Regulatory Diversity, an Imperative for the Bioeconomy: *Biopatenting, TRIPS, and the Public Interest in Sectors of Vital Importance*

> The strength of the general claim for policy equivalence in this area is not straightforward. The overall trade-offs between innovation and imitation may well differ from country to country.[1]

Patents are a form of intellectual property (IP) that until recently were country-specific and largely variable in direct reflection of a countries' internal industrial policy. The institutional prescription for securing patent rights, the costs, and scope of such rights, and mechanisms for their enforcement were largely left for regulatory governments within each nation state to determine in accordance with their own phase of social, economic, and industrial development, subject to some United Nations based agreements under the World Intellectual Property Organization (WIPO). With the shift to a 'knowledge-based' economy, facilitated transnational capital flows, and success in strengthening domestic IPRs through administrative and judicial systems, the IP generating industries began to politicize their objectives by aggressively lobbying their politicians for a trade-based approach to IP and for negotiation of substantive international IP protection within the multilateral trading regime.[2] Developing countries (DCs) ultimately acceded to these demands during the Uruguay Round of negotiations. While the inclusion of the Agreement on *Trade-Related Aspects of Intellectual Property*

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[1] Michael Trebilcock and Robert Howse, "Trade liberalization and Regulatory Diversity: Reconciling Competitive Markets with Competitive Politics" (1998) 6.1 E.J.I.L. ["Regulatory Diversity"] at 19. I owe a great debt to Professor Trebilcock for his sage supervision of my doctoral thesis, and ongoing mentorship, and for significantly advancing my thinking on this subject matter. The following paper is therefore drawn from the published monograph, Bita Amani, *State Agency and the Patenting of Life in International Law,* (Surrey, UK: Ashgate Publishing Inc., 2009) [*State Agency*]. I thank Christine ??? and Erica Maidment for research assistance for this draft.

[2] See *e.g.* Peter Drahos & John Braithwaite, *Information Feudalism: Who Owns the Knowledge Economy?* (London: Earthscan Publication, 2002) [*Information Feudalism*]. See also Peter Drahos & Ruth Mayne, *Global Intellectual Property Rights: Knowledge, Access and Development* (New York: Palgrave, 2002) and Susan K. Sell, *Private Power, Public Law: The Globalizing of Intellectual Property Rights* (Cambridge: Cambridge UP, 2003) [*Private Power*].

Rights (TRIPS)[3] as part of the 'total WTO package' is oft said to be "trade-off"[4] of competing economic interests by DCs, wherein IP protections were exchanged for concessions in textiles and agriculture,[5] more fulsomely, it reflects the then naïve belief that a formal linkage of IP to trade would help avert the growing unilateralism exercised by the United States under strengthened domestic laws and the inequality of bargaining power and coercion that governed the negotiating process.[6] Unfortunately, Drahos and Braithwaite observe, the threat of use of unilateralism under US domestic law[7], has actually *increased*:

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[3] *Marrakesh Agreement Establishing the World Trade Organization*, opened for signature 15 April 1994, 1867 U.N.T.S. 3 Annex 1C *Trade-Related Aspects of Intellectual Property Rights* [WTO Agreement], online: WTO <http://www.wto.org/english/docs_e/docs_e.htm>.

[4] Michael J. Trebilcock & Robert Howse, *International Trade Regulation*, 3d ed. (London and New York: Routledge, 2005) [International Trade Regulation] at 401.

[5] While there were some negotiated gains for DCs in the Round for trade in cotton and textiles, these could hardly be considered a *trade off* against strong universal standards in IPRs, however. The result was effectively to restore old promises rather than bargaining anew after 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.

[6] This is now well documented by several scholars, see *supra* note 2 *Private Power* at 108-120 describing bargaining strategies; Peter Drahos, "Developing Countries and International Intellectual Property Standard Settings" 5 J.W.I.P. 765 ["Standard Setting"] critiquing the "trade-off" theory of TRIPS as part of a larger package of concessions; and Keith Maskus, *Intellectual Property Rights in the Global Economy* (Washington D.C.: Institute for International Economics, 2000), for an empirical analysis.

[7] For example, the United States used the threat of withdrawing voluntary concessions, provided under the General System 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 & Doris Long, eds., *International Intellectual Property Law*, (Frederick MD: Kluwer Law International, 1997) at 67-70. Special 301 of the *Trade Act*, 19 U.S.C. ch.12 (1974) [US Trade Act] (section 1303 of the *Omnibus Trade and Competitiveness Act of 1988*, Pub. L. No. 100-148, 102 Stat. 1107 (1988)) 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. See also section 337 of the US Trade Act which provides inbound at the border protection. Unilateral retaliatory trade action against foreign products imported into the USA may be taken if there is a 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 and 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. Accordingly, this law too 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 rather than a countervailing 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. According to Trebilcock and Howse, sanctions as those under Special 301 are

> 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[8]

What TRIPS did was adopt established western IP standards as the baseline through which protection, and therefore financial returns, would be secured for private firms in foreign markets. And, although TRIPS did not create the mechanism for a global patent through a single application, it did generate a substantive code for universal minimum protections and enforcement of IP by each Member state within the multilateral trade regime. Formalizing monopoly-producing prescriptions within a free competition-promoting regime has fostered some formidable points of friction[9] and has meant that, globally, protected IPRs are subsidized by the people least likely to generate them by western standards, or afford them by any standards.[10]

The challenges of governing a biotechnology-based economy do not discriminate, however. Devising optimally efficient patent policies may soon constitute the most central innovation strategy, law, and policy challenge facing *all* regulatory governments. In part this is due to the numerous sectors that are affected by the proliferating technology and the need for coherent cross-policy coordination (as between industrial and health, or energy and waste management, for example) in developing as well as developed states. But, also, because extensive and differential public relations efforts will be required to foster greater acceptance for biotechnology, its applications, and its

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likely to be against the GATT MFN principle. See Trebilcock & Howse, *International Trade Regulation*, supra note 4 at 407 and chapter 16.

[8] *Information Feudalism*, *supra* note 2 at 106-107.

[9] Similar frictions are experienced nationally between patents and anti-trust. See *e.g.* Robin Feldman, "Patent and Antitrust: Differing Shades of Meaning" (2008) 13.3 Va. J.L. & Tech. 1.

[10] See generally chapter 6 in *State Agency*, *supra* note 1.

privatization by letters patent within each jurisdiction and for distinct governance sectors. The task will be further complicated by the impact of expanding populations and economic growth on food, energy, and the environment, and the need to ensure that economic prosperity is indeed sustainable. Over a decade ago, then Minister of Natural Resources Canada anticipated some of these challenges in his remarks at the Asia-Pacific Economic Co-operation (APEC) Economic Committee symposium in Saskatoon, stating:

> [w]hile technology provides some of the answers, it also presents us with additional challenges….[W]ith important new technologies like biotechnology[,]…we need to be both vigorous and vigilant. Vigorous – to ensure we reap the full advantages of increased productivity, greater crop variety, disease and chemical resistance, input cost savings and savings on fossil fuel consumption. And we must be vigilant – to be certain that all our processes and new products are safe, healthy, and environmentally sound so that we can *gain, deserve and maintain consumer confidence and trust in a rapidly changing marketplace.*[11]

In 2009, the Organization for Economic Cooperation and Development (OECD) published the results of a comprehensive "interdisciplinary, strategic foresight project" focused on providing "forward-looking, policy-oriented review of future developments" in the three sectors examined. In this sizable report entitled *The Bioeconomy to 2030: Designing a Policy Agenda*, we are told that "[t]he application of biotechnology to primary production, health and industry could result in an emerging "bioeconomy" where biotechnology contributes to a significant share of economic output."[12] But, the pursuit for an international policy agenda raises an issue that has straddled debates on biopatenting law and policy and animated the 'no patents on life' campaign for more than a decade since the inclusion of TRIPS in the WTO Agreement: is policy convergence and harmonization in this field possible or desirable?

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[11] Dan Ciuriak, ed., *Symposium Proceedings, Asia-Pacific Economic Cooperation November 1998*, (APEC Economic Committee Symposium on The Impact of Expanding Population and Economic Growth on Food, Energy and the Environment, Saskatoon, September 1997) at 13.
[12] OECD, "The Bioeconomy to 2030: Designing a Policy Agenda"(2009) www.oecd.org/publishing/corrigenda at 19 [OECD Report].

The belief that TRIPS unduly restricts a sovereign nation's ability to place its citizens' (democratic and human) rights over the private interests of (foreign) patentees is based on misgivings that are textually misplaced. As I have argued elsewhere, a textured review of recent trends and numerous examples will "demonstrate how states, through their own agents – namely, courts, administrative patent offices, law and policy makers, and trade technocrats, progressively emasculate their own agency through limited readings of human rights regimes."[13] Against growing fragmentation of international legal obligations, state agency will be critical in ensuring that the considerable freedom to choose different social policy responses against globalizing economic conditions will not be compromised by cautious reservation over anticipated disputes regarding the scope of, or restraints on, this freedom. In this paper, I revisit the claims for regulatory diversity in biopatenting as not only *permissible* and *defendable* under TRIPS but, in fact, *imperative* for maintaining the public's interest in the future bioeconomy. Part one will examine the case for regulatory diversity against globalizing trends in economics and liberalizing trends in trade by reviewing some of the key cogent arguments made by Trebilcock and Howse in their seminal article, "Trade Liberalization and Regulatory Diversity: Reconciling Competitive Markets with Competitive Politics"[14] Part two provides a brief conceptual account of how Articles 7 and 8 should be interpreted in support of the claim that WTO Members retain sufficient discretionary capacity over regulatory policies under TRIPS. Part three concludes by asserting that the qualified defence of regulatory diversity offered by Trebilcock and Howse will be of growing importance to the normative

[13] *State Agency*, *supra* note 1 at 7. At 6, Amani posits that "[o]vercoming such misapprehension is the major hurdle confronting civil society in its effort to convince representative government to act equitably in the patenting life debate, balancing individual human rights and the public interest with an efficient, coordinated set of laws and policies."
[14] "Regulatory Diversity", *supra* note 1.

approach to policy making for the bioeconomy to 2030, the particulars of which compel us to conclude that such diversity is, indeed, *imperative* for the public's interest.

Part One: Why Regulatory Diversity?

The post-war emergence and development of the multi-lateral trading regime, now functioning as the World Trade Organization (WTO), was built on a mutual desire for tariff reduction and the gradual elimination of other border measures, such as quotas. These objectives met with great success in effectively and dramatically reducing tariffs world-wide from an average of over 40% to 3% over the first eight Rounds of negotiations.[15] Yet, with successive negotiations, regulatory governments increasingly turned their attention to the potential trade distorting impact of non-tariff barriers to trade (NTBs), linking trade with regulatory measures and forming the basis for the gradual invasive encroachment of trade law on sovereignty, without public consultation or approval. NTBs are essentially domestic regulations that seek to address important public interest issues like health but are said to have an adverse trade impact. Trebilcock and Howse write:

> [t]hese regulatory trends can be viewed as part of the elaboration of the modern welfare state in much of the industrialized world, reflecting in part the proposition that greater safety, a cleaner environment etc. can be thought of as normal economic goods, the demand for which rises as income levels rise, so that greater prosperity (in significant part engendered by trade liberalization) has been accompanied by increased demands for these kinds of domestic policies….[T]hese "within border" regulatory measures are increasingly seen by many liberal trade proponents as the most prominent and arguably the most costly form of non-tariff barriers to trade (NTBs)."[16]

Trebilcock and Howse espouse a conservative view of harmonization or convergence of domestic regulatory policies through the recognition of appropriate limits on trade liberalization. They argue that the gains of international harmonization of "within-the-border" domestic policies are difficult to assert unequivocally and may even produce

[15] "Regulatory Diversity", *supra* note 1 at 6.
[16] *Ibid*.

some ambiguous welfare implications. Highlighting the importance of competitive governments and competitive politics over competitive markets, the authors concede that some mutual benefits may be gained through consensual forms of policy convergence, related in part to the reduction of the costs of divergence. Nevertheless, there is a strong case for "substantial national political autonomy in formulating domestic regulatory and related policies even though such policies will often have significant impacts on resulting trade flows."[17] Moreover, the authors argue, adoption of ground-rules in international trade treaties,

> pertaining to domestic policies as potential NTBs should minimize the extent to which harmonization can be induced by judicial fiat, on the one hand, or threats of unilateral sanctions, on the other, thus attenuating the "threat points" of nation states in interactions with each other, and conversely increasing the scope for mutually beneficial agreements on policy convergence.[18]

Their final premise is that the European positive integration model (with directives prescribing domestic policies member-states *must* adopt), as opposed to the traditional GATT emphasis on negative integration is "simply not feasible in most other institutional contexts."[19] This perspective is shared by Sylvia Ostry, former Canadian trade negotiator:

> The 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 model of negative regulation – what governments must not do–to positive regulations, or what governments *must* do.[20]

Trebilcock and Howse conclude by positing two primary objectives as central to the investigation of whether domestic policies constitute NTBs. They prioritize the primary principle of non-discrimination, the edifice on which the multilateral trading regime is ostensibly built, over harmonization of domestic policies. To this end,

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[17] *Ibid.* at 28.
[18] *Ibid.* at 9.
[19] *Ibid.*
[20] 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, delivered at the Kennedy School of Government, Harvard University, 1-2 June 2000) at 6, 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.

regulatory diversity should be encouraged so long as the domestic policies or practices do not violate the National Treatment principle and are not forms of disguised or unjustifiable discrimination offensive to trade. Espousing the rationales of Breton's theory, the authors assert that the benefits of regulatory competition is that it allows the possibility of making informed evaluation of different approaches to regulation (and their efficacy) which may in turn lead to more transparency in regulation and competitive politics, at both the domestic and international level. We may extrapolate from their arguments and reference to Breton's work that more important than trade formalism for its own sake is the accountability of regulatory governments to their constituents (and related gains of competitive politics) – a hallmark of a well functioning democracy – towards welfare maximization and the protection of basic rights and democratic values.[21]

Part Two: Regulatory Diversity in Biopatenting is Permissible and Defensible

That biotechnology will be life defining for future civil society is underscored by the OECD in its undertaking to study and anticipate the impact of external,[22] institutional, and social variables,[23] on driving the bioeconomy to 2030. Accordingly, there is no better contextual account for the Trebilcock and Howse 'cautious view towards policy harmonization or convergence,'[24] then the case of biopatenting. Biotechnology will soon be ubiquitous and biopatent policies will shape the level of incentives of, rewards for, transfer of and access to this technology, open states to examination of domestic

[21] See *e.g.* Kalypso Nicolaidis & Robert Howse, "'This is my EUtopia…':Narrative as Power" (2002) 40.4 J.Com.Mar.St. 767, in which the authors write, at 782, that while "one 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."
[22] Such as population and income; demographics and human resources; energy consumption and climate change; agriculture, food prices and water; healthcare costs; and supporting and competing technologies, see chapter 2 of the OECD Report, *supra* note 12.
[23] Such as public research, regulation, IP and social attitudes, see OECD Report chapter 5, *supra* note 12.
[24] "Regulatory Diversity", *supra* note 1 at 8.

regulation as NTBs. Some scholars express general concern over the potential scope of NTBs, negatively defined as anything that is not a tariff barrier, as being so broad in definition as to lack significant meaning.[25] Others argue that the descriptive problem does not adequately address the normative issue. David Vogel describes the quandary this way:

> [i]f all regulations that disadvantaged importers were classified as non-tariff barriers, then virtually all regulations could be considered protectionist. For example, the United States could not require that all product labels be printed in English, since this requirement clearly imposes additional costs upon foreign producers (or at least those from non-English speaking countries)…In short, defining NTBs very broadly would have the effect of subjecting virtually all national regulatory standards to those of the least stringent exporting country. At the same time, it would probably significantly expand international trade….The consequences of defining nontariff barriers very narrowly are equally significant. A nation could demand that all imported products be produced according to the same standards to which domestic producers are required to adhere....If such a regulation was not considered a non-tariff barrier, and was widely adopted, international trade would decline significantly.[26]

WTO Member states, however, are given some considerable scope, and therefore immunity from complaint, for shaping their biopatent policies under TRIPS.

TRIPS is almost always discussed in terms of the state obligations it creates for WTO members, such as Article 27.1 outlining what is to be patentable subject matter. But, states are also conferred rights under TRIPS, articulated as discretionary norms; these are significant for maintaining critical policy space. Article 27.2 provides, for example, that Members may exclude from patentability

> inventions, the prevention within their territory of the commercial expoloitation 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 their law.

Article 27.3 similarly provides WTO Member's the right to exclude from patentability diagnostic, therapeutic and surgical methods for the treatment of humans or animals in

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[25] See Frederico Ortino, *Basic Legal Instruments for the Liberalization of Trade: A Comparative Analysis of EC and WTO Law* (Portland: Hart Publishing, 2003) at 7-16.
[26] David Vogel, *Trading Up: Consumer and Environmental Regulation in a Global Economy* (Cambridge, MA: Harvard UP, 1995) at 3, cited in "Regulatory Diversity", *supra* note 1 at 9.

clause (a), and under clause (b), plants and animals other than micro-organisms, and essentially biological processes for their production. Some form of protection, whether patents, plant variety or by a sui generis regime, must be provided by Members for plants. Article 31 additionally provides Members the right to allow third party or government use of the patented invention so long as conditions precedent are met. The Doha Declaration noted the limited ability of some Members to exercise this right due to poor infrastructure and lack of manufacturing capacity[27] and led to a 2003 waiver, and ultimately the only TRIPS amendment to date.[28] In addition to the rights and obligations that TRIPS provides Member states, TRIPS provides a valid legal defence, I argue, that is analogous, in many respects to the affirmative defence provided by GATT Article XX.[29]

For example, a state may recognize as patentable genetically modified or living modified organisms (GMOs and LMOs), consistent with its trade obligations under TRIPS and yet have a related measure imposing regulatory standards for health risks that may independently be contested under the GATT 1947. If the measure is non-discriminatory it should be found to be GATT consistent[30] but, if the complainant proves

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[27] *Doha Declaration on TRIPS Agreement and Public Health*, WTO Doc. WT/MIN(01)/DEC/2 (14 November 2001), 4th Sess., online: WTO <http://docsonline.wto.org/DDFDocuments/t/WT/Min01/DEC2.doc>. Paragraph 6 of the Declaration recognized that some WTO members would have insufficient or no manufacturing capacity in the pharmaceutical sector and accordingly would be unable to make effective use of the compulsory licencing provisions and mandated the TRIPS Council to devise a solution before 2002.

[28] The provision has expanded in application to enable export of listed essential medicines by developed countries to poor Members. See WTO, Press Release, Press 426, "Members OK amendment to make health flexibility permanent" (6 December 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 WTO General Council, *Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health*, WTO Doc. WT/L/540 (30 August 2003)). For a detailed discussion, see Frederick Abbott, "The WTO Medicines Decision: World Pharmaceutical Trade and the Protection of Public Health" 99 A.J.I.L. 317 at 349 ["WTO Medicines"].

[29] For a detailed account, see *State Agency, supra* note 1 at chapter 7.

[30] "[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

that the measure is discriminatory 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. Still, the measure would have to pass scrutiny under the *chapeau* to determine whether the restriction is an arbitrary, unjustifiable, or disguised protectionist measure. This analysis would occur outside of a TRIPS inquiry on the domestic patentability issue and is consistent with the Appellate Body's (AB) 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[31] as between, for example, Article XX and a TRIPS obligation.[32] While the Article XX defence (and jurisprudence) has no influential or instructive role in TRIPS disputes, parties may be informed in their formulation of arguments consistent with the traditional scope of its policy space, when a measure is contested as a TRIPS-inconsistent NTB.[33]

Treatment under the GATT to ban or restrict A but not B." See Robert Howse "The WHO/WTO STUDY on Trade and Public Health: A Critical Assessment" 24 Risk Analysis 501 at 501.

[31] In *Japan-Taxes on Alcoholic Beverages*, the AB emphasized that a principal guide to treaty interpretation is the text of the treaty itself and this was echoed by the AB in *Beef Hormones.* See WTO Appellate Body, *Japan-Taxes on Alcoholic Beverages*, WTO Doc. WT/DS8/AB/R, WT/DS10/AB/R, WT/DS11/AB/R (4 October 1996), at 13. The AB echoed this perspective in *Beef Hormones, EC measures concerning meat and meat products (hormones)*, WTO Doc. WT/DS58/AB/R (12 October 1998).

[32] The affirmative defence of Article XX is, by the very language used in the text of the original GATT 1947, limited to "this Agreement" as set out in its "chapeau". Its extension into the GATT 1994 was by direct incorporation of the earlier GATT; consequently the Article XX defence is limited to GATT 1994 obligations and does not apply to those arising under other agreements such as TRIPS. WTO Dispute Settlement, *United States - Section 211 Appropriations Act; United States- Section 322 Omnibus Appropriations Act of 1998*, WTO Doc. WT/DS176/AB/R.

[33] See Michael J. Trebilcock & Robert Howse, *International Trade Regulation*, 3d ed. (London: Routledge, 2005) [*International* Trade] 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." In two disputes settlement reports on *Section 211 Omnibus Appropriations Act*, 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 is consistent with the "latter rule" of the Vienna Convention on the Law of Treaties on treaty interpretation and can also be normatively justified on the basis that all attempts should be made to read out conflict from international treaty 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 or *jus cogens* as within the sovereign jurisdiction of a state and this allocation to national governments of specific substantive, though trade-related, regulatory issues is a fundamental norm from which there can be no derogation. To the extent of any inconsistency, the norm may operate to invalidate any treaty agreement. The Vienna Convention on the Law of Treaties, (VCLT)[34] under Article 31.3(c), 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 Convention on Biological Diversity,[35] environmental regulation, from Article XX itself (which is relevant to the relations between the parties), and the principle entrenched after the *Lotus* case,[36] 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

[34] *Vienna Convention on the Law of Treaties*, 23 May 1969, 1155 U.N.T.S. online: UN < http://untreaty.un.org/ilc/texts/instruments/english/conventions/1_1_1969.pdf>.

[35] *United Nations Convention on Biological Diversity,* 5 June 1992, 1760 U.N.T.S. 142 online: CBD <http://www.biodiv.org/convention/articles.asp?lg=0&a=cbd-08> [CBD]. 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).

[36] *The S.S. "Lotus" (France v. Turkey)* (1927), P.C.I.J. (Ser. A) No. 10 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 Joost Pauwelyn, *Conflict of Norms in Public International Law: How WTO Law Relates to Other Rules of International Law* (New York: Cambridge UP, 2003). [*Conflict of Norms*] at 150 and n. 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.'"

these specific areas of law and public policy.[37] Second, examining the approach to the Article XX affirmative defence and its limitations may prove helpful to understanding Article 8 of TRIPS as, what I call, an Equitable Conduct/Public Interest Affirmative Defence (ECD).

Article 8 permits states to adopt 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 conceptually summarize the burdens under TRIPS explored with greater detail in another context,[38] we may say that 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 so exceeding, has abused its right and thus 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. Under Article XX, this would mean proving that the measure falls within the language of its

[37] The merits and validity of such an approach are beyond the current analysis. Note, however, this is contrary to the finding by the *Tuna/Dolphin II* panel, *United States – Restrictions on Imports of Tuna*, GATT Doc. DS29/R (1994), unadopted [*Tuna/Dolphin II*]., which held that other agreements were not relevant for the interpretation of GATT treaty obligations if they did not apply to the Contracting parties and suggesting that GATT was self-contained and impervious to rules of other international regimes. Compare this with the AB decision in *Shrimp/Turtles, United States- Import Prohibitions of Certain Shrimp and Shrimp Products*, WTO Doc.WT/DS58/AB/RW (1998), where international environmental law (hard and soft) was applied for interpreting the scope of the expression "exhaustible natural resources" in Article XX(g). See *International Trade*, *supra* note 33 and generally Joost Pauwelyn, "The Role of Public International Law in the WTO: How far can we go?" 95 A.J.I.L. 535 ["PIL"]. For a discussion on treaty obligations and *jus cogens*, see *Conflict of Norms*, *supra* note 36.

[38] See *e.g.* Chapter 7, *State Agency*, *supra* note 1.

clauses *and*, because of the AB's interpretation, that it does not *exceed* the scope of the textual defence. *Both* latter burdens would lie with the defending Member.

Many authors to date question the full utility of Articles 7 and 8 of TRIPS. Article 7 provides the *Objectives* of TRIPS:

> The protection and enforcement of intellectual property rights *should* contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.[39]

Article 8 provides the *Principles* to govern the WTO Members and provides:

> 1. Members may, in formulating or amending their laws and regulations, 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.

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, obligations, or exceptions thereto.[40] The alleged tautology is in that the discretion allowed under Article 8.1 is qualified by the language "provided that such measures are consistent with the provisions of this Agreement." Not surprisingly, ambiguous terminology finds its way into trade

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[39] Emphasis added. Note however that UNCTAD and ICTSD have argued that 'the wording of Article 7 ("The protection…should contribute") suggests that such protection does not automatically lead to the effects described'. See discussion in Sisule F. Musungu, "The TRIPS Agreement and Public Health" in Carlos M. Correa & Abdulqawi A. Yusuf, eds., *Intellectual Property and International Trade: The TRIPS Agreement*, 2d ed. (New York: Kluwer Law International, 2008) at 430 [*IP & International Trade*]. Musunga adds, "This suggests that the framers of the TRIPS Agreement did not believe, or at least did not agree, that the protection of IPRs would automatically lead to the promotion of technological innocation and the transfer and dissemination of technology and to a balance in the enjoyment of the benefits accruing to the users (availability and affordability of medicines) and producers of technology (profits)."

[40] See Jon R. Johnson, *International Trade Law* (Canada: Irwin Law, 1998) [*ITL*] at 199. Jon Johnson argues that Article 8 does not provide "true 'exceptions' such as those in Article XX of the GATT 1994. See also Nuno Pires de Carvalho, *The TRIPS Regime of Patent Rights* (New York: Kluwer Law International, 2002) at 118: "Nor is Article 8 about exceptions, because it in no way permits exceptions to the rights conferred by TRIPS provisions."

agreements because of the mutual desire to reach consensus on the treaty text for different negotiating members. The inclusion of this qualification in Article 8 does seem a bit tautological given that a Member's adoption of a TRIPS consistent measure can be for any purpose. However, the interpretative principle of effectiveness (*ut res magis valeat quam pereat)* provides that interpretation must give effect to all terms of the treaty.[41] The AB in *Reformulated Gasoline* referred to Article 31.3 of the VCLT to find 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."[42] This principle would support reading Article 8 as a defence (an argument could be made perhaps it is based on a right, such as to self determination in established sovereign areas) as opposed to a mere laudatory articulation of an overarching though unenforceable *principle* that would otherwise be superfluous given that Members inherently have a right to adopt *any* TRIPS-consistent measure for *any* purpose. If Article 8 is considered as providing permissible discretionary right-creating norms, similar in function to Article 31 on compulsory licencing, for example, the article could have a role to play in claim 1 or claim 2 in support of a defending party's shifting evidential burden. But, its greatest utility, I have argued, is as an affirmative defence. The compelling reason is that while *rights* create substantive protections for members to achieve particular public policy outcomes and the necessary

[41] This principle was cited by the Appellate Body in *Japan – Taxes on Alcoholic Beverages* to support the finding that no clause or paragraph may be reduced to "redundancy or inutility": *Japan-Taxes on Alcoholic Beverages* at 12. 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),* (Ardsley NY: Transnational Publishers Inc., 2001) at 78-85.

[42]WTO Appellate Body, *United States- Standards for Reformulated and Conventional Gasoline,* WTO Doc. WT/DS2/AB/R (20 May 1996) at 22.

institutional balance in their domestic IPRs by granting the discretion (through exemption/permission norms) to adopt diverse measures within their right (such as Articles 27.2, 27.3, 30 and 31 etc.), the concept of an affirmative "equitable defence" imports two important principles and extends beyond simply a *legal* defence. First, the idea of a defence supports the need for the complainant to contest the consistency of an impugned measure against some *other* provision first, 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 where contestability of a measure is based on whether it fits into the scope of the rights creating norm as discerned from the language of the provision. If it does, then the complaint will have successfully been defended on the terms of the provision challenged and if it does not, there would be liability without further defence. In that case, Articles 7 and 8 would merely interpretatively inform the conclusion of whether the measure exceeds the state's TRIPs right. Second, there are important reasons for characterizing this defence as "equitable" even though I argue it is derived from the TRIPS' text. Without reviewing all of the reasons here, we may say the most obvious is that the *equitable* defence is responsive to the idea of Article 8 as providing the overarching *Principles* governing the entire TRIPS agreement and locates these principles within broader understandings of national and international governance frameworks. It 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. The "public interest" referred to in Article 8, requires no less, however that interest is to be defined. It would enable governments to meet their other objectives such as "equitable sharing" under the

Convention on Biological Diversity (CBD)[43] and obligations such as the protection of social, economic, and cultural human rights under the ICESCR,[44] minimizing the trade-related costs of welfare and rights-promoting measures, as well as the associated costs of potential public authority liability for government failures towards a constituency.[45] Effectively, Article 8 should be understood as proving an ECD not only because such an interpretation is justified on the language of the text, but because it is desirable given the potential to reduce welfare-eroding regulatory transaction costs and to promote governmental economic efficiency. The ECD provides a procedural safeguard for minimizing state liability in one governance framework (*e.g.* for upholding particular human rights obligations of a State, for example) against the costs of non-compliance with a competing governance framework (*e.g* under TRIPS, in the multilateral trade regime). Article 8 is *equitable* because it helps minimize conflict into a reconcilable permissible category of sovereign self-determination in regulatory governance.

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.[46] Certainly, interpreting

[43] *Supra* note 35.
[44] *International Covenant on Economic, Social and Cultural Rights*, 16 December 1966, 993 U.N.T.S. 3, Supp. No. 16 (entered into force 3 January 1976), online: UN <http://www.hrweb.org/legal/escr.html>, [*ICESCR*]. Human rights are themselves characterized as income elastic.
[45] For example, a state may be domestically liable for human rights violations under its own legislation, under its Constitution, and under international instruments.
[46] Compare this, however, with the panel decision in *Canada-Generic Medicines, Canada—Generic Medicines* case (Panel Report, *Canada – Patent Protection of Pharmaceutical Products*, WTO Doc. WT/DS114/ Appellate Body Report, WTO Doc. WT/DS170/AB/ (12 October 2000), 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.

Article 8 as an ECD is less restrictive of 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."[47] The closing language of Article 8.1 was added at the last stages of the TRIPS negotiation.[48] 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. Members need not provide the motivation for any measure until the measure is contested and need not provide any explanation where it is not. This legal practice is consistent with the textual language of Article 8. 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

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While the testing provision was upheld as GATT consistent, the panel strangely decided that 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 create a windfall for the patentee (constituting additional ex post rewards rather than ex ante incentives). In determining whether the measures fell within 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. *International Trade*, *supra* note 33 at 416.

[47] *International Trade*, *supra* note 33 at 134.

[48] See Daniel Gervais, *The TRIPS Agreement: Drafting History and Analysis* (London: Sweet & Maxwell, 2003) at 122.

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. Under Article XX jurisprudence, this led to the difficulty of proving that a measure "necessary" was in fact the least restrictive means of achieving its objective. Carlos Correa contends that,

> [a]s illustrated by the concept of similarity under GATT, the same term need not be identically interpreted in different provisions or agreements. The meaning of 'necessary' in Article 8.1 of the TRIPS Agreement is not arguably as limited as interpreted in the context of Article XX of GATT, as the necessity is to be judged in the former in relation to very broad concepts, such as 'public interest' and 'socio-economic and technological development'. It would be unreasonable to give a restrictive interpretation to the concept in this context, as Members have significant room to define domestically the content and scope of measures they can adopt. However, the Member that has invoked it would be bound to demonstrate that a particular measure relates to the objectives set forth in Article 8.1 of the Agreement and that there is a link of necessity between the measure and the objective. [49]

Given the fresh start under Article 8, we may adopt the Trebilcock and Howse recommendation of a rebuttable presumption, once the defending party establishes that the measure is *prima facie* within the scope of the ECD within Article 8.[50] Under the ECD of Article 8, the evidential burden can shift to the complainant to establish that the measure does not exceed it and thereby shift the formidable challenge of proof from the defending party to the complaining party where a measure is *prima facie* justified as defensible. Such an approach to the Article 8 ECD removes the bad faith implication created by the AB under Article XX which is contrary to the principle of *pacta sunt servanda* codified in the VCLT. But if the argument is that the full legal burden is on the

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[49] Footnotes omitted. See Carlos Correa, *Trade Related Aspects of Intellectual Property Rights* (Oxford: Oxford UP, 2007) at 107 [*Trade Related Aspects*]. See also WTO Secretariat, *Necessity Tests in the WTO*, WTO Doc. S/WPDR/W/27 (2 December 2003).

[50] With respect to the AB's decision in *Reformulated Gasoline*, they write: "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 subtject to a rebuttable presumption that they are abusing rights acquired under the WTO law." Trebilcock & Howse, *supra* note 4 at 129.

partying invoking Article 8, then this is even more reason to consider its role as a legal defence given that this approach is even more consistent with our normative understanding of burdens of proof for legal defences. 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), or some broader concept of *international trade* (as would be the case with non-violation complaints) but with the "*provisions* of the Agreement" (TRIPS).

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 non-working or refusal to licence a patent. Rather, the anticompetitive behaviour of patent stockpiling in portfolios, the filing of bad patents, and predatory uses of these instruments in rent-seeking, would seem to be sufficient justification for invoking this defence.[51] Such market practices may constitute unfair competition and 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."

To summarize, 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 with possible shifting evidentiary

[51] Correa argues that a "number of anti-competitive practices may be particularily harmful to developing countries….The effective control of anit-competitive practices such as predatory pricing, collusive tendering, tied purchases and sales, may be an important target for developing countries." *Trade Related Aspects*, *ibid.* at 111.

burdens). If the complaining party is successful, the legal burden would shift to the defending party to invoke Article 8 as a defence with the full burden of 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, once the defence is raised, for a complainant to succeed it must discharge the burden of proving that the defending party's conduct somehow *exceeds* even the defence – i.e. it abuses the degree of permitted state discretion 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 8 "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?[52]

It is my view that the appropriate role of Article 8 within TRIPS disputes is as an affirmative defence. Defences in law must *a priori* be principled. Even if the full legal 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 a high evidential hurdle for the defending party. Finally, while textual language of a provision (consistent with Articles

[52] *International Trade*, *supra* note 33 at 411.

3.2 and 19.2 of the DSU[53]) must be adhered to, insofar as "the panel and Appellate Body cannot add to or diminish the rights and obligations provided in the covered agreements," recognizing the ECD would in no way be asking for "law making" on the part of the panel or AB in the domestic judicial-activism sense. Rather, it would be an 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.[54] The Objectives articulated in Article 7 inform all of the state undertakings and the Principles of Article 8 defend them.[55] This is an interpretative approach well within the mandate and jurisdiction of WTO jurists; indeed,

> [p]anels must take seriously the autonomy interests implicit in the structure of the international intellectual property system, and they must allow sovereigns to respond to changes in science, to the structure of their patent industries, or to other social needs. Otherwise, a series of worldwide disutilities will result…[V]arious systemic values that are crucial to this approach to analyzing TRIPS obligations [suggested are]: the incentives likely to optimize social utility may vary widely from country to country; permitting some diversity of approach allows nation states to act as laboratories in the development of international rules; affording space for the self-determination of sovereign states encourages voluntary and ultimately more effective compliance with international norms and, universality may have costs, whether measured in economic or non-economic terms.[56]

But it is also an approach highly contingent on institutional capacity. And, as Trebilcock and Howse express, cautious reserve is again merited here given the WTO 'institutional deficit' that TRIPS exemplifies:

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[53] 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: WTO < http://www.wto.org/english/tratop_e/dispu_e/dsu_e.htm>.
[54] *Doha Ministerial Declaration*, WTO Doc. WT/MIN(01)/Dec/1 (20 November 2001) at para. 19.
[55] DCs in particular highlight the importance of Articles 7 and 8, see the submission to the Council of TRIPS by the African Group, Barbados, Bolivia, Brazil, Dominican Republic, Ecuador, Honduras, India, Indonesia, Jamaica, Pakistan,Paraguay, Phillippines, Peru, Sri Lanka, Thailand, and Venezuela, IP/C/W/296, 19 June 2001. Developed countries, namely Canada and the EC in *Canada-Patent Protection of Pharmaceutical Products*, WTO Doc. WT/DS114/R (17 March 2000) at paras 7.25-26 also raised interpretive issues relating to Articles 7 and 8 but the panel declined to elaborate on the content or implication of these provisions despite the fact that these were specifically raised by the parties in their submissions. For a greater discussion of these issues, see *Trade Related Aspects, supra* note 49 at 101-102.
[56] Graeme B. Dinwoodie & Rochelle Cooper Dreyfuss, "International Intellectual Property Law and the Public Domain of Science" (2004) 7 J.I.E.L. 431 at 448.

> The case of TRIPs illustrates the difficulties of enforced policy uniformity within an institutional policy context designed for the interpretation and enforcement of general legal norms or rules such as National Treatment, MFN, and so forth. To some extent, the WTO TRIPs Agreement recognizes some limits on the case for uniform intellectual property protection…As an organization not largely preoccupied with the development of intellectual property law and regulation, the WTO has few resources available to support interpretations of these concepts by dispute panels.[57]

Part Three: Regulatory Diversity: A Public Interest Imperative for the Bioeconomy

> We test much of our legal system and rules by asking whether they fulfil people's legitimate or reasonable expectations. How does that apply to the IP system? How does it apply, in particular to these questions: (1) Can reasonable folk understand the system? And (2) Does the way the rules are expressed make sense to them?"[58]

That the WTO has been on the brink of a legitimacy crisis for some time is not simply speculation by well-reputed scholars working within this field.[59] It has manifested in mounting civil unrest, public contestation, and a current negotiating Round that, after close to a decade, has yet to successfully conclude or die a quiet death. While too much has been invested for parties to throw in the towel on the "Development Round" of negotiations, historical issues, such as agriculture and intellectual property, still prove intractable; perhaps more so now given the awareness of the important linkages between human rights (such as the right to health, farmer's rights to save seeds, cultural rights over traditional knowledge, the right to the highest attainable standard of health, etc.) and trade-related IPRs.[60]

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[57] "Regulatory Diversity", *supra* note 1 at 20.

[58] David Vaver, "Does the Public Understand Intellectual Property Law? Do Lawyers?" in Meredith Lectures 2009, *Intellectual Property at the Edge: New Approaches to IP in a Transsystemic World* (Montréal: Les Editions, 2007) at 2.

[59] For a review of this literature see *State Agency*, *supra* note 1, chapters 4-7.

[60] The tensions between patents and HR are not new; they have surrounded law and policy decisions in most jurisdictions around patented medicines, generic drugs, compulsory licences, the patentability of methods of medical treatment, and the patentability of food. 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. Deepak Gupta, "The Neoliberal Case for South African Patent Defiance", online: (2003) 2 L.G.D. <http://www.urfig.org/sup-eng-trips-human%20rights-pt.htm>. See also the 2001 "Nightmare Report" of the Expert Group of the UN Subcommission on Human Rights qualified the WTO as the "nightmare" of human rights. Sub-Commission on the Promotion and Protection of Human Rights, *The Realization of Economic, Social and Cultural Rights: Globalization and its impact on the full enjoyment of human rights*, UNESC, 52d Sess.,

Xavier Seuba critiques traditional economic rationales and finds that

> economic theory alludes to intellectual property as the answer to a fault in the free market to achieve the optimum assignation of resources for inventions, that is an economic political instrument that has the intention of having an effect on the productive system. However, this albeit plausible economic justification does note explain the relationship between the property granted and other social goods and values, nor does it determine the extent of the protection, extremes which will depend on the axiological make-up of each society.[61]

From an economic perspective, any additional monopolistic rights provided above the base amount necessary for innovation in any given state is *inefficient* and fails to achieve optimal patent policy even in the western world from which it is derived. TRIPS' "one size fits all" regime turns out to be ill fit for *any* according to David Vaver.[62]

E. Richard Gold and Mathew Herder, in their report to the OECD, write

> [t]o further highlight the arbitrary nature of the existing intellectual property system, we note that there is little good empirical evidence of the actual effect of intellectual property rights (IPR) on innovation and dissemination levels, let alone an indication of how differences in height, length, and depth of protection affects outcomes. This renders most discussions of the intellectual property rights in the biotechnology sector – whether calling for greater rights or greater inherent limitations on those rights - speculative…[W]e do not know whether, overall, the current patent system overprotects or underprotects patent holders.[63]

The domestic implementation of high prescribed standards of IP protection based on the executive branch of government's undertakings in multilateral negotiations is implicitly instrumental to an existing economic pattern that simultaneously enables the compromise

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E/CN.4/Sub.2/2000/13, (2000). This preliminary report was 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, E/CN.4/Sub.2/2000/13, "Globalization and Its Impact on the Full Enjoyment of Human Rights" (15 June 2000). See also Herder & Gold, *infra* note 63 at 9 wherein the authors contend, "[t]o address concerns of climate change and food security as well as the increasing convergence of agricultural and health biotechnologies, pressure will increase on finding collaborative mechanisims to manage intellectual property. These will be offset, although more in theory than in practice, by an increasing number of intellectual property rights in this [agricultural] sector."

[61] Xavier Seuba, "Human Rights and Intellectual Property Rights" in *IP & International Trade, supra* note 39 at 390.

[62] David Vaver, "Need Intellectual Property Be Everywhere? Against Ubiquity and Uniformity" (2002) 25 Dal. L.J. 1 ["Uniformity"], at 5. Vaver writes: "[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."

[63] Matthew Herder & E. R. Gold, "Intellectual Property Issues in Biotechnology: Health and Industry" Report for the OECD International Futures Project on "The Bioeconomy to 2030: Designing a Policy Agenda", Third Meeting of the Steering Group, 7-8 February 2008 at 4 ["Issues in Biotechnology"].

of attendant civil and political liberties while creating potential conflicts with inter-related social, cultural, and economic rights.

Not only is the impact of patents differential based on different industries (such as information and pharmaceutical industries), but Herder and Gold find that 'different biotechnologies, depending on their field of use and mode of application interact with the paten system in a different manner."[64] In fact, the authors find that it is changes in patent practice and not patent law that will be most determinative of the success or failure of the bioeconomy.[65] This observation may hold true as market solutions arise to address market problems in the absence of further regulation. For example, Robin Feldman and Kris Nelson argue that even if the existence of patent thickets and research bottlenecks may not be measured directly, that biotech based industries appear to be particularly at risk from over-patenting is discernable if one considers emerging market practices as evidencing indirect effects. To the extent that the disutilities and inefficiencies of resource allocations have emerged in the life sciences from too many patent rights, they have been met with some market ingenuity and initiative that seeks to reduce the transaction costs of research and development through open source, open access, and open transfer.[66] Herder and Gold believe that these complementary mechanisms (including others such as patent pools and patent clearing houses)[67] within the IP regime,

[64] *Ibid.* at 4. They write: "[R[esearch tools – which require no regulatory approval and are, as the name implied, used in research – have a very different profile from that of therapies and crops which undergo regulatory review. Industrial application of biotechnology similarly differ from health and agricultural biotechnologies in relation to not only regulatory approval, but in terms of industrial structure."
[65] "The changes made to intellectual property practice – which will be much more significant than those made to intellectual property law – to 2015 will set the stage for developments in the Bioeconomy to 2030. These changes will affect the agriculture, health and industry sectors differently." *Ibid.* at 9.
[66] See *e.g.* Robin Feldman & Kris Nelson, "Open Source, Open Access, and Open Transfer: Market Approaches to Research Bottlenecks" (2008) 7 Nw. J. Tech. & I.P. 14.
[67] Herder and Gold note how patent pools have already been created around the SARS virus to help foster vaccine development, for example. See "Issues in Biotechnology", *supra* note 63 at 6.

along with supplementary mechanisms outside the IP system (including instruments such as prizes, public sector grants etc), will continue to foster innovation and collaboration as we move into the bioeconomy. They predict continued heterogeneity for IP regimes and emphasize that the "Bioeconomy in 2030 will be the product of factors that lie largely outside of the intellectual property field. If countries, industry and public institutions manage to develop collaborative platforms for sharing and disseminating knowledge and innovation, then we can expect a dynamic Bioeconomy with reduced regulatory costs in 2030."[68] Nevertheless, TRIPS is not only inconsistent with the historical territoriality of patents, but also contradict the heuristic utilitarian and economic rationales that justify the state creation of domestic IP regimes, as stringent regulatory policies continue to depend on private market solutions for the problems they create. Moreover, globally, the principle of pareto-efficiency is inapt in justifying the imposition of higher IP protection through trade obligations because strengthened protection may improve welfare in some countries but would reduce it in others making it Pareto-inferior, or, as Trebilcock and Howse find, "[f]or a requirement of strengthened protection, in the case of at least some sectors, could increase economic welfare in some countries while reducing it in others."[69] As stand alone measures, they add, TRIPS is likely to reduce welfare in DCs by undermining their comparative advantage in imitation, imposing costs on knowledge diffusion, and limiting access to technology.[70] That welfare loss is a net gain subsidy of increase in first world corporate profits. Claims for policy convergence and

"*Ibid.* at 6.

[68] "Issues in Biotechnology", *supra* note 63 at 11.

[69] "Regulatory Diversity", *supra* note 1 at 19.

[70] *Ibid*. at 19-20. "A country where innovation is not a major source of economic activity and growth is likely to choose, on balance, a less stringent intellectual property regime than would a country whose economy is highly dependent on innovation. From this perspective, there is nothing suspect or unreasonable with the preference of many developing countries for a relatively lax system of intellectual property rights, provided this regime applies equally to domestic and foreign firms."

harmonization in this area are not, they argue, straightforward. If this is true, it is doubly so in relation to biopatenting.

Biotechnology promises to feed a growing population, address emerging issues in population and public health, provide alternative energy resources and waste management, and opportunities for climate control and sustainable development; essentially, that biotechnology can serve as a panacea for most of the significant governance issues facing regulatory governments world-wide is a position endorsed by the 2009 OECD report. Accordingly, the transfer of such technology and its access will raise important issues for human rights, human dignity and development. This means that trade-related intellectual property rights proscribed under TRIPS are equally human-rights related and contingent on the state for optimal mediation. The state also has an important role to play in shaping or reflecting social attitudes related to the technology.[71] The OECD has found that

> [a]n important influence on potential markets is the attitude of the public towards biotechnology products. Acceptance of biotechnology varies between health, agricultural and industrial applications, but also within applications. For instance, few people are opposed to the use of biotechnology in the development of therapeutics or vaccines; whereas stem cell research and genetic testing elicit a much wider range of opinions regarding the social, ethical,…and economic implications of these technologies. In primary production, animal cloning is more negatively viewed by the public than GM crops.[72]

Public attitudes towards biotechnology are noted in report as highly variable over different jurisdictions and in relation to different applications of the technology; they are susceptible to change over time and in correlation with new discoveries and media

[71] According to Herder and Gold, "concerns over the social value of and the health and environmental consequences of new biotechnologies will spill over into debates over intellectual property in the biotechnology realm. While early religious and other deontological concerns over owning life have abated, they are unlikely to disappear. They have, instead, mutated into a general scepticism about biotechnology and commodification that have ironically brought together religious communities with feminist and anti-globalisation advocates. This coalition is largely responsible for the lack of patent protection over embryonic stem cells in Europe and for the ban of the use of federal funds on these cells in the United States." See "Issues in Biotechnology" *supra* note 63 at 7.

[72] OECD Report, *supra* note 12 at 153.

coverage,[73] as well as continued assessments of the risks and benefits of the technology.[74] Moreover, the OECD Report notes how

> [t]he ethical views of a population can influence the bioeconomy through its impact on regulations and other laws that affect research (what is permitted and the level of public support for research), markets (what people will buy and at what price), and business models (what business strategies are legally permitted). Opinion survey research within the OECD countries suggests that public attitudes to biotechnology are influenced by a range of ethical views, including strong moral beliefs that some actions are inherently good or bad) [sic], utilitarian views, where a technology is accepted if its benefits are considerably greater than the amount of harm it causes; and by concepts of fairness, in terms of who obtains the benefits from new technology….[P]ublic attitudes to many other biotechnological controversies are strongly influenced by either utilitarian ethics, as in the case of GMcrops or stem cell research, or concepts of fairness, as with confidentially, informed consent, or bioprospecting.[75]

The Bioeconomy then, will very much depend on how public attitudes are mediated through state agency The 'public interest' is context specific and highly variable. It is not defined by TRIPS and is thus not likely to be made subject to any objective determination of its substantive content. Instead, it will be left for the Member to determine as "it is clearly a domestic issue. Members cannot challenge what 'public interest' is in accordance with the views of a particular Member.…[It] is a concept broader than 'ordre public' used in Article 27.2 of the TRIPS Agreement…[and] may be deemed to encompass any matter that affects the public."[76] Similarly, the remaining conditions of

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[73] For example, "….[I]n Europe, North America and Japan, the percentage of the population with a positive opinion of biotechnology declined in the late 1990s, when public debate surrounding GM crops was very active. Since 2000, the year in which there was extensive and positive media coverage of the human genome project, the share of the population with a positive opinion of biotechnology increased…Opinions also vary by country. In a 2005 survey of European attitudes to GM technology, 46% of respondents from the Czech Republic believed that GM should be encouraged, compared to only 21% of German respondents….", *ibid.* at 153.

[74] For example, "the percentage of Australian adults with a favourable view of GM crops increased rapidly from 45% in 2005 to 73% in 2007. This was largely caused by an increase in public awareness of the potential for GM technology to provide improved crop varieties that can tolerate drought and salinity, both sever problems in Australia…European public opinion towards GM could also become more favourable if GM crops offered European consumers clear environmental or other advantages." *Ibid* at 154.

[75] OECD Report, *supra* note 12 at 154. See also 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.

[76] *Trade Related Aspects*, *supra* note 49 at 105.

Article 8 are, again, subjective matters for the particular Member to decide. Correa shares some of insights on Article 8:

> On the one hand, 'sectors' may refer to economic activities at different levels of aggregation (eg agriculture, maize production), as well as to certain groups of economic agents (eg, small and medium enterprises). Although the adjective 'vital importance' would seem to limit the scope of the provision to specially significant sectors, which sector is important or not is also subject to determination by the concerned Member in light of its 'socio-economic and technological development…the concept of [which]… is broad enough to encompass any sector, socially, economically, or technologically relevant. Thus, the importance of a sector may be measured by its contribution to GNP; but it may be also socially important, despite a low contribution thereto.[77]

Given the OECD's focus on primary production, human health and industry, we might agree that, as a common denominator, biotechnological innovations in these areas can safely be considered as affecting sectors of vital socio-economic and technological development. That WTO member's enjoy considerable scope for national policy divergence is simply descriptive of the document's textual flexibilities. But, the normative claim advanced here is that states should seek to customize their policies by pursuing regulatory diversity to ensure that the public interest is in fact met by appropriately differentiated policies that are either needed in a given context, or demanded to the extent that they reflect important and distinct cultural, religious, ethical or other values shaping the public's interest, and demands for accountability thereto, whether or not such preferences may be considered *irrational* by some 'objective' external assessment. Public policy should continue to represent the democratically determined will of a government's constituents.[78] In the absence of political integration,

[77] *Ibid*. at 106.

[78] For 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). Feinteuck posits, "The question remains as to the extent to which it is possible to define a normative model of the public interest. It will be, to a degree, historically contingent, relating to the contemporary view of the state, and meshing with dominant values. It must, however, by reference to fundamental democratic principles represent the validity of arguments against any such dominant values where they threaten the underlying basis of the polity. Where public or private policy conflicts with fundamental democratic interests, then it may meaningfully be said to run counter to the public interest." At 27.

as with the EC, full economic integration at the policy level is simply not operational. David Kennedy has observed 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.[79]

Regulatory diversity is needed to retain legitimacy of the multilateral trade regime as much as it is needed to foster faith and consumer trust in the underlying technology. Stratified biopatent policies in accordance with a state's developmental position will increase global welfare and this should, in turn, have the results of increasing human rights which are "income elastic".[80] 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. Articles 8 and 27 serve to protect those interest from unnecessary and undue intrusion by regulatory governments through state-created and enforced IPRs. 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

[79] David Kennedy, "The Forgotten Politics of International Governance" (2001) 2 E.H.R.L.R. 117 at 120.
[80] 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. See *e.g.* Alan O. Sykes, "International Trade and Human Rights: An Economic Perspective" in Thomas Cottier, ed., *International Trade and Human Rights: Foundations and Conceptual Issues* (Ann Arbor MI: University of Michigan Press, 2006) 29.

interest. If their internationally mandated protection results in welfare loss by impeding a state from fulfilling other obligations or policy preferences, then these instruments of private property are no longer instrumental as global public goods and create incoherence for the international governance regimes in that 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). These costs 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. The effect is both human-rights eroding and Pareto-inefficient. The public who is to benefit from the very existence of IPRs would have to pay in many ways, indirectly and directly, if the scope for policy divergence under TRIPS is not retained:

> irst as tax paying subsidizers of innovation facilitating institutions such as public education and health; second as subsidizers of a publicly administered patent system and then again as rent payers on the patented inventions it generates; third as subsidizers of government liability to constituents for violations of human rights obligations or conversely patent infringement; fourth, as subsidizers of the costs of defending complaints; and finally, 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. 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 protection of this right and the individual's liberty to self-realize it. 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 that seeks to avoid direct royalty payment. [81]

The state's right to self-determination, as I have stated elsewhere, "has a moral force: even though states have often stood in colonial opposition to their peoples, human

[81] *State Authority*, *supra* note 1 at 321. See also Jan Klabbers, *The Concept of Treaty In International Law* (Boston: Kluwer Law International, 1996) at 161, providing that "Domestic courts…[i]n some cases…have simply applied resolutions such as the Universal Declaration on Human Rights without further ado; and in one case, the Universal Declaration overruled conflicting domestic legislation. To say that resolutions have been applied by domestic courts is, however not by definition tantamount to saying they were regarded as legally binding. Rather, in those cases where they have been applied, they have been assimilated to one of the more familiar sources of international law: treaties or customary international law." (Footnotes omitted).

rights need to be implemented in highly stratified contexts and are therefore conditioned on the state's appropriate exercise of its sovereign right. This means that diversity of regulation is constitutive of universal principles and at the save time preserves stratified cultural landscapes."[82] Trends towards the expansion of domestic regulations addressing health, safety, consumer protection, and the environment that have accompanied the dramatic decline in tariffs in each successive Round[83] suggest a growing commitment by regulatory governments towards preserving and prioritizing their public's interest and wellbeing. As the forgoing discussion of specific provisions demonstrates, TRIPS provides considerable scope for regulatory diversity in recognition of the sovereign right to (bio) self-determination, and in particular in relation to biopatenting (as articulated in its exceptions and permissions norms), and on issues for the balancing of rights and interests (Article 7) and in relation to public health, nutrition, and promoting the public interest in sectors of vital importance (Article 8). Domestic measures permitted under Article 8 may be those identified under TRIPS (such as compulsory licencing in Article 31) or they may be non-IPR related measures, such as price control mechanisms or health and safety regulatory requirements to be met before an invention may be commercialized, if so prescribed by domestic law.[84] Recognizing the gains of regulatory diversity for the bioeconomy would help update the WTO's mandate in the public eye to meet current

[82] *State Agency*, *supra* note 1 at 231.
[83] "Regulatory Diversity" *supra* note 1 at 6.
[84] See *e.g.* Lisa Austin & Bita Amani, "Patents on Genes: Identifying Issues and Responses" (2001) [discussion paper prepared for the Provincial Advisory Committee on New Genetic Technologies, Toronto] reproduced in Trudo Lemmens *et. al.*, *Reading the Future?: Legal and Ethical Challenges of New Predictive Genetic Testing* (Montréal: Les Éditions Thémis, 2007) at 105-139 ["Patents on Genes"]. See also, Nuffield Council on Bioethics, *The Ethics of Patenting DNA: A Discussion Paper* (20 July 2002), online: Nuffield Bioethics Council, <http://www.nuffieldbioethics.org>.

'social' challenges' and would endorse the central role of the state in overcoming them.[85] But it would also allow governments to promote reasonable understanding of domestic IPRs in a way that resonates with their values.

David Vaver's inquiry in the opening quote under this section would produce two negative replies. First, although the Supreme Court of Canada has accepted to hear a record breaking number of IP cases in recent years,[86] on the heels of two important Supreme Court of Canada cases on patent rights and higher (non-human) life, the law as it relates to the patenting of life is murkier today than it has ever been. Despite the incredible number of third party interveners – in *Harvard,* no less than twelve,[87] and in *Schmeiser* eleven including the Attorney General of Ontario – reflecting the public interest in the important industrial, ethical, personal, religious, environmental, regulatory, and public interest stakes involved,[88] few are satisfied with either decision.

Paradoxically, the result of the Supreme Court of Canada decisions combined is that in Canada, while you cannot patent plants or animals,[89] any patent over a smaller embodiment, such as a gene, micro-organism, or a vector, will effectively extend (back-

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[85] 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'*." *International Trade*, *supra* note 33 at 583.

[86] Teresa Scassa, "Patent Law at the Supreme Court of Canada: A Healthy Balance?" in J. Downie & E. Gibson, eds., *Health Law at the Supreme Court of Canada* (Toronto: Irwin Law, 2007) 337. See also Myra J. Tawfik, "No Longer Living in Splendid Isolation: The Globalization of National Courts and the Internationalization of Intellectual Property Law" (2007) 32 Q.L.J. 573.

[87] They were: The 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., Zoocheck Canada Inc.

[88] They were: 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.

[89] See *Harvard College v. Canada (Commissioner of Patents)*, 2002 SCC 76,[2002] 4 S.C.R. 45 [*Harvard*] and *Monsanto Canada Inc. v. Schmeiser*, 2004 SCC 34, [2004] 1 S.C.R. 902 [*Schmeiser*].

door) rights over any product embodying the patented invention – such that a plant, though not patentable, may nevertheless constitute an infringing *use* if it contains patented genetic material. Industrial policy incoherence results.[90] While Harvard University was unable to secure patent rights for its genetically modified oncomouse as a product, Myriad Genetic Laboratories Technologies Inc. (MGL), the American company based in Utah, USA that has caused great controversy in holding patents over the BRCA1 and BRCA2 genes and methods for their diagnostic testing (as well as their commercial licencing practices), would effectively enjoy patent rights over an oncomouse carrying these patented genes. The combined effect of the SCC decisions, in the absence of any further legislation, is particularly dire given that by, popular account more than 4,000 of the approximately 24,000 human genes have been claimed in U.S. patents – that's 20 per cent of the human genome patented, 63 per cent of which are assigned to private firms as compared to 28 per cent to universities[91] even though "the functions are unknown for over 50% of *discovered* genes"[92] and that the patenting of life and its genetic building blocks has occurred as a result of political inertia, administrative fiat, and judicial activism towards policy convergence with more stringent protection provided by our American neighbours. Canada risks repeating their mistakes. The United States, after leading the world down a path towards greater *property fundamentalism* now considers a new proposal to legislatively change course with a *ban* on patents for all human

[90] See *Schmeiser*.
[91] Stefan Lovgren, "One-Fifth of Human Genes Have Been Patented, Study Reveals" *National Geographic News* (15 October 2005), online: National Geographic <http://news.nationalgeographic.com>.
[92] Emphasis added. *The Science Behind the Human Genome Project*, online: Human Genome Project Science <http://www.ornl.gov/sci/techresources/Human_Genome/project/info.shtml>.

nucleotides (and possibly polynucleotide) and their functions.[93] In his introductory speech, Congressman Xavier 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….[94]

While neither of the SCC decisions affect the practice or legality of gene patenting in Canada, together they significantly expand the value and scope of gene patent rights after-the-fact. The Manual of Patent Office Practice confirms that plants, animals, seeds, and mushrooms, all examples of higher life, are therefore not patentable. Yet, standard patent practice now provides additional 'windfall' and unexpected licence generating streams for those who patent or have patented lower life and genetic material. The SCC decisions have in tandem produced consequences unanticipated by all parties including the issuing office when the grant was originally made and obfuscated the traditional distinction between product and process patents; they have also extended patent rights beyond the scope for which Canada is responsible under TRIPS. But they reflect mounting pressure on the judiciary towards policy convergence.[95] This brings us back to an important point made by Trebilcock and Howse: international ground rules should

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[93] On February 9, 2007, California Congressman Xavier Becerra and Mr. Weldon proposed a new Bill (U.S., Bill H.R. 977, *Genomic Research and Accessibility Act*, 110th Cong., 2007 online: Library of Congress <http://thomas.loc.gov/home/gpoxmlc110/h977_ih.xml> to Amend Title 35, United States Code).

[94] He continues, "[m]y 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 U.S., *Cong. Rec.*, daily ed., at E315 (9 February 2007) (Rep. Becerra).

[95] *Schmeiser* is often seen as a judicial 'correction' of the SCC's decision in *Harvard;* at the time, Canada was alone amongst the developed industrial nations of the world in finding Harvard's oncomouse not patentable.

minimize the extent to which harmonization can be induced by judicial fiat and international norms should seek to reduce the "threat points" of nation states in their interactions with each other. Sadly, the latter have also increased through TRIPS Plus agreements.[96]

A growing number of regional negotiations are modeled on TRIPS but provide more protective measures as collateral arrangements that seek to address American perceived deficiencies in TRIPS.[97] The "a very complex legal environment" is potentially at odds with the TRIPS MFN principle in Article 4 and may possibly give rise to de facto MFN discrimination according to Frederick Abbott.[98] The United States has actively pursued a number of bilateral trade treaties that strive to mirror and *enhance* the substantive protections prescribed by TRIPS through the exertion of political pressures for more stringent "TRIPS Plus" IP protection. These would substantially reduce critical policy space for their signatories by moving beyond the universal minimums required under TRIPS.[99] Not surprisingly, "U.S. PhRMA stands strongly behind these efforts".[100][101] For

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[96] See *e.g.* Justin Malbo, "TRIPS-Plus treaty terms: Dealing with coercion" in Justin Malbon and Charles Lawson, eds., *Interpreting and Implementing the TRIPS Agreement: Is It Fair?* (Cheltenham UK: Edward Elgar, 2008) at 181 providing that international law "remains unduly complacent about the abuse of dominant party position, which most likely harms the long-term stability of the existing international relations regime. Given this, it can be said the TRIPS-plus critics raise legitimate concerns about substantive fairness."

[97] The *Trade Act 2002*, Pub.L. No. 107-210, 116 Stat. 933, sets out as its objective to "ensure that the provisions of any bilateral or multilateral trade agreement concerning intellectual property, to which the United States is a party reflects a level of protection similar to that of the United States." See discussion in Xavier Seuba, "Human Rights and Intellectual Property Rights" in *IP & International Trade*, *supra* note 39 at 415.

[98] Frederick Abbott, "Towards a New Era of Objective Assessment in the Field of TRIPS and Variable Geometry for the Preservation of Multilateralism" (2005) 8 J. Int'l Econ. L. 77 at 97 ["New Era"]. See *e.g. Free Trade Area of the Americas*, online: FTAA http://www.ftaa-alca.org.

[99] 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 , and US-Singapore (January 15, 2003).

[100] "WTO Medicines", *supra* note 28 at 349.

[101] For a detailed and insightful discussion of criteria for TRIPS Plus status and a helpful table of the bilateral and regional agreements where developed states have secured these for biological material in DCs,

example, a bilateral agreement may include a commitment that a party provide patentability for plants or animals; or that there be accession to UPOV (providing stricter and stronger protection for plant varieties than TRIPS requires); or to the Budapest Treaty on the Deposit of Microorganisms for the Purpose of Patent Protection[102] (not mentioned in TRIPS); or to conform with the EPC (that allows patenting of transgenic plants and animals).[103] Having signed on to these TRIPS Plus agreements, countries can no longer take advantage of the flexibilities inherent in TRIPS nor of the extended exemptions offered under the transitional periods. A party's ability to invoke TRIPS based defences at the WTO will also be curtailed. 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 the WTO…, calling into question the relevance of the TRIPS Council deliberations"[104]

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).[105] Statistics Canada reports that Canada's biotechnology

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see GRAIN, "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>.

[102]*Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purpose of Patent Protection*, 28 April 1977, 1861 U.N.T.S. 361, 32 U.S.T. 1241 online: WIPO < http://www.wipo.int/treaties/en/registration/budapest/trtdocs_wo002.html>.

[103] *Convention on the Grant of European Patents*, October 1977, 1065 U.N.T.S. 199 [EPC], online: EPO http://www.european-patent-office.org/legal/epc/e/mal.html. For a list of existing or under negotiation agreements requiring TRIPS PLUS protection, see: GRAIN, "Bilateral Agreements imposing TRIPS plus Intellectual Property Rights on Biodiversity in Developing Countries" (August 2005) online: GRAIN < 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" (2002) 10 Cardozo J. Int'l & Comp. L. 79.

[104]"New Era", *supra* note 90 at 97.

[105]Industry Canada, *Canadian Biotechnology Advisory Committee Project Steering Committee on Intellectual Property and the Patenting of Higher Life*, online under publications: Strategis Canada <http://strategis.ic.gc.ca >. Specifically, the CBAC, *Biotechnology and Intellectual Property: Patenting*

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.[106] 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 be in this area."[107] Public attitudes to the underlying technology will continue to determine the success of biotechnology for fostering a strong economy in the various sectors but may be different for the different sectors.[108] It is critical that national policies reflect policy preferences and the divergent approaches demanded in regulation. Respecting the underlying cultural diversity that informs divergent national perspective inform any normative examination of regulatory measures as NTBs. A unified approach to biopatent regulation will be difficult to achieve across governance sectors and in different countries; it cannot be said to be justified. An international policy of *preference* instead should give way to a global policy of *deference* in shaping divergent national policies. Successive governments should not be fiscally punished or made 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 technocratically committed to by prior government and with current disutility. Robert Howse goes further in his vision of improving the democratic deficit of the WTO:

Life Forms and Related Issues (Interim Report) (Ottawa: Canadian Biotechnology Advisory Committee, November 2001).

[106] *Harvard*, *supra* note 81 at para. 16.

[107] Patenting of Higher Life Forms and Related Issues. (Ottawa: Canadian Biotechnology Advisory Committee, June 2002), CBAC, *supra* note 97 at 2.

[108] OECD Report, *supra* note 12.

> [W]hether this cashes out into greater democratic legitimacy depends on how well informed parliamentarians are, to what extent they are independent rather than subject to the discipline of the Party whip and therefore no real check on the executive, and also 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).[109]

Finally, regulatory diversity remains an imperative for the public's interest in the bioeconomy. It is the necessary means by which the United Nations Millennium Development Goals (MDGs), articulated under the Millennium Development Declaration (MDD) in order to galvanize world nations to cooperate towards their achievement, may be given effect.[110] The MDGs reinforce national commitments to economic, social and cultural rights by providing further positive state undertakings in relation to wealth distribution and the realization of welfare rights. 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. 191 UN Member States have pledged 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

[109] Robert Howse, "Human Rights in the WTO: Who's Rights, What Humanity? Comment on Petersmann", online: (2002) 12:2 Jean Monnet Program at 13 <http://www.jeanmonnetprogram.org/papers/02/021201-01.pdf>.. Howse adds, "[g]iven 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…" at 11.

[110] See UNDP, "Millennium Development Goals: A compact among nations to end human poverty. Overview Chapter of the *United Nations Human Development Report 2003*" (2003) 5 HDR. The MDD, adopted in 2000 at the largest ever gathering by 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.

partnership for development.[111] 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 can 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 privatization of traditional (cultural) knowledge. Strong uniform standards of IPRs will adversely affect the realization of several of the MDGs; most importantly, the g*lobal partnership for development* which, potentially, might subsume all the other substantive goals. Committing to partner towards development targets to deal with DCs "special needs" might focus on reducing their "debt" or include private sector cooperation for making essential medicines and enriched food available. The state's right to self-determination is critical for mediating the complex relationship between regulatory diversity, cultural diversity, and biological diversity. As Rosemary Coombe has warned,

> The 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.[112]

Conclusion

As IP has expanded to absorb developments in the life sciences, the regulation of biotechnology portends to be the most controversial and central challenge facing

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[111] United Nations, *UN Millennium Development Goals*, online: UN, <http://www.un.org/millenniumgoals/#>.

[112] See generally Rosemary J. Coombe, "Intellectual Property, Human Rights, and Sovereignty: New Dilemmas in International Law Posed by the Recognition of Indigenous Knowledge and the Conservation of Biodiversity" 6 Ind. J. Global legal Stud. 59 at 94.

governments in relation to diverse areas of public policy in the twenty-first century, including governance of public and population health genomics; alternative energy technology (biofuels) and waste management; environmental protection; food production and food security; sustainable development; national security and bioterrorism; and foreign policy with respect to aid as well as fair and free trade. Presumably, any society which deliberates the scope and use of a technology, and its limits within industrial policy, must do so with the framework of its own cultural and humanist aspirations. Terms, such as *dignity* are present in many international instruments yet remain amorphous and difficult to define as much as *development* and its *progress*, which are imagined differently across sectors as well as societies. The MDGs transplant to the global community the premise of the welfare state and aim to further the attainment of 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 a moral premise by extending the duties corresponding to the ICESCR beyond the individual state signatories, or in relation to their citizens but to the international community, focusing cooperation on the purpose of *development*, a UN goal that is shared in the current Doha Round.[113] Trade is only one means of attaining improved global welfare; foreign aid and divergent domestic regulatory policies are yet other means. To the extent that they are embraced by the WTO, they will help civilize economic globalization. The evidence on biopatenting

[113]According to David Kelley, "[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…" See David Kelley, "A Life of One's Own: Individual Rights and the Welfare State" in Henry Steiner & Philip Alston, eds., *International Human Rights In Context: Law, Politics, Morals*, 2d ed. (New York: Oxford UP, 2000) at 257.

simply does not support a strong case for convergence of policies, but for ultimate *deference* to regulatory governments acting first and foremost on behalf of their citizens, to the extent permitted under international law. Respecting regulatory diversity within a TRIPS review of domestic measures may prove to be a critical part of the transition from a knowledge economy to a bioeconomy,[114] not the least because

> for the intellectual property system to survive, it must gain and keep public respect. To be respected, It must be known. To be known, it must be understood. To be understood, it must be coherent and persuasive. There are now calls that the public should become better educated about intellectual property. Such calls are, naturally, music to the ears of any educator. But one must be prepared for the consequence that an educated public is entitled to demand greater coherence and persuasiveness from the intellectual property system than that system presently exhibits. If those calls are not met and answered, then greater knowledge will not produce greater public respect but instead cynicism, disregard and avoidance.[115]

[114] See generally Peter Drahos, "The Regulation of Public Goods" (2004) 7 J. Int'l Econ. L. 321. See also Peter Drahos, *A Philosophy of Intellectual Property*, (Sudbury MA: Dartmouth Publishing Company, 1996) at 57-60, arguing diverse regulatory approaches are needed no less because "[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)."

[115] David Vaver, "Intellectual Property Law: The State of the Art" (2000) 116 L.Q.R. 621.