to help ensure that such misappropriation of traditional knowledge does not occur. The People's Biodiversity Registers Programme is an initiative originally sponsored by the WWF India and coordinated with the Centre for Ecological Sciences of the Indian Institute of Science (IISC), and the Foundation for Revitalization of Local Health Traditions (FRLHT), and many NGOs since then with the mandate of providing a record of local knowledge for present and future use within those communities, preservation of the knowledge, and protection from foreign misappropriation. See *e.g.* Madhav Gadgil, "People's Biodiversity Registers: Lessons Learnt" online http://www.etfrn.org/etfrn/workshop/biodiversity/documents/gadgil/bioreg.pdf. For a greater discussion of these issues from various national perspectives, see also the draft report of The WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC) Tenth Session November 30-December 8, 2006, WIPO/GRTKF/IC/10/7 Prov., January 26, 2007, online: <http://www.wipo.int/edocs/mdocs>. The IGC was created by the WIPO General Assembly in October 2000 (document WO/GA/26/6) to examine issues and debate policy responses in an international forum, calling on a wide range of participants including states, inter-governmental organizations, and approved NGOs, concerning the interplay between intellectual property (IP) under TRIPS, and traditional knowledge, genetic resources, and traditional cultural expressions (folklore) with consideration to the demands of developing countries and indigenous peoples. Issues within its scope include creating searchable databases of contractual clauses in material transfer agreements, specifying conditions of access to genetic resources and benefit sharing, disclosure of biodiversity information/TK on patent applications, creating a TK database and finding means to document TK in public domain and providing rules for appropriate protections (i.e. through *sui generis* protection). See WIPO Press Release PR/2002/317: "IGC Moves Ahead on Traditional Knowledge Protection" June 25, 2002.

[1157] TRIPS does not prohibit revocation or forfeiture which remain within the regulatory right of domestic IP regimes. However, TRIPS Article 32 commands that opportunity for judicial review of such a decision be made available. As discussed in Chapter 3, revocation does not systemically solve broad policy issues.

considerations, a common sense approach to avoiding bad patents, and the use of attested domestic solutions first as prescribed in this thesis. However, as Dutfield warns, had the patent not been revoked, "Indians in the US using turmeric to treat their children's wounds were therefore infringing the patent [and if] the University of Mississippi had been awarded a similar patent in India, tens of millions of people would then have become patent infringers!"[1158] India could have been liable under TRIPS for lack of enforcement.

Dutfield suggests that Article 27.1 TRIPS contains positive commands in providing that "patents shall be available for" but also *negative* commands (prohibitions) - what he calls "compulsory exclusions" which provide that inventions that are not new, do not involve an inventive step, or are incapable of industrial application or fail to disclose the invention in a manner clear and complete enough to be carried out by a person skilled in the art *must* be excluded from patentability. He contrasts these with the permitted exclusions in Article 27.2 and Article 27.3[1159]- these, it will be recalled, were permissive discretionary norms that allowed sates to provide exclusions specifically related to life, health, morality, and *public ordre* (public policy) in domestic patent law.

Domestic law *can* impose *compulsory* exclusions by requiring *additional* pre-conditions, to those required by Article 27.1, for granting a patent. But, there is an error in inferring that these compulsory exclusions derive from TRIPS Article 27.1 which provides that if certain conditions precedent are met (the patentability requirements), Members are obliged by a command norm to issue the inventor a patent. If we were to reduce this to logical equation, it would be: "if A then B", where A represents the criteria

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[1158] Dutfield, *IPRS, Trade & Biodiversity, supra* note 22 at 65.
[1159] *Ibid.* at 19-20, 24.

for patentability and B represents a patent grant. The claim that Article 27.1 creates *compulsory exclusions* is to assert that the extended logical truth from this syllogism is "if not A, then not B"; but this is not a logically deduced argument. Nothing in the command norm of Article 27.1 legally *prevents* countries or prohibits them from providing a patent when these conditions precedent are *not* met- so long as they are additionally available when they *are* met. In fact, in this dissertation I have tried to draw attention to how lax patentability standards and the proliferation of bad patents suggest that patents *are* granted without the requirements *actually* being met even though this is, as Dutfield suggests, poor practice and a betrayal of the bargain with the Crown. Moreover, since TRIPS prescribes universal *minimum* standards, the language of Article 27.1 appears not to prohibit the adoption of other – additional- criteria for granting patents so long as patents are available, at a minimum, where its conditions precedent are met; this is supported by the language "patents shall be *available"* rather than "patents shall be *granted"*. Thus, in terms of inter-conflict norm, the conflict may be resolved domestically in a conciliatory manner with both CBD obligations and TRIPS obligations by giving interpretation to the content of the patentability criteria which are undefined in TRIPS and by allowing states to create additional standards if necessary to reconcile CBD obligations, such as evidence of informed consent, benefit sharing contracts, and other conditions imposed on ownership, as pre-conditions to patentability.

In terms of intra-norm conflict, the requirements of Article 27.1 could possibly be resolved with reference to the exemptions in Article 27.2, "Members may exclude from patentability inventions...necessary to protect *ordre public or morality, <u>including</u> to protect* human...health." The grounds for invoking this right are not exhaustive but

inclusive based on the language. Members also have rights of exclusion under Article 27.3(a) for therapeutic methods for the treatment of humans or could rely on clause (b) for plants (though *sui generis* protection is required as an alternative to plant patents).[1160] Articles 27.1 and 27.2 exemptions are discretionary and create *rights* for Members. In so doing, they pre-empt inter-norm conflict with TRIPS. That is not to say that inter-norm conflict between TRIPS and its predecessor, the CBD, is not possible. For example, it is not clear whether plant, animal, and human genetic resources fall within the language of Article 27.3(b) as "plants" or "animals" since they are merely a subcomponent of these. Thus, unless a Member invoked its exemption right under Article 27.2 or a liberal interpretation is given under 27.3(b) when a Member contests a measure pursuant to it, then genes would fall within the command of Article 27.1 as patentable. Yet, Article 15 of the CBD affirms the sovereign rights of states over their natural resources and

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[1160] Such regimes may provide more or less protection than patent rights and different standards as criteria. The template for such regimes usually advocated for is UPOV 1991 by developed countries and UPOV 1978 by developing countries due to the greater flexibility and weaker scope of protection. The latter upholds the farmer's privilege to save seeds form year to year and thereby would lessen intrusion on customary practices of plant variety breeding, but countries now joining UPOV are required to accede to the 1991 version. For a discussion of UPOV and recommendations reconciling potential UPOV and TRIPS obligations or CBD and TRIPS obligations through *sui generis* protection within patent legislation, within plant variety protection or possibly under biological conservation legislation see Graham Dutfield, *supra* note 22 at 75-85, 128-129. Neither the nature nor scope of a *sui generis* regime, nor the period for protection, is prescribed by TRIPS which is one reason that the United States has actively and consistently advocated for the removal of Article 27.3. IPRs have influenced the evolution of other international regimes governing plant genetic resources (PGRs) initially resisted and contested by developing country governments who considered them public goods defying private proprietary interests regardless of whether these resources were in their natural state (in situ) or in global seed banks (ex situ) or modified through human intervention creating new seed or plant varieties. Negotiations usually occur in the context of the Commission on Genetic Resources for Food and Agriculture (CGRFA) under the Secretariat appointed by the UN's FAO. See http://www.fao.org. Since 1983, the UN Food and Agriculture Organization (FAO) has been developing its Global System for the Conservation and Sustainable Use of Plant Genetic Resources for Food and Agriculture with the objective of promoting safe conservation and unrestricted availability and intergenerational sustainable use of PGR. The CBD, while addressing genetic resources generally, did not deal with PGR for food and agriculture specifically or the access rights to PGR ex situ (international seed banks). Much of the soft law declarations developed to protect farmer's rights, national sovereignty, public domain treatment of CGIAR seed holdings in the non-binding *International Undertaking on Plant Genetic Resources* (IUPGR) were finally codified into the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGR), http://www.fao.org/ag/cgrfa/IU.htm. For a broader discussion on potential conflicts between this instrument and TRIPS, see Helfer, *supra* note 1119 at 37-42. See also Dutfield, *IPRs, Trade, & Biodiversity, supra* note 22 at 100-105.

recognizes that the authority to determine access to genetic resources (coming from that country as a country of origin) rests with the national governments subject to national legislation. This is consistent with the permissive rights-creating norms of Article 27.2 and Article 27.3.

Article 15.4 and Article 15.5 of the CBD provide for access, and informed consent respectively; Article 15.6 supports the interpretation given by this thesis (chapter 5) that any HR to IPRs is a right of *participation* and *access*: "Each Contracting Party shall endeavour to develop and carry out scientific research based on genetic resources provided...with the full participation of, and where possible in, such Contracting Parties." Article 15.7 provides another command norm potentially in conflict with TRIPS:

> Each Contracting Party shall take legislative, administrative or policy measures, as appropriate and ...with the aim of *sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilization of genetic resources with the Contracting Party providing such resources.* Such sharing shall be on mutually agreed terms.[1161]

Access to, and transfer of, technology are similarly found in the command norms of Article 16.3:

> Contracting Parties...which provide genetic resources are provided access to and transfer of technology which makes use of those resources, on mutually agreed to terms, *including technology protected by patents* and *other intellectual property rights*, where necessary, through provisions of Article 20 [financial resources] and 21 [financial mechanisms] and in accordance with international law...

Article 16.5 "Recognizing that patents and other intellectual property rights may have an influence on the implementation of this Convention, [Contracting Parties] *shall cooperate in this regard subject to national legislation and international law in order to ensure that such rights are supportive of and do not run counter to its objectives.*" These provisions create tensions but they seem reconcilable with TRIPS- for example, with the provision for exception to the rights conferred (Article 30), compulsory licencing (Article 31), or

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[1161] CBD, *supra* note 1142.

even the revocation of such patents on the basis, for example, of strict domestic patentability standards not being met. The implication for (plant or animal) genetic resources unique to a particular state are controversial but less so than potential conflict over access to patented human genetic resources that may be conceived of as the *common* heritage of humankind, where to allow their patenting would foster *information feudalism.*[1162]

Some scholars believe there are *inherent conflicts* between TRIPS and the CBD that require TRIPS amendment[1163] because the latter allows patentability of genetic material which may encourage biopiracy of this material by private parties, conflicting with the CBD's confirmation of sovereign rights over genetic resources. The envisaged amendment would expressly exclude the patentability of life and parts thereof, the patentability of inventions contrary to Article 15 of the CBD and those based on traditional or indigenous knowledge. While express language would eliminate any doubt, there is nothing *inherently* conflicting about TRIPS if given proper interpretation. In fact, part of the functionality of apparent conflict is in generating system improving measures for their resolution. States can resolve any potential conflict by adopting stricter domestic requirements. For example, genetic patents could be excluded from patentability on the basis of "products of nature" or discoverability doctrines, or others

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[1162] Drahos & Braithwaite, *supra* note 116 at 219.

[1163] See e.g. V. Tejera, "Tripping Over Property Rights: Is it Possible to Reconcile the Convention on Biological Diversity with Art. 27 of TRIPS Agreement?" (1999) 33 New Eng. L. Rev. 967 at 983-985. NGOs, DCs and LDCS were proposing such an amendment during the final stages of Doha negotiations. See "NGOs, Intellectual Property Rights, and Multilateral Institutions" Queen Mary Intellectual Property Research Institute, online, http://www.ipngos.org/casestudies/agriculture/index.html.

currently not found in the law)[1164] or reconciled with Member rights that the exemption norms of Article 27 provide.

Article 27.3(b) has an internal provision for review with respect to the patentability of plant varieties, animal inventions and the production processes for these, "four years after the date of entry into force of the WTO Agreement". Unlike other TRIPS provisions, this Article does not expressly state by *whom* that review is to occur and therefore the various UN reports outlined in this dissertation on the interplay of TRIPS, HR, and HD are relevant. Nevertheless, the TRIPS Council commenced its own review in 1999 which was broadened by para. 19 of the 2001 Doha Declaration to include consideration of the relationship between the TRIPS and the UN CBD, traditional knowledge, and folklore and has yet to be completed.[1165] The Declaration also provides that the Council's work programme, including overseeing implementation issues pertaining to the whole of TRIPS under Article 71.1 and the review of Article 27.3(b), is to be guided and informed by the objectives and general principles of the agreement as provided for under Articles 7 and 8 respectively, taking development issues fully into account.[1166]

In any event, what is emphasized in the CBD is not that such information *cannot* be patented but to ensure co-operation amongst states for equal access and benefit sharing, which TRIPS mandated exclusive proprietary "rights" curtail, and proper

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[1164] Although patent law's traditional distinction - between inventions, which are patentable because of the value added by the innovator and discoveries, which are to remain in the public domain because that which is discovered has always been there - is gradually being eroded in the biotech sector. See Peter Drahos, "Biotechnology Patents, Markets and Moralilty" (1999) 21 Eur. I.P. Rev. 441.

[1165] Other provisions requiring notification of Council by Members are Articles 63(1), 1(3), 3(1), 4(d) and 69. For a detailed history and discussion of the Council's formal meetings since 1999 and his view on the review provisions, see Gervais, *supra* note 493 at 27-67, 227-232.

[1166] See para. 19, Doha Ministerial Declaration, *supra* note 12. See also WTO's reference on this relationship at http://www.wto.org/english/tratop_e/TRIPS_e/art27_3b_e.htm.

obtaining of prior informed consent by relevant communities in advance of prospecting for genetic resources. Accordingly, as Dr. Bodeker suggests, if greater use of traditional knowledge (especially the health benefits of such traditional medicinal knowledge) is to be made for the benefit of all interested stakeholders, it would be prudent for "WIPO, the CBD and the WTO to coordinate their policies and instruments in partnership with traditional knowledge holders as well as with conventional stakeholders such as governments and industry."[1167] Patenting life, preservation of biodiversity, equitable access, and benefit sharing formed formidable challenges to TRIPS' inclusion in the Uruguay Round.[1168] The relationship between the CBD and TRIPS remained unresolved and was left for another day- perhaps another document.[1169] The Doha Round succeeded in achieving a limited improvement for HR through the public health amendment to the TRIPS text and should serve as an instructive precedent for obtaining social justice in the future through coordinated efforts.[1170] Additionally, the specific reference to biodiversity, traditional knowledge and folklore protection in the 2001 Ministerial Declaration

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[1167] Gerard Bodeker, "Traditional Medical Knowledge, Intellectual Property Rights and Benefit Sharing" 2 Cardozo J. of Int'l & Comp. Law 785 at 812.

[1168] Gervais, *supra* note 493.

[1169] There is some discussion of the possibility of a TRIPS II emerging from the general nature of the review under Article 71.1 to address issues from the built in agenda- such as whether the only acceptable *sui generis* regime under Article 27.3(b) would be a UPOV system. New issues such as stronger substantive requirements (TRIPS Plus) for protection and a strengthened enforcement section allowing, for example trade associations to act before judicial authorities, freezing of bank accounts and assets and winding up companies in serious commercial infringement cases are all concerns, see Gervais, *ibid.* at 48. Gervais does not believe TRIPS will be modified and that a separate agreement is more likely.

[1170] The review of Article 27.3(b) has lead to extensive discussions on substantive and procedural issues. As part of the Council's process of information gathering, many Members have submitted formal communications to the Council (Brazil, India, Japan, Mauritius on behalf of the African Group, Singapore and the United States); two have submitted informal communications (India and Singapore). Additionally, the Secretariats of the FAO, CBD, UPOV, and WIPO provided information for this review. In October 2000, the Special Session of the General Council (SSGC) on Implementation requested the Council to continue its ongoing work to clarify the relationship between TRIPS and the CBD; the informal discussions have yet to result in formal conclusions. See Document WT/CG/M59, para.43 and discussion of these proceedings in Gervais, *ibid.* at 38-40. The SSGC urged the TRIPS Council to grant observer status to the CBD Secretariat but no consensus was reached on this and the matter was left for the Chairperson to report to the SSGC on his responsibility. (See Document IP/C/21.)

promises to level the gains of IPRs by offering interpretive insight on how to treat the hitherto parasitic relationship of 'First World' inventions and 'Third World' inputs consistently with TRIPS rights-creating exemptions that relegate these to a sovereign's discretion.[1171]

6.8 Conflict Avoidance: Vienna Convention and Interpretation Issues

Most apparent intra or inter conflicts can be avoided through interpretation principles applied to treaties if the obligations set out in the treaties are *performed* in good faith as required by the principle of *pacta sunt servanda* (Article 26) codified in the Vienna Convention on the Law of Treaties (VCLT).[1172] The VCLT defines "treaty" exhaustively by stating in Article 2.1(a) that "treaty" "means an international agreement concluded between states in written form and governed by international law, whether embodied in a single instrument or in two or more related instruments and whatever its particular designation." Treaties must also be "*interpreted* in good faith in accordance with the *ordinary meaning* to be given to the terms of the treaty *in their context* and in the light of *its object and purpose*" (Article 31.1). The WTO Agreements are treaties for the purpose of international law and subject to the VCLT's rules on treaty interpretation.[1173] The WTO Appellant Body (AB) has held in several cases that the rules of the VCLT enjoy the status of customary international law and that terms of an agreement must be interpreted in light of their object, purpose and context.[1174] Under Article 31.2, the

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[1171] Doha Declaration, *supra* note 12, para. 19. See generally, Daniel Gervais, "Traditional Knowledge & Intellectual Property: A TRIPS-Compatible Approach" (2005) Spring Issue 1 Mich. St. L. Rev. 137 at 146.
[1172] *Supra* note 1090.
[1173] Note, there is a technical distinction within domestic American law between treaties and trade agreements in the different approval procedures each requires for implementation. As a trade agreement, the WTO would require approval by a simple majority of both Houses of Congress, while treaties require approval by two-thirds of the Senate. See Johnson, *ITL supra* note 645 at 40, footnote 21.
[1174] See *United States- Standards for Reformulated and Conventional Gasoline,* WT/DS32/R (29 January 1996) (96-0236) [*Reformulated Gasoline, Panel*] and *Japan-Taxes on Alcoholic Beverages,*

"context" includes, the text, preamble, annexes, subsequent agreements or instruments between the parties in connection with the conclusion of the treaty, as well as subsequent agreements on interpretation or practice or special meaning if intended by the parties. Supplementary means of interpretation may be resorted to in order to confirm the interpretation under VCLT Article 31 or resolve any ambiguous or obscure meaning from the interpretation given (Article 32). However, there are general rules for priority of treaty obligation set out in VCLT Article 30, which provides that earlier obligations between the same parties of a later treaty will only apply to the extent that they "are compatible with those of the latter treaty."

6.9 TRIPS Conflicts internal to the WTO

The global governance institutions have been instrumental for *a priori* conflict avoidance amongst nations despite the increased conflict potential that legal fragmentation has wrought. The mode of analysis adopted in this section is to consider the kinds of conflicts that may arise and prescribe a sensible legal approach (a human rights framework) and a legal defence such that Members may predict the outcome of a WTO dispute with rational acceptance of this as a statutory defence, and choose *not* to complain to enforce perceived TRIPS violations relating to life forms on the same principle of *pacta sunt servanda*: agreements shall be observed. It would be tantamount to evaluating the merits of bringing a civil action in domestic law in light of its facts, issues, *and* the applicability of available *defences*. It would also reduce the number of

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WT/DS8/AB/R, WT/DS10/AB/R, WT/DS11/AB/R, Appellate Body Report (10 April 1996) at 11. The *Japan-Taxes* AB noted that Article 3.2 of the DSU requires that the provisions of "covered agreements" and the GATT 1994 be clarified "in accordance with customary rules of interpretation of international law." For a more detailed discussion of a number of decisions, see generally, Terence P. Stewart & Amy S. Dwyer, *Handbook on WTO Trade Remedy Disputes: The First Six Years (1995-2000),* (USA: Transnational Publishers Inc, 2001) 78-85.

cases that do get "litigated" and the uncertainty of having a dispute settlement body seized of these issues within a broader debate of WTO jurisdiction.[1175]

The best approach for a state to defend against a WTO complaint is to reduce the matter to intra-conflict (between one member's rights and another's obligations) within TRIPS narrowing the issues to an interpretive exercise of a single text. In *Japan-Taxes on Alcoholic Beverages,* the AB emphasized that the principal guide to treaty interpretation is the text of the treaty itself while refusing to interpret these agreements in "clinical isolation" from other areas of international law.[1176] The question is,

> how WTO jurists will respond to claims that TRIPS is inconsistent with the treaty commitments and soft law norms of other international regimes. Although such claims of inconsistency may have substantial persuasive force when used to support treaty amendments or promote soft lawmaking, they are likely to be viewed quite differently when raised during a WTO dispute settlement proceeding.[1177]

Helfer argues that soft law can be effectively used to interpret TRIPS obligations even if it cannot be used to justify a violation of TRIPS obligations. He writes:

> because implementing TRIPS does not compel a violation of these agreements or standards (even though it may narrow the discretion or options available to states), WTO jurists are likely to reject claims that violating TRIPS is necessary to avoid conflict with other treaty commitments or regime objectives. The fact that noncompliance with TRIPs cannot be excused on these grounds does not, however, preclude states from arguing that TRIPs should be interpreted in a manner that avoids such conflicts and harmonizes international objectives. Soft law will be an important tool for WTO panels to use in resolving such arguments.[1178]

In addition, Helfer argues that soft law may also "serve as foundation for the evolution of binding international custom, which *is* accepted as a rule of international

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[1175] For a thorough list of recent articles on the trade-human rights relationship, see Marceau, *supra* note 1104, footnote 1. Some scholars believe that conflicts between trade and human rights laws are really about conflict in systems of values unlikely to be resolved by dispute settlement alone as they need to be addressed as policy issues in political arenas. See for example, Jose Alvarez "Trade and the Environment: Implications for Global Governance: How Not To Link Institutional Conundrums of an Expanded Trade Regime" (2001) 7 Widener L. Symp. J. 1.

[1176] *Japan- Taxes on Alcoholic Beverages,* supra 1174 at 13 and 11 respectively. See also Gabrielle Marceau, "A Call for Coherence in International Law: Praises for the Prohibition Against "Clinical Isolation" in WTO Dispute Settlement" (1999) 33 J. World Trade 87, cited in Helfer, *supra* note 1119 at 68.

[1177] Helfer, *supra* note 1119 at 68.

[1178] *Ibid.* at 71, footnotes omitted.

law."[1179] Helfer's insights are useful in the interpretive phase of treaty provisions for conflict avoidance. However, the scholarly focus on appropriate interpretation of treaty obligations in the literature often neglects the utility of referring to TRIPS *rights* as to inform legal understanding of the issues in a conflict minimizing manner.

TRIPS confers onto WTO Members specific *rights* by providing for a number of Exemption and Permission norms, most of which have been set out in chapter 3 of this thesis as TRIPS compliant domestic solutions, that give a state the right to exercise discretion in meeting other command (obligatory) norms, such as the legal taking provision of Article 31 which is not limited to compulsory licencing for government use but can be extended to any third party use so long as it is provided for in domestic law.[1180] The permission norm of Article 31 pre-empts conflict. Paragraph 5(b) of the Doha Declaration on TRIPS and Public Health recognizes that the TRIPS does not limit the grounds for issuing compulsory licences and paragraph 5(c) confirms the Member's right to determine what constitutes national emergency or extreme urgency.[1181] Thus a Member cannot complain that another state invoked a compulsory licence or that the case was not a national emergency or extreme urgency although there may be possible complaint on other vague language such as "reasonable commercial terms".[1182] Article

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[1179] *Ibid.*

[1180] The opening paragraph to Article 31 provides 'where the law of a Member allows for other use of the subject matter of a patent without authorization of the right holder, including use by the government or third parties authorized by the government, the following shall be respected..." and proceeds to list conditions.

[1181] *Supra* note 918.

[1182] Trebilcock and Howse argue that what should be taken account in making this determination is more than the economic interests of the private intellectual property rights holder to just compensation but also the economic and social interests that TRIPS provides for including the transfer and dissemination of technology to the mutual advantage of producers and users under Article 7 and the need to prevent abuse of IPRS (under Article 8) all of which should be considered in interpreting the rights and obligations under Article 31. See Trebilcock & Howse, *supra* note 237 at 412.

31's remedial domestic response is enhanced by the precedent for a TRIPS amendment to deal with the trade-public health conundrum of production of generic drugs for export.

The nature of the Member's right in Article 31 is such that a measure that falls within the language of the provision is prima facie legally justified. It would not be enough for the complainant to argue that, for example, Article 28 outlining the exclusive rights conferred under patent, are violated by a government grant of a compulsory licence under Article 31 because that licence is well within *the right-creating* norm of TRIPS and takes priority over any obligation. Article 3 of the DSU provides that a proper balancing between rights and obligations of Members is to be achieved through dispute settlement. Consequently, a complainant would have the burden of proving that the alleged violating Member's action did not *comply* with the text of the compulsory licence provision and the text may subsequently be opened for interpretation. The AB has recognized that the burden of proof requires that the party who asserts a fact,

> whether the claimant or the respondent, is responsible for providing proof thereof. Also, it is a generally-accepted canon of evidence...that the burden of proof rests with the party, whether complaining or defending, who asserts the affirmative of a particular claim or defence. If that party adduces evidence sufficient to raise a presumption that what is claimed is true, the burden then shifts to the other party, who will fail unless it adduces sufficient evidence to rebut the presumption.[1183]

The complainant must establish that the measure, which is prima facie compliant, does not in fact comply (perhaps because its application is discriminatory) or it fails to meet an internal requirement for the exercise of the right. Interpreting Article 31 as a TRIPS norm-creating right, instead of as a defence, gives the Member who operates under this right the benefit of the burden of proof by imposing on the complaining party the burden of proving that the contested measure exceeds the scope of the Member's

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[1183] United States- Measures Affecting Imports of Woven Wool Shirts and Blouses from India, WT/DS33/AB/R (5/23/97) [*Shirts and Blouses*] at 14, footnotes omitted.

right. Article 31 is not a complete solution, however, for a Member as the restrictions on production for domestic consumption apply to other areas of technology and vital sectors, such as food, outside of the "essential medicines" allowance made during the Doha Round. Moreover, certain textual ambiguities exist (what does "predominantly" in Article 31(f) mean in quantifiable terms?). Many conflicts of norms may be avoided by the recognition of Member rights but some may need to proceed to dispute settlement.

Other textual permission norms provided in TRIPS include the right a Member has to provide limited exceptions to the exclusive patent rights conferred (Article 30) but this is limited by the proviso that the exception does not "unreasonably conflict with a normal exploitation of the patent" and does not "unreasonably prejudice the legitimate interest of the patent owner, taking account of the legitimate interest of third parties." Article 27.2, Article 27.3, and Article 8 also give the State regulatory discretion over certain domestic matters. Again, these exemption and permission norms preserve state domestic regulatory sovereignty by creating *rights* for the Member which *prima facie* justify an action within their scope. They place the burden on the complainant to prove a violation, sufficiently, at least, to give rise to a rebuttable presumption. The language of these provisions defines the scope of a *positive right* of a Member rather than stating an *affirmative defence* to the allegation of a breach of some other *positive obligation* of the Member.

The exemption and permission norms should be effective in avoiding conflict by signalling that the Member is well within its rights to adopt a given measure. However, it is foreseeable that an intra-textual, even intra-provisional, conflict dispute may arise on whether a measure does actually fall within the *scope* of the right and the task for the

panel or AB will be to balance the interests of the parties taking into account TRIPS rights and obligations. The AB or panel, when deciding a case are effectively acting as law makers vis-à-vis interpretation of textual and customary international obligations much like domestic courts do, though decisions are only binding on the parties and the DSB cannot add or diminish TRIPS rights or obligations (Article 3, DSU).

To date, the balance in patent complaints seems to be skewed in favour of property rights holders (or states acting on their behalf) with a rather conservative interpretation being given to TRIPS rights.[1184] Despite the permissive exemption norm of Article 30, its interpretation in the *Canada-Generic Medicines* case,[1185] has all but vacated its utility. Trebilcock and Howse write:

> [The panel] considered the meaning of the expression 'limited' solely from the perspective of the rights-holder, and without regard to the policy goals or purposes of the exception (para. 7.13). Even though dealing with an explicit 'exceptions' provision, comprehensible only if there are legitimate competing policy interests, *the panel was only interested in how much the rights-holder might lose, not in how much society might gain, from a given exception. It never asked what scope the exception might require to achieve the social purpose at issue.* It also failed to consider the scope indicated by the expression 'limited' in light of the protection of public health, an objective explicitly affirmed in Article 8.1 of the TRIPs Agreement.[1186]

Regrettably, the same normative force of property fundamentalism that ushered in the judicial extension of patenting life forms through domestic law continues to infuse the reasoning of WTO decisions relating to the balance of interests under TRIPS disputes.

[1184] In *India-Patent Protection for Pharmaceuticals and Agricultural Chemical Products,* WT/DS50/AB/R, adopted January 1998, the AB upheld a decision of the panel that found that the administrative means of maintaining patent applicants' priority cue during a transition period for implementing TRIPS obligations did not comply with its "mail-box" condition which would require legislative oversight to secure the applicants' interest despite members' implementation discretion under Article 1.1 which places the burden on complainants to establish that the non-legislative method chosen was non-compliant. In *Canada- Term of Patent Protection,* WT/DDS114/R, adopted 7 April 2000) the AB rejected Canada's argument that the 20 year period would not have to be extended to pre-TRIPS patents granted. *Canada-Patent Protection of Pharmaceutical Products,* WT/DS170/AB/R adopted 12 October 2000, the panel was split on two issues finding that regulatory testing before patent term expiry was permissible but manufacture and stockpiling of generics was not. For greater detail, see Trebilcock & Howse, *supra* note 237 at 417-423.

[1185] *Ibid.*

[1186] *Ibid.* at 418-419, emphasis added. See also Robert Howse, The Canadian Generic Medicines Panel: A Dangerous Precedent in Dangerous Times, (2000) 3 J. World Intell. Prop. 493 critiquing the Panel Report (WT/DDS114/R), *supra* note 916 and 918 for that dispute.

But the TRIPS text does allow a state to tighten patentability standards or apply more stringent disclosure criteria (Article 29) and thereby achieve desired policy outcomes in health. Once grounds for granting a patent have been met, the exclusive rights attached to the patent, set out in TRIPS Article 28.1, extend to "owners" of a patent but no definition is offered. Nor are there any restrictions internal to TRIPS on states adopting specific criteria for the "owner" status (to neutralize the corporate "person" for example), other than the cornerstone criteria of NT and MFN.[1187] Trebilcock and Howse contend this has

> major implications for the ability of developing countries, for instance to ensure that patent protection does not conflict with their development needs. Technology transfer, acceptance of price controls, etc. could all be imposed as conditions for an entity to be recognized as an 'owner' of a patent...[1188]

6.10 Remapping WTO Cartography with the GATT Article XX Defence

Unlike the exemption and permission norms giving Members certain discretionary rights discussed in the last section to be weighed against a Member's TRIPS obligation, there are some WTO discretionary norms that may be better characterized as 'affirmative defences' to be invoked by the party complained against and considered by the panel only *after* the complainant has discharged its burden and proven a violation of some *other* provision of the covered agreement.[1189] Then, as with regular civil litigation in most common law jurisdictions, once a violation of the other provision has been established, the legal burden shifts to the party complained against to prove the

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[1187] See discussion by Trebilcock & Howse on the implications to other areas of IP of the AB's decision and analysis of "ownership" in the *Havana Club* case, *United States- Section 211* Omnibus Appropriations Act of *1998,* WT/DS176/AB/R, adopted 1 February 2002, where the EC challenged US legislation denying ownership and legal protection to trademarks associated with businesses and property confiscated by Castro's regime. The AB found that it was a legitimate basis for doing so. See also Trebilcock &Howse, *supra* note 237 at 425.

[1188] *Ibid.* at 426.

[1189] *United States- Standards for Reformulated and Conventional Gasoline,* Report of the Appellate Body, WT/DS2/AB/R, (adopted May 20, 1996) at 16 [*Reformulated Gasoline, AB*].

affirmative defence in order to escape liability. The difference is not only technical but legal as it affects the burden of proof on the respective parties.

On the one hand, the legal burden of proof on a defending party for an affirmative defence is more onerous than the evidentiary burden of rebutting a presumption of non-compliance that a complaining party may successfully raise. The complainant still carries the burden of proving that what is claimed is true in a dispute and whether, if true, the allegedly violating act exceeds the scope of a *right* and thereby gives rise to the complaint that the measure breaches an obligation (the obligation to conform domestic measures to treaty rights). Conversely, with affirmative defences, the burden is on the defending party with respect to *all legal and factual tests in that defence*[1190] but only *after* the complainant has successfully established a breach of some other obligation. Having a formally recognized affirmative defence offers the defending party additional procedural recourse to negate liability once the complaining party has succeeded in making its case on some other provision and the defending party has already been determined unable to discharge the shifting evidential burden to rebut it.

In *Shirts and Blouses,* the AB gave Article XX as the obvious example of an affirmative defence.[1191] In *Reformulated Gasoline,*[1192] the AB found that the burden of proof for showing that a measure was not an abuse of an exception (that it does not exceed it) falls on the defending party even after proving that the disputed measure falls within the enumerated exceptions under the paragraphs of Article XX.[1193] Regrettably,

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[1190] Subject to specific language in the text to the contrary. See *Shirts and Blouses, infra* note 1191 at 16. See also Trebilcock & Howse, *supra* note 237 at 129.

[1191] *United States-* Measures Affecting Imports of Woven Wool Shirts and Blouses from India, Report of the Appellate Body, WT/DS33/AB/R (23 May 1997) (97-133), AB-1991-1 [*Shirts and Blouses*].

[1192] *Reformulated Gasoline, Panel, supra* note 1174.

[1193] *Reformulated Gasoline, supra* note 1189 at 22. But see *Japan-Measures Affecting the Importation of Apples,* WT/DS245/AB/R (adopted 10 December, 2003), wherein the AB noted: "It is important to

the implication of this decision is a presumption of bad faith contrary to the principle of *pacta sunt servanda* codified in the VCLT. The decision has been rightly criticized by Trebilcock and Howse:

> The AB, however, gave no explicit justification for this finding—one could as easily have argued that once a measure is shown to fall within an exculpating category, the burden of demonstrating that it is being used abusively shifts back to the complaining party, based upon the notion that Members of the WTO should not generally be subject to a rebuttable presumption that they are abusing rights acquired under the WTO law.[1194]

The Analysis that follows in the next section strives to operationalize their suggestion.

6.10.1. Article XX Jurisprudence for Interpreting the Defence

Article XX(d) of GATT 1947 allowing Contracting Parties to adopt or enforce measures to ensure compliance with domestic IP laws[1195] recognized the historically territorial quality of IPRs and meant that as an enumerated exception to the basic GATT trade obligations, domestic regulation of IPRs were largely excluded from GATT disputes.[1196] However, jurisprudence under the Article XX exemption norms of GATT 1947 will provide some insight into the conventional understanding of how the "statutory" Article XX defence operates; an important inquiry in light of the scope and field of numbered exceptions provided under it. Some of the key sub-provisions relevant

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distinguish, on the one hand, the principle that the complainant must establish a *prima facie* case of inconsistency with a provision of a covered agreement from, on the other hand, the principle that the party that asserts a fact is responsible for providing proof thereof. In fact, the two principles are distinct." at paragraph 157.

[1194] Trebilcock & Howse, *supra* note 237 at 129.

[1195] Specifically, measures "necessary to secure compliance with laws or regulations which are not inconsistent with the provisions of this Agreement...[for] the protection of patents...and the prevention of deceptive practices..."

[1196] In *United States- Section 337 of the Tariff Act of 1930* (EEC v. US) (1988), GATT Doc L6439, 36th Supp. B.I.S.D.(1988-89) 345, a GATT panel reviewing Section 337 of the US Tariff Act under Article XX (d) in 1989 as a violation of NT required under Article III found that it did violate that obligation since it entailed domestic enforcement measures procedurally weaker for foreigners than that offered to nationals violating American IPRs. The NT required "treatment no less favourable" under Article III which was interpreted as requiring "effective equality of opportunities" in domestic laws and regulations. Once the EU established its complaint under Article III, the burden shifted to the US as defending party to justify the measures under Article XX. The panel found that measures were not "necessary" to the enforcement of domestic intellectual property laws as other countries enforced their domestic IPRs adequately and equally through measures that applied to both nationals and foreigners and provided the same legal processes.

to the patenting life debate are Article XX(a) on the party's adoption of measures *necessary to protect public morals* and Article XX(b) *necessary to protect human, animal or plant life or health* (repeated in the language of TRIPS discretionary norms), subject to the proviso in the "Chapeau" of Article XX that the measure must not be applied "in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or a disguised restriction on trade."[1197] These provisions have been explored by a number of panels and AB in their reports.[1198] Decisions under the DSU since the formation of the WTO also contribute insight into the workings of the affirmative defence and are essential guidelines on issues of interpretation. However insightful they are, adopted panel reports and AB decisions are not *binding* on parties outside of the dispute to whom they applied.[1199]

The Article XX defence allows members to adopt certain measures notwithstanding GATT obligations. The complainant must first establish the inconsistency of the measure with GATT obligations, the burden then shifts to the defending party to establish that the measure falls within the scope of the exception and

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[1197] While there is debate about whether the opening language of Article XX means that Article III on NT applies regardless or whether a weaker standard of it applies only to the matters listed due to the words "between countries where the same conditions prevail", The GATT panel decision of US-Section 337 of the Tariff Act, *supra* note 689 and 1196 on the GATT consistency of s. 337 of the US Tariff Act held that the Article XX(d) exception may be claimed for measures that would otherwise violate Article III. See Trebilcock & Howse, *supra* note 237.

[1198] It is important to remember that prior to the WTO DSU, a decision could be not adopted if the losing party vetoed the decision because adoption required consensus. See chapter 5 in text.

[1199] *Japan- Taxes on Alcoholic Beverages, supra* note 1174 at 16. "Adopted panel reports are an important part of the GATT *acquis*...They create legitimate expectations among WTO Members, and, therefore, should be taken into account where they are relevant to any dispute. However, they are not binding, except with respect to resolving the particular dispute between the parties to that dispute...." In addition, the AB concurred with the panel that unadopted reports have no legal status in the GATT or WTO system but could be used as useful guidance to a panel. But, the AB in *Argentina-Measures Affecting Imports of Footwear, Textiles, Apparel and Other Items* (WT/DS121/AB/R) (98-1190), AB-1998-1 (27 March 1998) was critical of the panel for relying on unadopted panel rulings as legal authority and in the Shrimp/Turtle implementation ruling, *United States- Import Prohibitions of Certain Shrimp and Shrimp Products,* Report of the Panel. WT/DS58/R (15 May 1998) (98-17-10), the AB held that though not binding, future panels were to be guided by prior rulings of the AB.

to do so that party needs to establish that the policy objective of the measure is within the range of policies captured by the exception invoked, that the measure is, in relation to Articles XX (a), (b) and (d), "necessary" and satisfies other language internal to these paragraphs, and that the measure is applied in conformity with the introductory clause ("chapeau") of Article XX.

6.10.2 Is the policy objective of the impugned measure within the scope of Article XX and "necessary"?

In *US-Section 337 of the Tariff Act of 1930,*[1200] a GATT panel held that even if a policy objective is within the scope of Article XX, a defending party cannot justify the measure as "necessary" if there is an alternative measure available that is not inconsistent with other GATT provisions. If all measures directed at the objective are GATT inconsistent, the least inconsistent alternative should be adopted. The reasoning employed by the panel in this decision in deciding whether Article XX(d) applied was extended to Article XX(b) in *Thailand Restrictions on Importation of and Internal Taxes on Cigarettes.*[1201] Here, the panel accepted that smoking was a serious risk to health and that the Thai governments' ban on foreign cigarettes (from the US) for this policy purpose while allowing the sale of domestic cigarettes under the regulated industry was within the scope of (rationally connected to) the exception. But, in determining whether it was "necessary" the panel found that the measure was not the least restrictive of trade means available for achieving this objective and in applying a form of proportionality test, it determined that the ban could not be justified under Article XX(b) of the

[1200] US- Section 337 of the Tariff Act of 1930 (EEC v. US) (1988), GATT Doc. L/6439, 36th supp. B.I.S.D. (1988-89) 345.
[1201] (US v. Thailand) (1990) GATT Doc DS10/R, 37th Supp. BISD (1989-1990) 200 [Thai Cigarettes].

GATT.[1202] The panel failed, however, to give proper consideration to the interests of the defending party when imposing the need to adopt alternative non-trade measures where possible; this requirement is very invasive and reaches deep into the regulatory framework of a state potentially imposing greater domestic costs for regulatory monitoring and enforcement associated with the alternative measure.[1203]

In the *Tuna/Dolphins I* case, the measures considered by the panel were American quantitative import restrictions (contrary to Article XI) on Mexican fish or fish products harvested using a method that endangered the life of dolphins accompanying the schools of tuna in the eastern tropical Pacific Ocean contrary to domestic standards used. The panel determined the measures taken to protect dolphin life and preserve biodiversity were policies within the scope of the Article XX(b) and (g) exceptions, neither of which in their text impose any limitation requiring that the life, health or natural resources being protected fall within the territorial jurisdiction of the defending party asserting sovereign jurisdiction in taking the measure under Article XX of the GATT. However, on the issue of proportionality required by "necessary" in the Article XX paragraphs, the panel found that the US failed to show it exhausted all options less restrictive of trade and gave the Articles a narrow interpretation, finding that the exceptions did not extend to production or consumption outside of the defending party's jurisdiction. In *Tuna/Dolphins II*[1204] the challenge was to a secondary embargo in US tuna legislation by the EU which contested the GATT consistency of this measure designed to prevent transhipment and importation

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[1202]The ban was because the marketing, advertising and additives to US cigarettes posed greater health risks by attracting younger consumers and increasing the probability of their addiction. Less restrictive measures would have, for example, targeted the control of advertising and content requirements that applied on a non-discriminatory basis to both domestic and foreign cigarettes rather than banning imports altogether.

[1203] See Trebilcock & Howse, *supra* note 237 at 516.

[1204] *US- Restrictions on Imports of Tuna: Report of the Panel* (1994) GATT Doc DS29/R [*Tuna/Dolphins II*].

of dolphin-compromising tuna through third countries. The panel reconsidered its approach in the earlier tuna case and found that there was nothing requiring the policy objective under Article XX to be limited to protection within the defending party's territory and that global commons/environmental policies could be justified under this defence so long as the desired policy impact within the scope of the defence was not achieved solely through the inducement of policy changes in *other* countries because this would seriously impair GATT objectives. Because the objective of the measure was determined to create positive policy changes in other jurisdictions, this was determined to be outside the scope of both exception Article XX (b) or (g).[1205]

6.10.3 Does the contested measure conform to the "Chapeau"?

If a defending party is successful in establishing that the measure is directed at a policy within the scope of Article XX, and that it is "necessary", or "relating to" as the respective paragraphs warrant, the measure must of course be applied even-handedly in order to withstand allegations of discrimination and disguised protectionism.[1206]The

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[1205] *Ibid.* at 5.26 regarding GATT Article XX(g) and at 5.38 regarding Article XX(b).

[1206] For example, *Canada- Measures Affecting Exports of Unprocessed Herring and Salmon*, BISD 35S (1988) 98; see also Trebilcock & Howse, *supra* note 237, at 515, a Canadian regulatory measure requiring fish caught in Canadian waters be processed in Canada before export was held to be a violation of Article XI and failed to meet the Article XX(g) test set out by the GATT Panel. The Panel interpreted the wording that measures be 'related to' conservation of exhaustible natural resources "as meaning 'primarily aimed at' such conservation, but it viewed this as weaker than the requirement of 'necessity' imposed by Article XX(b)." In this case, accurate statistical data which was the purported objective of the measure, could be collected without the ban as was done for other species whose exports were not banned but that were subject to conservation measures. See also *In the Matter of Canada's Landing Requirement for Pacific Coast Salmon and Herring,* Final Report of the Panel, 16 October 1989 where a seemingly neutral measure requiring that Canadian water fish be landed and unloaded in Canada was found to have a disparate impact on US destined fish (that would have to land there too) and was appropriately struck down by an FTA panel as a violation of Article XI and disguised protectionism of the British Columbia fishing industry. The panel ruled that alternative means less trade restrictive were available to Canada to meet its objectives of monitoring and compliance with its domestic conservation scheme such as co-operation with US authorities or on board inspections of catches and cargo such that the measure's objective of conservation could not be considered as the 'primary purpose' and therefore Article XX(g) would not apply. Trebilcock & Howse argue that the "the availability of a hypothetically less restrictive means of achieving the same goals should not necessarily mean that the measures under scrutiny fail the least-restrictive means test." *Ibid.* at 517.

liberal use of the enumerated exceptions is firmly curtailed by reference to the "chapeau" portion preceding it:[1207]

> Subject to the requirement that such measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or a disguised restriction on international trade, nothing in this Agreement shall be construed to prevent the adoption or enforcement by any contracting party of measure.[1208]

The chapeau is considered in the manner in which the measure is applied and while the language has some ambiguity, the fundamental theme is to be found in the purpose and object of avoiding abuse or illegitimate use of the exceptions under Article XX.[1209] While the 'object and purpose' of the treaty has been a common approach to interpreting trade obligations by panels and the AB, in *Beef Hormones*[1210] the AB emphasized that it cannot be the basis for ignoring a textual analysis based on the wording of a provision.[1211]

6.11 Does the Article XX Defence Apply?: Differentiating Article XX from the Equitable Conduct Defence

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[1207] See *Reformulated Gasoline,* Report of the Panel, WT/DS2/R (29 January 1996), *supra* note 1189. The Appellate Body's (AB) review of the Panel's findings was the first environmental decision by the AB and was significant in establishing a methodology for examining a contested measure under Article XX (b) and (g): "[T]he AB in *Reformulated Gasoline* had stated that the application of Article XX is a two-step process, involving first of all a determination of whether the measures fall within a particular exception, and second, whether they meet the criteria in the chapeau....[T]he AB had distinguished between the first step, the determination of whether a measure falls within a particular exception, and the second step, that of ascertaining whether the *manner of application* of measures is reasonable or abusive." [emphasis in original, footnotes omitted] see Trebilcock & Howse, *supra* note 237, at 526-528. Equally important, is the AB's refusal to give the words "necessary to" and "relating to" anything other than an 'ordinary meaning' thereby rejecting the 'least-restrictive means' test from XX(g). The AB considered whether the measure as a whole, and not just the GATT-illegal element was aimed at conservation.

[1208] Art. XX GATT 1994.

[1209] *Reformulated Gasoline, supra* note 1189 at 85. See also *Shrimp-Turtles, supra* note 1199.

[1210] *EC measures concerning meat and meat products (hormones)* WT/DS58/AB/R Appellate Body report adopted on October 12, 1998 [*hereinafter* Beef Hormones]. The 'dioxin crisis' that hit Belgium in Spring of 1999 after it was discovered that the meat and eggs of chickens that had consumed tainted feed contained levels of the noxious chemical sufficient to harm its consumers, coupled with the hormone-beef concern may have spurred the EU to solidify its position on the precautionary principle in a Communication [COM (2000) 1 final], see Natalie McNelis, "EU Communication on the Precautionary Principle" (2000) J. of Int'l Eco. L. 545. Here the EU imposed an import ban on beef from cattle raised with growth hormone because of concerns that consumption of such beef may be carcinogenic. A violation of the WTO's Agreement on Sanitary and Phytosanitary Measures Article 1(2) and Annex A Nr 1.which limits national regulations to those aimed at protecting human, animal, or plant life or health from specifically defined 'food-borne' or 'pest-or disease-related' risks was found against the EU despite the fact that it was not shown that the ban had the effect of restricting international trade. The AB held that the EU was not entitled under the SPSA to maintain this prohibition.

[1211] See also the *Reformulated Gasoline*, *supra* note 1189; *Japanese Alcoholic Beverages*, *supra* note 1174.

If the Article XX defence were to apply to TRIPS disputes, it would create another source of inter-textual conflict (intra-system conflict) within the WTO. This next section considers whether the defence applies and if not, the lessons that can be learned in interpreting the TRIPS Article 8 provision as a similar affirmative defence.

It would appear that Article XX does not apply to TRIPS disputes. The VCLT (Article 30) provides that absent an express rule to the contrary, later specific agreements on the same subject by the same parties prevail over earlier treaties. While the introductory note to Annex 1A of the WTO Agreement provides that in the case of conflict between GATT 1994 and a provision of another Agreement in Annex 1A, the provision of the other Agreement prevails to the extent of the conflict, no WTO rule describes the relationship between agreements in different annexes. In *Canada-Certain Measures Concerning Periodicals*,[1212] the issue of the relationship and the potential for inconsistencies between two agreements (GATT 1994 and GATS) were addressed. Both the panel and AB found that the obligations under the different agreements can co-exist without overriding each other[1213] and therefore, state measures must conform to each agreement to which a state is party. For example, a measure may be TRIPS consistent yet inconsistent with a different GATT provision but nevertheless justified within the

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[1212] *Canadian Periodicals: Canada - Certain Measures Concerning Periodicals*, AB-1997-2, WT/DS31/AB/R, (adopted 30 July 1997) [*Canada Periodicals* AB]. Canada argued that its 80% tax on advertising revenues from split-run editions of periodicals was a measure regulating access to the magazine ad market and covered by GATS under which Canada had not committed in relation to the provision of advertising services and thus did not have to comply with the NT requirement of Members (at 5-6). The panel had found that the measure (an import restriction on split-run periodicals) to secure compliance with tax laws did not fall within the scope of the policies excepted under Article XX and thus the defence failed without further analysis of the elements under Article XX.

[1213] *Canada Periodicals,* Panel Report, WT/DS31/R,[Periodicals Panel], at 73-73, para. 5.17 and *Periodicals AB, supra* note 1212 at 17. This same approach was adopted by the AB in *EEC-Regime for the Importation, Sale and Distribution of Bananas,* WT/DS27/AB/R (25 September 1997) at para. 221.

exemption norm of the affirmative Article XX defence.[1214] Let us imagine a state recognizes in its law the patentability of genetically modified or living modified organisms (GMOs and LMOs). This is completely consistent with its trade obligations under TRIPS. The state may have a related measure imposing regulatory standards for health risks related to trade in GMOs and LMOs and this measure may be contested under the GATT 1947. If the measure is non-discriminatory it should be found to be GATT consistent.[1215] However, if the complainant proves that the measure is discriminatory, a problem for the defending party under Article XX, or that the products are "like" products so that the effect is discriminatory, then the burden would shift to the defending party to invoke GATT Article XX(b) proving that the measure was "necessary" for the purpose of, *inter alia*, the protection of human life and health. A ban on a new variety hamster tobacco plant to be introduced into the environment, for example, would arguably fall within Article XX(b) as "necessary to protect human, animal or plant life or health."[1216] Still, it would have to pass scrutiny under the chapeau to determine whether the restriction is an arbitrary, unjustifiable, or disguised

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[1214] For example, the basic GATT obligation relevant to domestic health regulation is non-discrimination. Howse writes, "health measures that neither treat products from some WTO Members better than others nor treat "like" domestic products better than imports are consistent with WTO law, and do not require a justification under the health "exception" in Article XX of the GATT because, in determining "likeness", WTO rules permit health risks to be taken into account." See Robert Howse "The WHO/WTO STUDY on Trade and Public Health: A Critical Assessment" online, http://faculty.law.umich.edu/rhowse/Drafts_and_Publications/WHOWTO.pdf#search=%22howse%20critical%20assessment%22 at 1. See also AB decision in *European Communities-Measures affecting Asbestos and Asbestos-Containing Products*, Report of the Appellate Body, WT/DS135/AB/R (12 March 2001) where Canada challenged a ban by France on all asbestos and asbestos containing products and the AB, reversing the panel's finding, found that the health effects of the products could be considered in determining likeness under article III.4 but in upholding the panel's finding that the measure could be upheld under Article XX(b).

[1215] "[E]ven if imported product A and domestic product B are alike in many other respects, if imported product A creates health risks that domestic product B does not, it would be consistent with National Treatment under the GATT to ban or restrict A but not B." Howse, WHO/WTO Study, *ibid.* at 1.

[1216] Although hamster gene tobacco to be smoked by consumers (as a commodity) may be found to be against the Cartegena Protocol for the protection of the Environment itself and if challenged under the GATT, the restricting Party may have to argue that the measure was necessary to protect human health under Article XX(b) relying more on the harm of tobacco than the fact that it is genetically modified.

protectionist measure. This analysis would occur outside of TRIPS and is consistent with the AB's finding that measures must conform to each agreement to which a state is party. However, there is no prescriptive guidance on resolving intra-WTO conflict of norms as between, for example Article XX and a TRIPS obligation.

In *Japan-Taxes on Alcoholic Beverages,* the AB emphasized that a principal guide to treaty interpretation is the text of the treaty itself[1217] and this was echoed by the AB in *Beef Hormones.* The affirmative defence is, by the very language used in the text of the original GATT 1947, limited to "this Agreement". Its extension into the GATT 1994 was by direct incorporation of the earlier GATT; consequently, the defence is limited to GATT 1994 obligations and does not apply to those arising under other agreements such as TRIPS. In two disputes settlement reports on *Section 211 Omnibus Appropriations Act,*[1218] whether the general exceptions of Article XX could be permitted under TRIPS were raised before the AB which concluded that no new exception based on the GATT would be allowed if it violated substantive TRIPS provisions. This understanding can also be normatively justified on the basis that all attempts should be made to read out conflict from international treaty obligations.[1219] Still, that is not to say that the Article XX defence (and jurisprudence) has no influential role. In fact, it can be informative on several levels to parties in formulating arguments consistent with human rights obligations but apparently inconsistent with TRIPS obligations.

[1217] *Japan – Taxes on Alcoholic Beverages*, *supra* note 1174 at 13.
[1218] US- Section 211 *Appropriations* Act: United States- Section 322 Omnibus Appropriations Act of 1998. complaint by EC (WT/DS176/AB/R).
[1219] See Trebilcock & Howse, *supra* note 237 at 546, agreeing that "as a general matter, the dispute settlement organs ought not easily to assume a conflict of obligations exists, but instead begin by attempting to read the WTO rules in such a manner as to fulfill or not frustrate the other treaty rights and obligations."

First, there may be an argument to be made that certain provisions of Article XX have gained international recognition as part of customary law (*jus cogens*) as within the sovereign jurisdiction of a state to regulate. Article 31.3(c) of the VCLT provides under the general rule of interpretation that what shall be taken into account is "*any* relevant rules of international law *applicable in the relations between* the parties". Evidence could be adduced from other international soft and hard law, the existence of collateral treaties developed under the auspices of the UN, like the CBD, environmental regulation, and from Article XX itself which is relevant to the relations between the parties, as well as the principle now well entrenched since the *Lotus* case[1220] that the sovereignty of states is presumed to be unlimited in its own territory unless bound by specific rules of law and particularly so in these specific areas of law and public policy.[1221] The merits and validity of such a claim are well beyond the scope of this thesis and will not be explored further.[1222] More important for present purposes, the approach to the affirmative defence may be helpful in embracing or rejecting a similar interpretive approach to any affirmative defence raised in relation to a *prima facie* inconsistent measure located within TRIPS.

[1220] S.S. "Lotus" (France v. Turkey), 1927 PCIJ (Ser. A) No. 10 (Sept. 7) at 18, the Permanent Court of International Justice finds: "the first and foremost restriction imposed by international law upon a State is that – failing the existence of a permissive rule to the contrary – it may not exercise its power in any form in the territory of another State. In this sense jurisdiction is certainly territorial; it cannot be exercised by a State outside its own territory except by virtue of a permissive rule derived from international custom or from a convention." See generally Pauwelyn, *supra* note 12 at 150 and footnote 199 describing how this decision stands for the 'residual negative principle' in international law which posits that "'everything which is not expressly prohibited is allowed.'"

[1221] This is contrary to the finding by the *Tuna/Dolphin II* panel which held that other agreements were not relevant for the interpretation of GATT treaty obligations if they did not apply to the Contracting parties suggesting that GATT was self-contained and impervious to other rules of other international regimes. Compare this with the AB decision in *Shrimp/Turtles*, *supra* note 1199 where international environmental law (hard and soft) was applied for interpreting the scope of the expression "exhaustible natural resources" in Article XX(g). See Trebilcock & Howse, Chapter 4 Dispute Settlement and references therein. See generally Joost Pauwelyn, "The Role of Public International Law in the WTO: How far can we go?" 95 AJIL 535 [Pauwelyn, "PIL"].

[1222] For a discussion of the interaction of treaty obligations and *jus cogens*, see Pauwelyn, *supra* note 16.

The Equitable Conduct Defence proposed in this dissertation justifies deviations from trade obligations in terms of market access rules in the same manner that the Article XX defence does. Both are based on discretionary norms (permissions) created within the treaty text as a means of balancing state interests against obligations raised in other provisions of the same text. And the approach taken to formulating and asserting this defence before the WTO can well be enhanced and informed by the existing jurisprudence of Article XX reviewed above.

6.12 The Equitable Conduct Defence: A Public Policy/Interest Affirmative Defence

The supporting text for founding an Equitable Conduct/Public Interest Defence (ECD) is set out in TRIPS Article 8 permitting measures necessary to "protect public health and nutrition" and "to promote the public interest in sectors of vital importance to socio-economic and technical development..." To summarize the burdens analyzed so far, we can say:

The complaining party in a trade dispute must prove:

Claim 1: *A violation of an Obligation as set out in a provision of the text* or

Claim 2: *The violation of a Right- that is, the defending party has exceeded the scope or jurisdiction of the discretion arising from a provision of the text and in exceeding its right, has violated an obligation.*

Within these two contexts, there may be shifting evidential burdens of proof but the legal burden remains with the complainant. Once discharged, the legal burden shifts to the defending party to establish an affirmative defence in order to avoid liability and as discussed above, for Article XX this means proving that the measure falls within the language of Article XX but also, because of the AB's interpretation, that it does not

exceed the statutory defence.[1223] Earlier, Article 8 was included as part of the rights creating norms of TRIPS (functioning similar to Article 31 on compulsory licencing for example). However, Article 8 may need to be re-imagined as an affirmative defence akin in spirit and function to the GATT Article XX affirmative defence.[1224] Article 8's existence and dual identity as a *right* creating norm means that it may have a role in claim 1 or claim 2 in support of the defending party's shifting evidential burden but its greatest utility is as an affirmative defence.

The most compelling reason to consider Article 8 as creating a *defence* rather than a *right* is that the latter creates substantive protections for members to achieve particular public policy outcomes and the necessary institutional balance in their domestic IPRs by granting the discretion (through exemption/permission norms) to adopt diverse measures within their right (such as Article 30 and Article 31). In contrast, the concept of an "equitable defence" imports two important principles. First, the idea of a defence supports the need for the complainant to contest the consistency of a measure against some *other* provision before the legal burden shifts to the defending party to establish legal justification under Article 8. This is different from the interpretive approach taken to the rights creating discretionary norms of TRIPS (i.e. Articles 27.2/3, 30, 31 etc.) considered in text above; there, the contestability of a measure was based on whether it fit into the scope of the rights creating norm as discerned from the language of the provision; if it did not, there would be liability without a defence. Second, there are important reasons for characterizing this defence as "equitable" even though I argue it is

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[1223] See in text discussion, *supra* at page 394.
[1224] See discussion in text above, pages 90-93.

derived from TRIPS' text and in that regard is a "statutory" defence. These are enumerated below:

1. "equitable" helps contextualize the defence as one necessary to overcome the formalism of the law in pursuit of just equitable outcomes within the broader relationships of disputing parties under TRIPS as required by the "public interest" referred to in Article 8 and "equitable sharing" under the CBD.

2. Characterizing Article 8 as an equitable defence reflects the potential liability of a state to its respective publics under other instruments if strictly adhering to strict IPR protection above all other competing domestic regulatory policy objectives. What is the responsibility of a representative government to its constituents and should meeting that responsibility be fettered due to TRIPS mandated IPRs? For example, a state may be domestically liable for human rights violations under its own legislation, under its Constitution, and under international instruments. The Article 8 ECD is a procedural safeguard for upholding particular human rights obligations of a State for which it may be domestically liable. Otherwise a state will be placed in a very precarious position acting on the one hand in a manner to minimize its own potential liability to its citizenry domestically for HR violations but may nevertheless be exposed to foreign liability and resulting trade sanctions undermining the welfare interests of the very public whose HR were being observed. If the state takes a measure that is prima facie inconsistent with a TRIPS right or obligation, then that measure may be justified and should equitably be recognized as such if it falls within the language of Article 8 just as a public policy objective within the scope of Article XX is defensible. This is "equitable" in that it provides a trade-related safeguard against trade related hazards of HR promoting

domestic measures. Successive governments should not be fiscally punished and subject to increased domestic liability to individual citizens for their respective individual rights and civil liberties on the basis of international trade and intellectual property obligations, though utilitarian, committed to by prior governments and with current disutility.[1225] Trade theory and policy are designed for maximizing the public interest by reducing consumer costs through the reduction of trade barriers. The normative justification for trade and institutional IPRs is similarly focused on the public interest. If their internationally mandated protection results in welfare loss by impeding a state from fulfilling its HR obligations then these instruments of private property are no longer instrumental as global public goods and result in incoherence of the international system for global (self) governance. After all, any gains to be had in giving human rights domestic priority would have to be set off against the costs that non-compliance with international law might impose (such as carousel trade sanctions); costs that are ultimately borne *by the peoples* in the aggregate (primarily as consumers) in order to protect the rights of *peoples* (as citizens of a state) individuated and humanized.

3. The ECD is mindful of transaction costs and is therefore economically efficient. The public who is to benefit from the existence of IPRs has to pay at least three but perhaps four times: first as tax paying subsidizers of innovation facilitating

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[1225] "The extent to which we believe that approval of today's government is enough to provide legitimacy for rules that will have significant impact long after that government is gone, and which it is costly for future government to reverse (as, in practical terms, it would either have to get the consent of all other members to change the rules or accept a waiver, or be faced with the very high-stakes choice of withdrawing from the WTO)." Robert Howse, "Human Rights in the WTO: Who's Rights, What Humanity? Comment on Petersmann, online <http://ejil.org/journal/Vol13/No3/art2.pdf> at 11. He adds: "Given the cost of reversibility by a future government, my own view is that the people should be consulted directly by referendum on the results of the Doha round, and that all governments should undertake to translate the proposals into local languages, and distribute them to the entire populations..." (*ibid.*).

institutions such as public education and health; second, as rent payers on the patented inventions; third, as subsidizer's of government liability to constituents for violations of human rights obligations; and fourth, as consumers bearing greater consumption costs upon an adverse finding of non-compliance by the WTO DSB for regulatory measure that are, I suggest, justifiable. Governments tend to be self-insurers. If the right to health is at a minimum a negative right to have one's health free from government interference, it would impose on the government an obligation not to harm its individual citizens by creating statutory measures (IPRs) *contrary* to the realization of this right.[1226] If the claimant is able to establish that this interference is unconstitutional, a monetary award may be granted or patents invalidated. Assuming a government were held liable and forced to pay, the monies paid would come from public coffers and effectively, the harm created to the benefit of private property rights holders in the patented invention would be further spread as a cost to society with the public having to pay for the patented invention *directly* in its grant and *indirectly* (through their taxes) for a trade-inconsistent measure taken by their government in order to avoid *direct* royalty payment for their common use.

4. The ECD may restore some of the legitimacy of the WTO by enabling a fairer application of the rules without which, the very existence of the WTO is threatened. In the absence of a multilateral trade system threats of unilateralism, illegitimate sanctioning, restrictive border and/or tariff barriers, and bilateralism between strong and weak countries, may re-emerge with beggar-thy neighbour policies of a State in pursuit of self-sufficiency. A 'race to the bottom' may take place as protectionist regimes send us

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[1226] A constitutional challenge may successfully be raised whether or not ECSR are expressly entrenched in a country's Constitution; *Chaoulli, supra*, note 841 seems to leave this door open, even though the Canadian Charter does not constitutionally guarantee the protection of socio-economic rights. See also Amani, "Patents & the Charter" *supra* note 793.

back in time to a grim period of non-specialization, non-interdependence, non-co-operation, and a resulting poorer world. The ECD would recognize the importance of updating the WTO's mandate to meet current 'social' challenges' and the central role of the state in overcoming them.[1227]

These paradoxes should not be institutionally perpetuated and though the conundrum is not easily reconcilable with the existing TRIPS jurisprudence, it may become so with the recognition of an Article 8 defence. What is needed as a guide to interpretation is a comprehensive understanding of the purpose, mandate, scope, jurisdiction, and unifying principle for the WTO and its place in global and local regulatory institutions. Using Article 8 as an affirmative defence rather than a right helps overcome criticisms by some commentators that Article 8 is tautological and as an articulation of "principles" has no direct bearing on the parties in terms of creating rights and obligations. The alleged tautology is in that the discretion allowed under Article 8.1 is qualified by the language in the text "provided that such measures are consistent with the provisions of this Agreement." That ambiguous or seemingly tautological terminology finds its way into trade agreements is not surprising and follows from the desire to make treaties more acceptable to different negotiating members. A member's adoption of a TRIPS consistent measure can be for any purpose and so the inclusion of this qualification in Article 8 does seem superfluous. However, the interpretative principle of effectiveness (*ut res magis valeat quam pereat)* provides that interpretation must give effect to all terms of the treaty. This principle was cited by the AB in *Japan* –

[1227] Trebilcock and Howse argue for rejuvenating the WTO: "The perspective from which the policies of Members are examined needs revision. Currently, the only issue considered in these examinations is whether a Member's policies and practices support free trade. It is clear, however, that the perspective through which a Member's policies are reviewed should not be that of free trade alone but rather that of the *'functioning of the multilateral trading system'*." Trebilcock & Howse, *supra* note 237 at 583.

Taxes on Alcoholic Beverages to support the finding that no clause or paragraph may be reduced to "redundancy or inutility".[1228] In *Reformulated Gasoline*, the AB, referring to Article 31.3 of the VCLT, found that "interpretation must give meaning and effect to all the terms of the treaty. An interpreter is not free to adopt a reading that would result in reducing whole clauses or paragraphs of a treaty to redundancy or inutility."[1229] This principle would support reading Article 8 as a defence (perhaps based on a right) as opposed to a mere laudatory articulation of an overarching though unenforceable principle that would otherwise be superfluous; Members inherently have a right to adopt *any* TRIPS consistent measure for *any* purpose and need not provide an explanation where the measure is not contested. Article 3.2 of the DSU confirms that the "DSB cannot add to or diminish the rights and obligations provided in the covered agreements."

While Jon Johnson argues that Article 8 does not provide "true 'exceptions' such as those in Article XX of the GATT 1994,"[1230] on the contrary, there are good reasons for interpreting this permission norm as a full fledged defence. In *Beef Hormones,* the AB found that the interpretive principle of *in dubio mitius* requires that where two plausible approaches to the interpretation of a treaty provision exist, the interpreter must adopt the interpretation that is less restrictive of the sovereignty of the state or states undertaking the obligation.[1231] Certainly, interpreting Article 8 as an ECD is less restrictive of

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[1228] *Supra* note 1176 at 14 (AB).
[1229] *Supra* note 1174, at 22 (AB).
[1230] Johnson, *ITL supra* note 645 at 199.
[1231] Compare this, however, with the panel decision in *Canada-Generic Medicines, supra* note 916 contesting the Canadian provision allowing competing generic manufacturers to test patented products before the required 20 year protection period had expired and to stockpile production of generics 6 months before the expiry. While the testing provision was upheld as GATT consistent, in a very strange decision of the panel, the stockpiling was not despite the fact that the nature of the rights is to protect the patentee from competition and thus rents during the patent period. The result was that the additional term it would take to produce generics post expiration would effectively be a windfall for the patentee constituting additional ex post rewards rather than ex ante incentives. In determining whether the measures fell within

sovereignty over regulatory matters that are specifically exempted in the language of the provision's text. And while a purposive approach cannot compromise an interpretation on the textual wording of a provision in dispute settlement, "textualism should not mean a neglect of inquiry into purpose and object, when considering the exact words of the text."[1232] The closing language of Article 8.1 was added at the last stages of the TRIPS negotiation.[1233] On one level it provides the rationale for measures taken under Articles 30, 31, and 40. However, our discussion illustrates that the utility of Article 8 must go beyond that if the principles of treaty interpretation are to be given any effect. That is, a Member need not provide the motivation for any measure until the measure is contested. If a complainant is able to establish that a measure exceeds the defending party's rights under a different provision, like Articles 30, 31, and 40, then Article 8.1 will allow the defending party to try to provide legal authority and justification for that measure; this may be easier to do where the TRIPS is silent on a matter or has created an exemption or permission norm such as those related to the patenting of life in Article 27.2 and 27.3.

If it is a defence analogous to Article XX, the approach to interpreting this defence and the words "necessary to protect" in Article 8 need not be subject to the burden imposed by the AB in *Reformulated Gasoline* which required the defending party to establish that the contested measure did not abuse the discretionary permission norms of Article XX by proving that the contested measure was within the scope of Article XX, *and* did not actually exceed it. This led to the difficulty of proving that a measure

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Canada's Article 30 rights that formed an exception to TRIPS, the panel's interpretation of "limited" failed to consider Article 8 and the legitimate interests of the defending party to protect public health. For a discussion of this, other TRIPS decisions, Article 7, and Article 8, see Trebilcock & Howse, *supra* note 237 at 416.

[1232] *Ibid.* at 134.

[1233] Gervais, *supra* note 493 at 122.

"necessary" was in fact the least restrictive means of achieving its objective. Given the fresh start under Article 8, we may adopt the Trebilcock and Howse recommendation of a rebuttable presumption ensuing once the defending party establishes that the measure is *prima facie* within the scope of the ECD within Article 8. The evidential burden can shift to the complainant to establish that it does not exceed it. This will shift the formidable challenge of proof from the defending party to the complaining party where a measure is prima facie justified as defensible and thereby removes the bad faith implication created by the AB under Article XX.

Some readers may disagree with my characterization of Article 8 as a defence and yet insist that whatever the status of the provision, the language imposes the full burden on the defending party. In that case, Article 8 would be more of a defence than Article XX since the latter artificially imposes the full burden on the defending party (by the AB's decision) whereas Article 8 would do this based on the different language of its text. A full burden of proof textually imposed for establishing a legal justification and authority is more consistent with our normative understanding of burdens of proof for defences in the law. At the same time, Article 8 has reduced the scope of that burden by requiring proof of consistency not with the *Agreement* (required by Article XX) or *obligations under the Agreement* (the language in an earlier draft of Article 8)[1234] or some broader concept of *international trade* (as would be the case with non-violation complaints) but with the *provisions* of the Agreement.

The language of Article 8.2 does not provide any textual basis for limiting measures taken to prevent abuse to any particular conception of "abuse" such as the non-working or refusal to licence a patent. Rather, the anticompetitive behaviour of patent

[1234] See discussion in this thesis, *supra* page 308 and accompanying footnotes.

portfolios and bad patents and the unfair competition practices that result from the predatory uses of patents discussed in Chapter 3 and 4 would seem to be sufficient justification for invoking this defence as certainly they result in the unreasonable restraint of trade domestically. There is nothing to suggest that the reference to "trade" in Article 8.2 should be interpreted as *international* trade; in fact, the inclusion of the adjective "international" before "transfer of technology" seems to negate such an interpretation with respect to trade.

On a common sense reading of this provision, a complaining party would first have to establish that a measure was inconsistent with a provision of the TRIPS (a right was exceeded or obligation not met), the burden would shift to the defending party to invoke Article 8 as a defence with the full proof of establishing, as with Article XX jurisprudence, 1) that the object and purpose of the measure falls within the scope of the Article 8 exceptions; 2) that it was "necessary" or taken "to promote"- different criteria just as in Article XX(b) and (g); and 3) is consistent with the provisions of the Agreement, which include NT and MFN obligations. On my formulation, the burden then would shift to the complainant to establish that the defending party's conduct exceeds even the defence (abuses state discretion permitted under Article 8). Trebilcock and Howse contend that the role and interpretation of Article 7 and 8 remain uncertain:

> It remains an open question whether...a foreign patent-holder who refused to comply with policy measures aimed at facilitating technology transfer or preventing anti-competitive abuse of patent protection could be legally denied the level of protection specified in the TRIPS agreement. In other words, are domestic policy measures that condition the granting of rights under the TRIPS Agreement on compliance with the kinds of measures contemplated in Article 7 and 9 "consistent" with the TRIPS Agreement? A further interpretive issue is whether Articles 7 and 8 could be used as a 'shield' by developing or other countries against unilateral US action in response to policies in conformity with the Uruguay Round TRIPS Agreement but nonetheless considered 'unfair' by US trade authorities? [1235]

[1235] Trebilcock & Howse, *supra* note 237 at 411.

I suggest that the appropriate role of Article 8 within TRIPS disputes is as an affirmative defence. Moreover, the argument for the ECD would suggest "yes" as the appropriate response to these interpretive questions and the language of consistency with the "provisions". Even if the full burden was to be imposed on the defending party under Article 8, it is much narrower and less onerous than that under Article XX's chapeau where the AB has interpreted "unjustifiable discrimination" and "a disguised restriction on international trade" sometimes in terms of *the least restrictive means,* creating an evidential hurdle for the defending party.

The need to adhere to the textual language of a provision is consistent with Articles 3.2 and 19.2 of the DSU that provides "the panel and Appellate Body cannot add to or diminish the rights and obligations provided in the covered agreements." Recognizing an ECD would not be asking for any such law making on the part of the panel or AB but rather would be the appropriate way of interpreting what is already provided for in the Agreement text and has been renewed as a commitment in the Doha Ministerial Declaration where Articles 7 and 8 were highlighted as having special importance.[1236]

6.13 Additional Recommendations for the Stewardardship of the WTO

> Civil society groups worried over threats from industry on the basis of TRIPS Agreement rules may find a modicum of comfort in the appointed guardian of the TRIPS Agreement- the WTO Appellate Body. There is a difference between threatening countries on the basis of unwarranted interpretations and the reality of persuading the AB. However, just as the US Supreme Court does not intervene on each occasion an accused is improperly imprisoned, so the AB is not involved in the daily implementation of the TRIPS Agreement. Its influence is somewhat remote and symbolic.[1237]

This chapter has tried to provide a human rights framework for defending against an allegation that a measure is TRIPS inconsistent but is nevertheless justified on the

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[1236] Doha Ministerial Declaration, *supra* note 12 at para. 19. See also fn 1170, *supra* and related text.
[1237] Abbott, "New Era", *supra* note 739.

basis of an affirmative defence supported by the text of Article 8. In addition to the substantive considerations, certain institutional measures can be taken to facilitate the WTO's role as steward of trade and *other* values through the dispute settlement process. Many scholars have criticized the trade-IPR linkage.[1238] It is up to the WTO to mediate the competing values because, as Abbott notes, "IPRS are not only trade-related. They are also education-related, health-related, nutrition-related, defense-related, environment-related, energy related and so on."[1239] Abbott emphasizes the importance of a collaborative and co-operative ethos in the WTO:

> Multilateral organizations such as the Food and Agriculture Organization and the World Health Organization have important interests in the way rights granted with respect to inventions within the scope of their regulatory mission are used. It is therefore not remarkable that these organizations have sought to play a more significant role in the implementation of the TRIPS Agreement and in the formulation of new rules.[1240]

On the issue of consultation and collaboration, greater efforts should be made to encourage the participation of the Specialized UN bodies (such as WHO, FAO etc) in the consultation that occurs before a panel is struck. In addition, under Article 13.1 of the DSU, each panel has the right to seek information and technical advice from "any individual or body which it deems appropriate." Under Article 13.2, the panel may seek information from "any relevant source and may consult experts to obtain their opinion on certain aspects of the matter." The WTO would be well served by drawing on resources from international UN based institutions like WIPO and the World Health Organization (WHO) through expert consultation in dispute proceedings and by providing a more formal role for Amicus Curie briefs by NGOs than currently embraced.[1241] Such

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[1238] For a critical review, see generally R. Michael Gadbaw, "Intellectual Property and International Trade: Merger or Marriage of Convenience? 22 Vand. J. Trans. L 223 (1989).
[1239] Abbott, *supra* note 739 at 85.
[1240] *Ibid.*
[1241] Dunoff, *supra* note 604.

consultation and collaboration may also provide essential assistance in the work of the TRIPS Council. TRIPS Article 68 allows the TRIPS Council to consult and seek information "from any source"; civil society and NGOs can play an important role in this respect. Article 1 of the DSU requires that "the rules and procedures set out in this Understanding should be used to the extent necessary to avoid conflict." Industry may resist, but this is a common tension "between the regulator and regulated"[1242] Greater consultation and collaboration will promote the sharing of inter-institutional regulatory responsibility over these global public goods.[1243]

Third party participation by NGOs and others in terms of *Amicus Curiae* Briefs would be a vital step towards creating greater legitimacy at the WTO, improving public participation, fostering transparency in the process, and achieving more just results.[1244] Simultaneously, incorporating diverse interests and world views into WTO jurisprudence may be achieved more discretely through the composition of panels under DSU Article 8 by selecting panel members with great inter-disciplinary and inter-institutional strengths from more varied cultural backgrounds and both genders. If the WTO is increasingly perceived as a rule based judicial body, it would make good sense to integrate some of the institutional supports commonly associated with such a system such as a means for providing Legal Aid to developing and least developed countries through a defence

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[1242] Industry's resistance was evinced in the Access to Essential Medicines debate predating Doha (see www.accessmed-msf.org. and also during the negotiation of the international treaty on Plant Genetic Resources for Food and Agriculture at the FAO where substantial lobbying by biotech intensive seed/plant producers to eliminate provisions regulating patenting of inventions from materials withdrawn from the multilateral system. See Abbott, *supra* note 739 at 85.

[1243] "Distributed Governance at the WTO-WIPO: An Evolving Model for Open-Architecture Integrated Governance 3 JIEL (2000) 63 and Abbott "Coherence, Co-option, Flanking and Containment: Distributed Governance Revisited" ASIL, HR & Trade Conference, April 2004.

[1244] Robert Howse, "Membership and Its Privileges: The WTO, Civil Society, and the Amicus Curiae? Brief Controversy" (2003) 9 Euro. L. J. 496. Currently, participation is limited to what parties allow.

fund.[1245] This could be similar to The Doha Trust Fund, established since 2001 following the WTO Ministerial Conference in Doha.[1246]

Finally, the current funding for the WTO is dolefully inadequate. The annual budget is less than $100 million. "As a result," Bhagwati writes, "the WTO essentially has to rely for trade analysis on the "foreign legions" at the World Bank, the OECD etc... [At] WTO meetings, the world's media typically focus not on the WTO's analysis and economists, but on those from these other institutions. This is a travesty. It needs to be put right."[1247]

6.14 Conclusion

> We are in a period in which tremendous pressure is exerted at the bilateral and regional level for new and more restrictive rules that eliminate policy space in developing and developed countries. A presumed objective is to force the multilateral system to accommodate to a new reality or face the prospect of irrelevance. Benign neglect does not appear to be a constructive option.[1248]

Further attempts to liberalize trade require a concurrent commitment to further legitimize the system through conformity with broader conceptions of normative social ideals of individual rights and distributive justice articulated in UN HR and HD instruments. The universal ideals further the original ethos of co-operation and promote the mutual reciprocal benefit of all Members while leaving it to the culturally diverse regulatory mechanisms of each state for implementation and enforcement. Successive WTO Round negotiations should endeavour to remedy apparent institutional inequalities and bridge the growing gap between stated ideals and real practice in order to preserve the welfare maximization mandate of liberal trade without losing sight of the fact that

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[1245] Helleiner, *supra* note 694.
[1246] The "WTO Doha Development Agenda Global Trust Fund was created following the 2001 Doha Ministerial Conference and is used to fund trade-related technical assistance, Doha WTO Ministerial Conference, http://www.wto.org/English/thewto_e/minist_e/min01_e/mindecl_e.htm.
[1247] Bhagwati, *supra* note 1195 at 7.
[1248] Abbott, "New Era", *supra* note 739 at 100.

maximizing human welfare is not to come at the cost or compromise of individual rights but rather, as a means of increasing the realization of such rights in the aggregate.

The lack of a clearly tangible definition for the *essence* of 'human rights' is not limiting as a state can provide the contours of the right-preserving measure in a manner consistent with human rights instruments and the demands of its public(s). The normative interpretive prescriptions for reconciling obligations should remain relevant regardless of the debate on the substance of any individual human right or rights in their aggregate. The tradition in the trade literature has been to discuss the linkage, nonetheless, not in terms of defined understandings of human rights, but more abstractly as a matter of principle or policy preference or in terms of the constitutionalization of human rights within the WTO.[1249] Along these lines, one may conclude for a variety of

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[1249] See Ernst-Ulrich Petersmann, "Time for Integrating Human Rights into the Law of Worldwide Organizations: Lessons from European Integration Law for Global Integration Law" Jean Monnet Working Paper 7/01,online http://ejil.org/forum_tradehumanrights/ on the right of property and freedom of contract as worthy of ICESCR HR protection but lacking protection because of an 'anti-market bias'. On this basis, Petersmann argues for the constitutionalization and enforcement of human rights in the WTO as a means of achieving democratic legitimacy and social justice [at 624] but his constitution has the idea of property central to it and has been criticized by leading human rights scholar Philip Alston, "Resisting the Merger and Acquisition of Human Rights by Trade Law: A Reply to Petersmann" Paper No. 12/02, Jean Monnet Working Paper Series, Symposium: Trade and Human Rights: An exchange, online http://ejil.org/forum_tradehumanrights/ for approaching human rights from "within the citadel of international economic law" (at 2) and by privileging a particular conception of human rights as economic rights (the right to property and the right to trade) for integration in WTO law over all other human rights such as the important social rights such as the right to health and food. Alston writes that "the real focus of his concept of human rights is remarkably narrow...In his scheme of things, the WTO is never going to be called on to promote social rights, which means that despite the homage paid to them they remain entirely marginal to the essential thrust of his proposals." (at 18). For additional criticisms of Petersmann's vision of "free trade constitutionalism", see Robert Howse, "Human Rights in the WTO: Whose Rights, What Humanity? Comment on Petersmann" Jean Monnet Working Paper Series, no. 12/02, Symposium: Trade and Human Rights: An Exchange online, *(ibid)*. Howse commends Petersmann for his early appreciation of the importance of *rules* such as non-discrimination for constraining "cheating" on bargained concessions and undermining issues of justice in the governance of multilateral trade but is critical of his proposition that WTO legitimacy, as a juridical system, "depends on the transformation of what he calls 'market freedoms' into 'fundamental rights'. (at 5): "To the extent that the public policies in question themselves happen to be based on human rights (for example, social rights), we can see clearly the hierarchy of rights that Petersmann is proposing. Social and their positive human rights may only be pursued by governments to the extent to which they can be shown as 'necessary' limits on market freedoms. But why not the reverse? Why not subject *free trade rules* to strict scrutiny under a necessity test, where these rules make it more difficult for governments to engage in interventionist policies to protect *social rights*? (At 6). For a

reasons that as between trade and human rights obligations (however defined), the latter should always be given priority, *de facto* or *de jure.* However, such a conclusion is not without its problems. The universal trumping of human rights domestically is not the argument sought to be sustained by this dissertation, although it is an argument that certainly can be supported by our discussion of the major issues explored. Rather, a more modest and conservative view subsumed within this assertion is advanced as my central thesis based on the fact that there is a (functional) dependence of human rights on national and international constitutional restraints: if a State is desirous (as it should be) of actualizing human rights obligations owed to its citizens and to giving these domestic regulatory priority (in this case where industrial patent policy over life forms may conflict with human rights), *so long as it does so in a non-discriminatory manner*, economic and trade commitments should *not* serve as international legal impediments. This chapter provides the second of the bifurcated prescription of how to ensure that it does not.

The crisis of legitimacy that the WTO faces is not only in terms of the issues of social justice and democratic accountability to the public interest raised for civil society and developing countries, but to the delicate balance that must be achieved in meeting the objectives of both the UN and the WTO through the protection of human rights and the promotion of human development. Renewed commitments outside of the WTO reinforce the need to integrate a human rights and development framework for resolving disputes.

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reply in defence , see Ernst-Ulrich Petersmann, "Taking Human Dignity, Poverty and Empowerment of Individuals more Seriously: Rejoinder to Alston" Jean Monnet Working paper No.12/02 online, at 2, Petersmann claims that his arguments have been misconstrued as support for a 'free standing human right to trade' when in actuality they merely extend constitutional liberty rights to economic and professional activities, "including the movement of goods, services, person and capital across frontiers....The everyday experience of billions of people who can survive only by trading the fruits of their labour in exchange for goods and services...should be recognized as a human right problem rather than merely as a legislative or administrative task to be left to 'benevolent governments'."

Although the analysis offered in this dissertation would lead to the conclusion that disputes *should not* arise regarding patenting life matter given the inherent flexibilities built into TRIPS as a means of overcoming differences in Members' views at a time when the Convention on Biological Diversity, ostensibly antithetical to TRIPS, was already committed to broadly. But should they arise, the ECD will be the optimal remedy. It should be pleaded by defending states and accepted by the DSB.

There are some serious threats to the WTO's well-being and they emanate primarily from two directions: "the escalating erosion of non-discrimination and the steady encroachment by rich-country lobbies seeking to impose their unrelated agendas on trade agreements."[1250] Institutional reform requires, according to Bhagwati, two main changes: "relaxing the "tightness" of obligations that the WTO now incorporates and creates political waves, and augmenting its minuscule resources."[1251] Recognizing the ECD is one way of reducing the "tightness." The fundamental criteria of the multilateral regime GATT incorporated into the WTO system and Agreements was the founding principle of non-discrimination (based on the NT and MFN clauses). The MFN ensured that all GATT members automatically were extended the benefits of lowest tariff rates and other benefits extended to other members with few explicit exceptions (Article 24 for Preferential Treatment Agreements (PTAs)) and some transitional arrangements for LD and DCs. But today, Bhagwati writes, "the central principle of non-discrimination has been virtually destroyed. Thus, PTAs have proliferated to close to 300 and the number is growing by the week. The agreements which the architects of the GATT thought would

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[1250] Jagdish Bhagwati, "Reshaping the WTO" (Jan/Feb 2005) Far Eastern Economic Review, online: <http://www.columbia.edu/~jb38/FEER%20Final%20Edited%20by%20Restall%20and%20Bhagwati.pdf>

[1251] *Ibid.* at 4.

be minor exceptions have now swallowed up the trading system."[1252] This leads to a problem he calls the "spaghetti bowl", well recognized by economists, in which the "world trading system is characterized by a chaotic criss-crossing of preferences, with a plethora of different trade barriers applying to products depending on which countries they originate from."[1253]The implication, in many instances has been to convert the MFN into the LFN (least favoured nation) and, in the long term, it is not a sustainable system for trade governance.[1254] What the ECD tries to achieve is some equilibrium that will allow state sovereign discretion within the limited textual scope provided for in Article 8 without compromising the respective parties' preference for using and maintaining the WTO system over other bilateral and regional arrangements. At the same time, the defence recognizes that even in democracies built on embedded liberalism and social welfare policies, individual civil liberties cannot be compromised as the two goals are intertwined. By legitimizing the conduct through a defence, the value of human rights is preserved amongst the global governance institutions and the state is concurrently given an escape valve for responding to such obligations in a manner condusive to fostering *home-grown development* without being subject to threats of unilateralism or trade sanctions pursuant to a TRIPS complaint.

[1252] *Ibid.*

[1253] *Ibid.* At 6, Bhagwatti offers the EU as a lucid example: "MFN tariffs now apply only to five countries, with all others enjoying politically driven lower-tariff access to the EU under multiple PTAs, differentiated GSP (General scheme of Preferences), EBA (Everything but Arms) and other Schemes. Evidently, the MFN tariff in the EU has now become the LFN, the least favored nation, tariff!"

[1254] "This is a fool's way doing trade- not only does it destroy the efficient allocation of resources, but it flies in the face of the fact that today it is becoming almost impossible to define which product is whose. It is hard to believe that sensible men in charge of trade policy today, including the USTR, the EU Trade Commissioner and other luminaries of trade are so unmindful of the fact that, in the name of free trade, they are damaging the world trading system through discriminatory PTAs as much as the protectionists did in the 1930s." *Ibid.*

Chapter Seven

CONCLUSION

It's easier to resist at the beginning than at the end.
- Leonardo Da Vinci

The State is made for man, not man for the State.
- Albert Einstein, *The World as I See It*

Ours is a culture of diversity: biodiversity, regulatory diversity, and cultural diversity centered on the universality of human rights; it is a culture worth preserving and proselytizing. The patenting of life raises a variety of important issues that challenge our normative understanding of intellectual property rights and draws attention to the need for institutional reform within domestic law. Extending patent protection to genetic information surrenders control to property holders, primarily large corporations, over access and use of this information, restricts individual liberty rights and jeopardizes the future direction of genomics research and application. It is not only incongruent with traditional doctrines in domestic patent law but is also inconsistent with numerous international human rights instruments that reflect the special character and our communal claims to life and its genetic building blocks. These issues have become arguably more significant in Canada given our Supreme Court's determination that non-human higher life are *not patentable* and yet that any life containing a patented subcomponent, such as a gene, or a vector would be an infringing *use* of the underlying patented invention. Our government, though familiar with patent controversy at the intersection of health policy and human rights, has responded to the occurrence of this tension in other jurisdictions in relation to essential medicines without a second thought to critically examining how patent law may be impacting health policies, such as who and how many are tested for genomic-related diseases, at home. As a result, we have a

laudable Parliamentary response for legislative amendment to Canadian patent law in order to supply foreign (DC and LDCs) governments with necessary drugs without similar legislative initiatives to address the persuasively more important issue of patenting life; the life science industry will soon replace traditional pharmaceuticals with genomics and pharmacogenomics in public health with a significant impact on the future delivery of population health, food security, and other important human rights. The health rights and interests of our own citizens must be as important as those of our human family internationally, which Canadian law now serves to protect.[1255] Canada has been a leader in initiating changes to TRIPS to allow compulsory licencing and parallel importing to countries with little or no manufacturing capacity. It should make similar efforts to resolve the legal quagmire of patenting life, an issue that is so fundamental to the cultural, ethical, and social fabric of our society. Failure to undertake a political process of review has led to an incremental development of patent law by judicial fiat lacking in broader social context and a coherent foundational patent policy with a focus on the proper balancing of private and public interests. As a result, current domestic patent protections unnecessarily exceed that which is prescribed under TRIPS provisions related on biopatenting with the effect of limiting optimal cross-policy co-ordination and unnecessarily hampering the realization of HR. This, despite the urging by the Supreme Court of Canada in its two recent life patent decisions and the recommendations of the Biotech Advisory Committee inviting a legislative response to settle this debate.

The public protests preceding TRIPS resulted in the TRIPS exemptions for domestic patents related to health, morality, public ordre and living matter and are

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[1255] See Government of Canada Reinstates Legislative Proposals to Enable Export of Low-Cost Pharmaceutical Products to Least Developed and Developing Countries" Industry Canada, February 12, 2004 News Release, online http://ic.gc.ca/cmb/welcomeic.nsf.

consistent with well established claims for a moratorium on life patents until a public participatory process legitimizes their grant. With the current indeterminate state of Canadian law, the dire circumstances surrounding growth in the number of applications, and the paucity of institutional resources, a pause is merited now more than ever. In the interim, the TRIPS compliant recommendations made in chapters 3 and 4 should offer some relief from pressure for convergence towards higher and stricter standards. These constitute the first branch of my bifurcated prescription for regulatory agency to address the patenting life issue and empower domestic re-evaluation of an institutionalist instrument to better accord with its social purpose, the nature of the scientific paradigm, our collective interest in genetic information, and even patent doctrine itself.

If and when our government does act, then the discussion of the current problems in the patent system as well as the need to consider different conceptual understandings and approaches to increasing incentives for innovation explained in this thesis are meant to inform that process with the hope that the least inefficient and most equitable design is domestically implemented. TRIPS has sufficient "wiggle room"; coupled with the appropriate interpretative approach I suggest in chapter 4-6 of this dissertation, any reservation expressed by governments are illusory and draw attention to partisan politics.

The domestic recommendations I make are necessary but may be insufficient- they may not be equally viable for all states. Their adoption may depend as much on infrastructure, industry, and technology as on political will. Nations, like Canada, have already established sophisticated IP systems, mature and uncorrupt judiciaries, democratic institutions for public participation and access to greater resources and are thus advantaged in their ability to adopt these solutions. Other nations may be too poor

to succeed in implementing domestic TRIPS compliant solutions. Alternatively, the adoptable domestic measures may be contested as non-compliant for a host of other reasons including as negotiating leverage in an existing trade dispute between the parties. Accordingly, the prescription for appropriate state response cannot end merely with the contestable TRIPS compliant national measures; the domestic approach is only part of the normative prescription advanced as a possible state response to balancing domestic interests. Where a domestic measure, though trade impacting is non-discriminatory and with good faith objectives of prioritizing human rights promoting policies, the international community should refrain from bringing a WTO complaint, respecting that state's exercise of sovereignty and self-determination over its genetic and natural resources. However, if a complaint is brought, the potential for conflict should be resolved by the panel or AB's recognition of an ECD based on Article 8 of TRIPS.

The ECD is the second branch of the bifurcated prescription for state agency comprised in my thesis and is meant to create a safety net whereby governments can garner the confidence to take appropriate domestic measures without fear of liability under TRIPS. These prescriptions create a conceptual framework for legally resolving sites of conflict that arise in relation to patenting life in order to provide a coherent understanding of international institutions. Together, this dually targeted prescription constitutes the original contribution of this dissertation and stresses the need to preserve state sovereignty over discretion needed to allow for a participatory process in the patenting life debate. If a measure resulting from such a process is contested, the concrete recognition of an affirmative defence before the WTO should protect the

propriety of the internal state measure in most instances so long as the measure observes the foundational non-discrimination tenet of multilateral trade.

Canada is in an interesting predicament as 2006 is the year for its human rights review to measure compliance with the ICESCR as well as its special review under the US priority watch list for section 301. Our position is compromised; let our values not be. The Canadian government should respond, as called upon, legislatively but also with the non-legislative approaches available to it, defending this conduct under the new ECD which essentially provides a HR approach to interpreting TRIPS obligations. HR as a shield would allow governments the ability to defer to these obligations while encouraging more efficient alternative regulatory responses. It would also be an important step forward in allaying the legitimacy crisis of the WTO.

The growing animosity towards the WTO, as evinced from the acrimonious protests surrounding Ministerial meetings in Seattle, Cancun, Montreal, and Italy indicate the need for improvement in WTO operations, the desirability of reconciling obligations arising under the trade, human rights, and other instruments, and our inability to continue to ignore the human and social dimension of trade if there is to be a comprehensive order for effective global governance.[1256] This analysis is relevant to developing countries as well as developed countries who wish to retain some domestic regulatory control over domestic policy setting where human rights obligations, and their attainment, are concerned. In the absence of a global sovereign government, the hegemony of trade has

[1256] These considerations are "[...]of extreme systemic importance for the system of international law[;]...they are heavily value-laden and go to the heart of much of the critique against globalisation: is globalisation only about the economy and making profit or is it counterbalanced also by other factors such as environmental protection, development of weaker regions, social protection and safety nets?" Pauwelyn, *ibid.* at 2. For our discussion, I have adopted the operational definition offered by Mendes & Mehmet, *supra* note 598. They define global governance to include "not only the institutions set up to deal with issues of global scope, but also the situations that evolve in the absence of appropriate and effective institutions to deal with such global matters" (Mendes & Mehmet, *ibid.* at 1).

forged the conditions for its own regime of neoliberal governmentality and a powerful politics of instrumental regulation. But trade is not and should not be valued as its own moral imperative. Rather, trade is utilitarian as a means of facilitating the ends of improved welfare which formed its original mandate.[1257] Today's society demands no less. Accordingly, the role of the WTO is broader than some might envisage. The WTO should accept its emergence as the institutional steward of trade and *other* values. Its institutional structure and juridical dispute resolution mechanism can facilitate the realization of those values better than any existing alternative and invariably, since trade is a *means for achieving* HR ends, the two will always intersect. Since DCs and LDCs are at a comparative disadvantage in the negotiating process and in their ability to enforce measures, such a defence would create some equity through dispute settlement by recognizing the legitimacy of other domestic imperatives even if not specifically 'bargained for'. The preambles to the WTO, the GATT provisions reviewed, and the 2001 Ministerial Declaration on Health highlight the entrenchment of other values implicit in and integral to trade theory and practice. Consequently, the operations of the WTO must remain within the paradigmatic framework of an integrated international *system* of law informed by the objectives of the twin institutions for global governance (trade and human rights) and renewed commitments to co-operation and equal access to global public goods.[1258] Any normative prescription, as posited in this dissertation, that free trade can be fettered where the measure is taken to further the domestic realization of one set of international norms over another (i.e. human rights over trade) must subject the impugned measure to scrutiny for at least consistency with fundamental trade values to

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[1257] Pauwelyn, "Conflict of Norms", *supra* note 12; Esty, *supra* note 571.

[1258] "[f]air net benefits for all are an important ingredient of *successful cooperation*. But it is one thing to share net costs fairly and another to share net benefits fairly." Kaul, *supra* note 151at 58, emphasis added.

ensure that such human rights justified measures do not discriminate between states and are genuine; that is, they are not merely disguised protectionism.

The bifurcated prescription for conflict resolution advanced in this dissertation is in the co-operative spirit of international law and respects the political democratic process that enables public participation in domestic governance issues. It is the role of Parliaments and governments around the world to offer palatable substantive solutions to which their 'publics' are amenable. My framework offers a fundamental respect for regulatory and cultural diversity to allow for optimal governance and fulfillment by a state of its international obligations. I advocate that some deviation from trade objectives are permissible and are in the ultimate spirit of trade and human rights objectives; they are defensible if challenged in a trade dispute. HR policy preferences, when used by a state, are simply another means, alternative to trade, for achieving the same welfare objectives (development, raising the standards of living etc) it aims to facilitate. Human rights compliance will help ensure a more stable, healthy, operational, economically viable, developmentally mature and independent Member and should be encouraged. Such a Member is in a better position to participate fully in a multilateral trading regime and is well within its rights to adopt the approach I suggest for resolving the patenting life debate to accord with its public's interest.[1259] The TRIPS we are stuck with does not have to lead to a "dead end". States have various options to allay the friction TRIPS is perceived to have created, armed with the mandate of promoting human rights and

[1259] "The minimal preconditions which make the bestowal of authorial rights a social good in the public interest-however narrowly that public may be defined-are not in place in the social contexts in which we are so anxious to extend authorial power and privilege. This speaks, of course, to the absurdity of dividing questions of trade from question of human rights, and to the growing anachronism of modernity's mappings of public and private international law." Coombe, "Authorial Cartographies", *supra* note 58 at 1365.

development. Since these recommendations can be implemented, they *should* be implemented by our regulatory governments; after all, attaining a *Realistic Utopia* requires more than monetary aid.

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