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**FOSTERING DYNAMIC INNOVATION,
DEVELOPING THE TRADE:
INTELLECTUAL PROPERTY AS A CASE
STUDY IN GLOBAL ADMINISTRATIVE LAW**

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Fostering Dynamic Innovation, Development and Trade: Intellectual Property as a Case Study in Global Administrative Law

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Abstract

International intellectual property law furnishes a case study on the need for norms of global governance. In an earlier era, multilateral intellectual property instruments recognized the dynamic nature of information production; under their terms, nations could balance the interests of producers in earning a return from their intellectual investments against the interests of users in accessing new knowledge for both consumptive and productive purposes. Now that IP is part of the WTO trade regime, information streams have been intensely commodified and an emphasis has been placed on raising IP protection to ever-higher levels. While there are traders in the North and in some emerging economies that are reaping rewards from this system, the TRIPS Agreement is operating as a tax on the South and is chilling innovation in the North.

Ostensibly, TRIPS permits nations to strike the appropriate local balance between proprietary and access interests. However, because the drafters of TRIPS incompletely theorized the function of exclusive right regimes, WTO adjudicators have had difficulty evaluating challenges to public-regarding legislation and nations have little guidance for enacting TRIPS-compatible law. But TRIPS does include two potential saving graces. It contemplates close cooperation with WIPO, which now administers upward of 20 intellectual property instruments. Furthermore, the Agreement sets up a Council to oversee compliance. The combined expertise of these two entities could be exploited to rectify the deficits in TRIPS.

This paper explores the institutional design issues that must be resolved for these institutions to function effectively. These include mechanisms for incorporating WIPO's expertise into the interpretive process, for insuring that WIPO and the Council operate within the scope of authority delegated by WTO members, and for controlling forum shopping. Another constellation of issues relates to questions of transparency, competence, and participation. While it is attractive to bring together the intellectual property expertise of WIPO and the trade expertise of the TRIPS Council, it is necessary to take a close look at the source of these institutions' knowledge bases. The confluence of interests among the South, low protectionists in the North, and emerging economies suggests that the dynamics of negotiation within WIPO and the Council are changing. Nonetheless, it is imperative to develop global administrative norms and, as important, a means for insuring their application. In addition to these rules, which are largely derived from domestic administrative law, special attention needs to be paid to the international context. Indeed, because TRIPS could keep countries at a comparative disadvantage, there is an obligation to develop both procedural and substantive norms to protect their interests.

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**Fostering Dynamic Innovation, Development and Trade:
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The WTO is currently suffering from a law-making deficit. Reliance on consensus-based decisionmaking has stymied the political process. At the same time, lawmaking through the Understanding on Dispute Settlement (DSU)¹ suffers from concerns about the legitimacy of law created through “adjudication” rather than party agreement.² Less well understood are the special problems that this deficit poses for TRIPS, the intellectual property portion of the WTO Agreement.³ Admittedly, a great deal of attention has focused on the question of making essential medicines available in the developing world.⁴ However, that issue barely scratches the surface of the problems that the creative community is facing.

As Andreas Lowenfeld and I suggested when the Uruguay Round ended, fitting intellectual property into a trade agenda distorted perceptions about the structure of intellectual property law.⁵ While domestic regimes strive to strike a balance between the interests of producers in earning a return from their intellectual investments and the interests of users in accessing new knowledge, the WTO’s concern was with creating “trading chips”—with commodifying information streams and turning knowledge products into articles of commerce. As a result, the TRIPS Agreement deals almost exclusively with proprietary interests. It obliges members to recognize a series of intellectual property rights (patents, trademarks, copyrights, as well as rights over trade secrets, geographic indications, layouts of integrated circuits, and industrial designs), it specifies the minimum contents of these protective regimes (the term of protection, the scope of exclusivity, limits on defenses to infringement, and such), and sets out required methods of enforcement (including specific judicial procedures and forms of relief).

¹ Understanding on Rules and Procedures Governing the Settlement of Disputes (Apr. 15, 1994) Marrakesh Agreement Establishing the World Trade Organization [hereinafter WTO Agreement], Annex 2, Legal Instruments - Results of the Uruguay Round, 33 I.L.M. 1125 (1994) [hereinafter DSU].

² See, for example, C D Ehlerman & L Ehring ‘The Authoritative Interpretation Under Article IX:2 of the Agreement Establishing the World Trade Organization: Current Law, Practice and Possible Improvements’ (2005) 8 *J Int’l Econ. L.* 803 [hereinafter Authoritative Interpretation]; C D Ehlerman & L Ehring ‘Decision-making in the World Trade Organization’ (2005) 8 *J. Int’l Econ. L.* 51; D C Esty ‘Good Governance at the Supranational Scale: Globalizing Administrative Law’ (2006) 115 *Yale L. J.* 1490. See also C E Barfield *Free Trade, Sovereignty, Democracy: The Future of the World Trade Organization* (2001) AEI Press; T Broude *International Governance in the WTO: Judicial Boundaries and Political Capitulation* (2004) Cameron.

³ Agreement on Trade-Related Aspects of Intellectual Property Rights (1994) [hereinafter TRIPS Agreement or TRIPS], WTO Agreement, Annex 1C, Legal Instruments-Results of the Uruguay Round, 33 I.L.M. 1197.

⁴ See World Trade Organization, Ministerial Declaration of 14 November 2001, WT/MIN(01)/DEC/1, 41 I.L.M. 746 (2002) [hereinafter Doha Declaration], available at http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_e.htm; Declaration on the TRIPS agreement and public health, WT/MIN(01)/DEC/2 (14 November 2001), available at http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm. See generally F M Abbott & J H Reichman ‘The Doha Round’s Public Health Legacy: Strategies for the Production and Diffusion of Patented Medicines Under the Amended TRIPS Provisions’ (2007) 10 *J. Int’l Econ. L.* 921.

⁵ R Dreyfuss & A Lowenfeld ‘Two Achievements of the Uruguay Round: Putting TRIPS and Dispute Settlement Together’ (1997) 37 *Va. J. Int’l L.* 275.

Unlike other intellectual property instruments which similarly focused on right holders' interests, TRIPS makes these obligations subject to international dispute resolution. While the Agreement also claims that its goal is to balance proprietary and access interests and includes "flexibilities" that give members authority to support the public interest,⁶ these provisions are highly circumscribed.⁷ In disputes over their scope, WTO adjudicators have proved wary of expansive interpretations.⁸ As a consequence, WTO members at all points along the development spectrum are now concerned that they lack the leeway they need to support creative production, keep the law responsive to a changing technological landscape, and safeguard the interests of consumers of intellectual goods.

In truth, the deficit in lawmaking is not only a function of WTO involvement in the intellectual property system. Because intellectual property law is expressly aimed at fostering dynamic innovation, the responsiveness of lawmakers to the information sector is an issue at the national level as well. For example, the Internet has revolutionized how copyrighted material is distributed and, in some cases, produced. Where patents were once associated with individual products, they map onto information technology in entirely new ways; manufacturers must now assemble a multiplicity of patents before they can bring products to market. By the same token, international travel, global distribution, and Internet marketing broaden consumers' knowledge base and call the territoriality of trademark protection into question. Equally important, the differential impact of new technological opportunities on various creative sectors has altered the political economy. As demonstrated by the continuing difficulty in adopting an EC-wide patent system and reforming the US Patent Act, domestic lawmaking is also at something of an impasse.⁹

Just as the WTO has, essentially, deflected lawmaking to DSU adjudicators, several countries have tried to solve their various lawmaking problems with specialized courts. The process is particularly well advanced for patents, where something of a crisis has been produced by the critical nature of the subject matter (medicines are a good example), abstruse science (e.g. biotechnology), shifts in the organization of the technological enterprise (including university spin-offs and private/public joint ventures), and changes in the way that patents are utilized (e.g. defensive patenting and trolling).¹⁰ Trial-level patent courts have enjoyed considerable success in practitioner circles, in large part because expert judges are better at understanding the technological complexity of the facts with which they are presented. But trial courts do not make, or definitively interpret, law. In the United States, the decision was therefore made to experiment with an appellate court with exclusive authority over patent law. Unfortunately, in its 25 years of existence, the Federal Circuit has proved somewhat disappointing. Although it

⁶ Articles 7 & 8 of TRIPS.

⁷ See, for example, Articles 13 (limitations permitted to copyright protection) 17 (trademark) 26 (industrial designs) 30 (patents) and 31 (conditions for permitting compulsory patent licenses) of TRIPS.

⁸ See, for example, G B Dinwoodie & R C Dreyfuss 'Intellectual Property Law and the Public Domain of Science' (2004) 7 (2) *J. Int'l Econ. L.* 431 at 442.

⁹ Cf. D R Cahoy 'An Incrementalist Approach to Patent Reform Policy' (2005-2006) 9 *N.Y.U. J. Legis. & Pub. Pol'y* 587 (describing various approaches to reform).

¹⁰ See, for example, A B Jaffe & J Lerner *Innovation and its Discontents* (2004) Princeton University Press.

has managed to make patent law more uniform and predictable, the substance of its lawmaking has been heavily criticized.¹¹

To many, this experience suggests that new lawmaking mechanisms are needed. Because patents are issued only after applications are reviewed by technically trained examiners, presumably familiar with both the applicable law and relevant scientific developments, there is growing interest in placing primary responsibility for administering patent law in the agencies that issue patents. For example, the US Patent and Trademark Office (US PTO) has enacted a series of guidelines on both prosecution and substantive issues.¹² Similarly, the European Patent Office (EPO)¹³ has become a focal point for studying the impact of new technologies and business trends.¹⁴ Indeed, in a move that might ultimately lead to an alternative international patent law regimes, the US PTO, the EPO, and the Japanese Patent Office (JPO) meet regularly to harmonize their approaches to patentability determinations, with an eye toward building worksharing arrangements.¹⁵ There is now a growing literature on whether these agencies are capable of becoming the architects of patent jurisprudence; on the kinds of changes that would have to be made to give them the right mix of expertise; and most important, on how to assure that they maintain a broad view of the factors that promote innovation, do not become subject to capture, and act in accordance with recognized standards of procedural and substantive fairness.¹⁶

Given these developments at the national and regional stage, the time is ripe to consider whether patents and other intellectual property should also be regulated in this manner at the international level—by a specialized body capable of tracking developing technologies, recognizing emerging problems, and marshalling economic, scientific, and legal expertise. Expertise at the global stage would not only enhance the flexibility member states enjoy; it could also provide them with guidance on how to structure their domestic regimes. Two candidates recommend themselves as potential regulators. One is the World Intellectual Property

¹¹ See e.g., id.; National Research Council *A Patent System for the 21st Century* (2004) The National Academies (Washington D.C.); Federal Trade Comm'n *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy* (2003).

¹² See, for example, 60 Fed. Register 36263 (July 14, 1995)(utility guidelines); 71 Fed. Reg. 48 (Jan. 3, 2006)(continuation rules). There is, however, considerable doubt that the US PTO has authority to engage in substantive rulemaking, see *In re Fisher* 2005 (421) F.3d 1365 (Fed. Cir.)(agreeing, but not deferring to, utility guidelines); *Tafas v Dudas* 2007 (511) F. Supp. 2d 652 (E.D. Va.) (preliminarily enjoining continuations rules on the ground that there is substantial likelihood that their promulgation exceeded the US PTO's authority).

¹³ The EPO administers the European Patent Convention (EPC). The EPC is not related to the European Communities, although all of the members of the European Union are members of the EPC.

¹⁴ See, for example, EPO Conference on the Patentability of Biotechnology, available at <http://www.epo.org/about-us/events/biotechnology.html>; European Patent Office (EPO) *Scenarios for the Future—How Might IP Regimes Evolve by 2025? What Global Legitimacy Might Such Regimes Have?* (2007) [hereinafter *Scenarios*] available at <http://www.epo.org/focus/patent-system/scenarios-for-the-future/forum.html>.

¹⁵ See, for example, the Website of the Trilateral Cooperation, <http://www.trilateral.net/>. See generally, J G Mills III 'A Transnational Patent Convention for the Acquisition and Enforcement of International Patent Rights' (2006) 88 *J. Pat. & Trademark Off. Soc'y* 958. See also P Drahos *Trust Me: Patent Offices in Developing Countries* (2007) available at <http://ssrn.com/abstract=1028676> (noting the influence of the trilaterals on other nations' patent offices and suggesting that patent offices are playing increasingly important roles in negotiating certain treaties).

¹⁶ See, for example, C Allen Nard & J F Duffy 'Rethinking Patent Law's Uniformity Principle' (2007) 101 *Nw. U. L. Rev.* 1619; A K Rai 'Engaging Facts and Policy: A Multi-Institutional Approach to Patent System Reform' (2003) 103 *Colum. L. Rev.* 1035.

Organization (WIPO). WIPO administers the patent, trademark, and copyright conventions on which the TRIPS Agreement is based and it provides support to the WTO and its members.¹⁷ The other is the Council for TRIPS, which is charged with monitoring the operation of the Agreement.¹⁸ Among other things, the Council was entrusted in the Doha Round with finding a solution to the essential medicines problem.¹⁹

Delegating authority to either of these “agencies” raises many questions. The consensus rulemaking of the WTO, while ineffectual at keeping law current, does assure that its actions are aligned with the interests of its members; a move to agency rulemaking would need to be accompanied by procedures that protect the sovereign interests of the parties. Furthermore, while the confluence of interests in the North and the South suggests that the interest in flexible intellectual property laws are well- represented in these fora, both WIPO and the TRIPS Council have been criticized for a lack of transparency and participation.²⁰ Thus, as with national systems, the institutional design must also include assurances of good administrative practice—that the agency has the requisite expertise, is open to input from all relevant stakeholders, reaches reasoned decisions, and is free of corruption.²¹ Given the multiplicity and overlapping interests of intergovernmental organizations, new rules will also be needed to allocate jurisdiction both horizontally (between agencies) and vertically (between agencies and members) and to protect these lawmaking authorities from opportunistic practices, particularly forum shopping.

Using patent law as its focus, Part I provides an overview of the problems confronting producers and utilizers of protected materials and demonstrates that the debates over international intellectual property protection should not be viewed simply as a fight between the North and the South—that in fact, there are many commonalities between the interests of developed and developing countries. This part then moves on to examine the ways that the WTO system currently permits nations across the development spectrum to accommodate their interests. Part II assesses the relative advantages of channeling lawmaking to WIPO or residing greater authority in the TRIPS Council. Part III concludes with the lessons that the intellectual

¹⁷ See, for example, Articles 63.2 & 68 of TRIPS Agreement; Agreement Between the World Intellectual Property Organization and the World Trade Organization (December 22, 1995), available at http://www.wipo.int/treaties/en/agreement/pdf/trtdocs_wo030.pdf. WIPO administers the Paris Convention for Protection of Industrial Property, Mar. 20 1883, 21 U.S.T. 1583 (last revised, July 14, 1967) [hereinafter the Paris Convention], which is partially incorporated into TRIPS by virtue of TRIPS, art. 2.1, and the Berne Convention for the Protection of Literary and Artistic Works, Sept. 9, 1886, as revised at Paris on July 24, 1971, and amended in 1979, S. Treaty Doc. No. 99-27, 1161 U.N.T.S. 3 [hereinafter Berne Convention], which TRIPS partly incorporates in art. 9. It also administers 22 other instruments related to intellectual property, including the Madrid System for the International Registration of Marks and the Patent Cooperation Treaty, see <http://www.wipo.int/treaties/en/>.

¹⁸ Article 68 of TRIPS.

¹⁹ Declaration on the TRIPS agreement and public health (n 4) ¶ 6.

²⁰ In addition, WIPO has recently had a brush with corruption, see, for example, Bridges, WIPO General Assembly Ends in Disarray, Amidst Divisions Over Leadership, 10 Oct. 2007, available at <http://www.ictsd.org/weekly/07-10-10/story2.htm>; Intellectual Property Watch, Idris’s Age Corrected At WIPO Amidst Speculation Of Benefit-Seeking, 13 July 2006, available at <http://www.ip-watch.org/weblog/index.php?p=362>. Idris has since resigned as Director General of WIPO, see IP Organization Unveils Proceedings To Nominate Replacement Director-General (2007) 75 *Pat. Trademark & Copyright J.* 117.

²¹ For a full description of the constellation of relevant concerns, see B Kingsbury, N Krisch & RB Stewart ‘The Emergence of Global Administrative Law’ (2005) 68 *Law and Contemporary Problems* 15.

property story teaches about global governance and the need for international administrative norms.

I. Patents, the Political Economy, and TRIPS

Although much of the critique of the TRIPS Agreement focuses on its differential impact on developing countries, it is becoming increasingly clear that the enforceable obligations that it imposes have negative effects in the developed world as well. Although the problems are hardly comparable in terms of their magnitude and impact on human welfare, the alignments and cross linkages among interests at both ends of the development spectrum are nonetheless worth exploring. They demonstrate where modifications in the international regulation of intellectual property are needed, point to the forces that can be harnessed to effectuate change, and suggest how the international intellectual property system might be reconfigured.

A. TRIPS and developing economies

The problems that developing countries are experiencing with TRIPS are well recognized. As with the WTO as a whole, one set of problems centers on voice—on the difficulty that countries with fewer resources and poorer markets encounter when they seek to participate in international trade negotiations, and on the failure of the negotiators to take account of their perceptions, traditions, and experience. Thus, during the TRIPS drafting process, compromises were made to assuage strong concerns by the South about the value of intellectual property protection to their economies. The TRIPS Agreement begins with statements about “Objectives” and “Principles,” which acknowledge the goal of “promoting technological innovation ... to the mutual advantage of producers and users”²² and an understanding that members can modify their laws to “promote the public interest in sectors of vital importance.”²³ In addition, the Agreement includes its vaunted “flexibilities,” along with transition provisions and promises of technical assistance and technology transfer.²⁴ Furthermore, representations were made that TRIPS would act, at least in certain respects, as a ceiling to demands by the North—that TRIPS would, in effect, replace the unilateral trade sanctions previously used by the United States to “encourage” countries to strongly protect intellectual property within their borders.²⁵

In reality, however, these assurances have come to very little. The transition provisions, which were meant to be temporary, turned out to be far too short.²⁶ Of the provisions that were

²² Article 7 of TRIPS.

²³ Article 8 of TRIPS.

²⁴ Articles 65-67 of TRIPS. See generally J H Reichman ‘Universal Minimum Standards of Intellectual Property Protection Under the TRIPS Component of the WTO Agreement’ (1995) 29 *Int'l Law*. 345.

²⁵ See D Gervais *The TRIPS Agreement: Drafting History and Analysis* 2 ed (2003) Sweet & Maxwell 12-26. Cf. J P Trachtman ‘The Constitutions of the WTO’ (2006) 17 *Eur. J. Int'l L.* 623, 633 (noting that the United States agreed to give up unilateralism under § 301 of its Trade Act in exchange for a stronger dispute settlement system). See also A Lowenfeld *International Economic Law* 2 ed (2007) Oxford University Press § 8.8; J Croome *Reshaping the World Trade System: A History of the Uruguay Round* (1999) Kluwer Law Int'l 113.

²⁶ In some cases, the transition provisions were extended, see, for example, Decision by the Council for TRIPS of 27 June 2002, Extension of the Transition Period under Article 66.1 of the TRIPS Agreement for Least-Developed Country Members for Certain Obligations with respect to Pharmaceutical Products, WT/IP/C/25 (1 July 2002);

intended to be permanent, many are proving illusory.²⁷ And as the essentials medicine debate showed, TRIPS was crafted without sufficient understanding of the challenges developing countries face. Thus, while the negotiators recognized that there would be occasions when compulsory licensing would be necessary, the essential medicines crisis arose, in part, because they overlooked the possibility that some countries would have such inadequate manufacturing capacity, they would not be able to satisfy their own needs. Accordingly, the Agreement permitted members to authorize compulsory licenses, but only when the goal was “predominantly for the supply of the domestic market of the Member authorizing [the] use.”²⁸

To a great extent, however, the problems that developing countries have with the TRIPS are very much ones of substance. For patents, the TRIPS Agreement is beneficial only to countries that can either invent at world levels—and therefore enjoy the benefits that derive from encouraging innovation—or make enough use of the marketing opportunities created by the other WTO agreements to compensate for the tax that patents impose on local consumption. For truly under-developed economies, neither of these conditions is met. For these, the requirements in the Agreement largely serve to extract wealth from local populations and, to the extent that patents cover educational inputs, to make it more expensive for inhabitants to learn enough to advance to the technological frontier.²⁹ To be sure, there are some nations that were on the cusp of becoming inventive at the time TRIPS entered into force; TRIPS incentives may well be helping to turn these countries into innovative forces.³⁰ But even for these economies, there is substantial question whether TRIPS’ requirements are flexible enough to permit incipient creativity to fully flourish.³¹

To make matters worse, the costs associated with patenting are largely uncontrolled. Prior to TRIPS, many countries did not have a tradition of protecting knowledge products, and thus had no occasion to develop rules to safeguard the public interest. Since many continue to lack competition laws, patent holders can often wield more power in poor countries than they are

Decision of the Council for TRIPS of 29 November 2005, Extension of the Transition Period under Article 66.1 for Least-Developed Country Members, WT/IP/C/40 (30 November 2005).

²⁷ As discussed in the text at notes 42, 75 & 127, *infra*, the language on Objectives and Principles is considered merely precatory and technical assistance has tended to be self-serving. See generally M P Pugatch *The International Political Economy of Intellectual Property Rights* (2004) Edward Elgar 138-40. The United States continues (apparently consistent with United States-Sections 301-310 of the Trade Act of 1974, WT/DS152/R (22 December 1999)), to put countries it believes to be violating its intellectual property interests on watch lists and has also begun to use bilateral agreements to achieve “TRIPS-plus” concessions. There has been little in the way of technology transfer, see *Report of the UK Commission on Intellectual Property Rights* (2002) [hereinafter CIPR Report] available at http://www.iprcommission.org/graphic/documents/final_report.htm at 28-30. See generally F M Abbott ‘Intellectual Property Rights in a Global Trade Framework: IP Trends in Developing Countries’ (2004) 98 *Am. Soc’y Int’l L. Proc.* 95; G C Shaffer *The Public and the Private in International Trade Litigation* (2002) available at <http://ssrn.com/abstract=531183> at 50-54.

²⁸ Article 31(f) of TRIPS. See Abbott and Reichman (n 4).

²⁹ See generally, J H Reichman & R C Dreyfuss ‘Harmonization Without Consensus: Critical Reflections on Drafting a Substantive Patent Law Treaty’ (2007) 57 *Duke L.J.* 85 ; cf. M Chon ‘Intellectual Property and the Development Divide’ (2006) 27 *Cardozo L. Rev.* 2821 (discussing the education problem posed by copyrighted materials).

³⁰ See, e.g., J M Mueller ‘The Tiger Awakens: the Tumultuous Transformation of India’s Patent System and the Rise of Indian Pharmaceutical Innovation’ (2007) 68 *Pitt. L. Rev.* 491; D Gervais ‘TRIPS and Development’ in D Gervais *Intellectual Property, Trade and Development* (2007) Oxford University Press 3 & 36-40.

³¹ For further discussion, see text at note 53, *infra*.

permitted to exercise in rich ones. Supporting a patent system is also expensive: countries are required to establish and maintain examination offices—and must use some of their best trained scientists to staff them.³²

B. TRIPS in developed countries

Somewhat surprisingly, countries that are net information exporters are also finding that the over-all impact of the TRIPS Agreement is suboptimal. Of course, many current patent holders are thriving from the added revenue available from WTO-wide protection. However, the dynamics of information production are changing in ways that put pressure on the existing system and TRIPS makes revision difficult. Patent law was, after all, developed at the time of the Industrial Revolution, when fundamental science was perceived as very different from technological application, when patents covered end products that were generally free-standing, and when products were usually associated with only one (or a few) patents. In that environment, the law could distinguish between ideas (unpatentable) and their application (patentable) and the scope of patents could usually be readily defined. Inventors were protected from free-riding, but the system also fostered a rich public domain of scientific knowledge.³³

In the knowledge-based economy, the situation is very different. New scientific enterprises emerged and patent law grew to encompass them. In many of these fields, the old rules no longer protect the public interest effectively. In biotechnology and computer science, for example, science and technology have coalesced, so that a patent on a product will tend to cover the scientific advance that made the product possible.³⁴ If the scope of infringement is broad, then second-generation innovators cannot freely make further use of the underlying idea to push the knowledge frontier forward. Products in the information sector are often composed of many separately patented features and are meant to interoperate with advances that are also subject to multiple patent rights. With many patents required to make novel products and pursue new technological opportunities, transaction costs rise and the probability of hold outs increases.³⁵

In addition, the business of science is changing. Universities are aggressively pursuing patent protection for foundational advances that, in an earlier era, would have entered the public domain and furnished researchers with a base of inventive opportunities. The shift from curiosity- to business-driven research also affects the ethos within the innovation sector. Some academic researchers have gone into business for themselves, spinning off “boutiques” that look

³² Cf. Agreed Statements by the Diplomatic Conference Regarding the Patent Law Treaty and the Regulations under the Patent Law Treaty ¶ 4 (adopted by the Diplomatic Conference on June 1, 2000)(promising developing countries assistance in meeting their obligations under the PLT, which facilitates patent prosecution), available at <http://www.wipo.int/treaties/en/ip/plt/statements.html>.

³³ See generally, R Dreyfuss ‘Protecting the Public Domain of Science: Has the Time for an Experimental Use Defense Arrived?’ (2004) 46 *Ariz. L. Rev.* 457.

³⁴ Both products and processes can be patented; this article uses the term “product” to encompass both unless otherwise indicated.

³⁵ See, for example, National Research Council *Reaping the Benefits of Genomic and Proteomic Research: Intellectual Property Rights, Innovation, and Public Health* (2006); National Research Council (n 11); Federal Trade Comm’n (n 11); The Royal Society *Keeping Science Open: The Effects of Intellectual Property on the Conduct of Science* (2003) available at <http://www.royalsoc.ac.uk/displaypagedoc.asp?id=11403>.

to patents as a way to attract venture capital and joint venturers.³⁶ “Open” collaborative communities, built on sharing norms, are discouraged.³⁷ With fewer information exchanges and less tolerance for unauthorized experimentation, there is increasing risk that the pace of innovation will slow.³⁸ A vicious cycle can eventually take hold: when some participants in an industry acquire patent protection, others begin to patent defensively in order to acquire the bargaining chips they will need to settle lawsuits. With more patenting activity, new business models develop. So-called “trolls”—non-market participants—buy up patents and, free from the constraints of the market, use their positions to threaten ongoing businesses. The explosion in patenting puts pressure on even well-financed national patent offices, leading to patents on developments that should have been freely available. These low-quality patents further increase transaction costs, create barriers to entry, and breed even more need for patent protection.³⁹ With higher costs, follow-on innovation is discouraged.

C. Achieving balance

While it may initially appear that countries at different ends of the development spectrum experience TRIPS in radically different ways, there is, in fact, a great deal of commonality. In both cases, the Agreement’s focus on commodification—on providing a return for initial innovators—ignores the real goal: improving social welfare. Instead of providing assurances that inventions will be optimally utilized, the Agreement fosters deadweight loss—for some countries, in the form of foregone consumption and for others, in the form of lost opportunities for follow-on production. Furthermore, the ways to revise patent law to mitigate these problems are quite similar: places where patenting is particularly dysfunctional could be excluded from protection (medicines in the South; fundamental discoveries in the North); new privileges could be recognized (compulsory licensing in the South, experimental usages in the North), and remedies could be altered (replacing injunctive relief with damages would reduce market manipulation in both the South and the North). Finally, striking a new balance in any of these (or other) ways is proving equally difficult for both the South and the North, and at both the national and international levels.

1. National stage

In some ways, developing countries are in a good position to maintain laws that are responsive to the needs of both information producers and users. For many, TRIPS was a hard sell to begin with and TRIPS skeptics still tend to outstrip its supporters. Thus, there is

³⁶ See, for example, C Long ‘Patent Signals’ (2002) 69 *U. Chi. L. Rev.* 625.

³⁷ See, for example, A K Rai ‘Regulating Scientific Research: Intellectual Property Rights and the Norms of Science’ (1999) 94 *Nw. U. L. Rev.* 77. K J Strandburg ‘Curiosity-Driven Research and University Technology Transfer’ (2005) 16 *Advances in the Study of Entrepreneurship, Innovation, and Econ. Growth* 97 (noting changing pressures in academia).

³⁸ See, for example, J P Walsh, C Cho & W M Cohen ‘Patents, Material Transfers and Access to Research Inputs in Biomedical Research’ in *Final Report to the National Academy of Sciences Committee Intellectual Property Rights in Genomic and Protein-Related Inventions* (2005) National Academies of Science (finding a declining willingness to transfer materials); J P Walsh, A Arora & W M Cohen ‘Effects of Research Tool Patents and Licensing on Biomedical Innovation in Patents in the Knowledge-based Economy’ in W M Cohen & S A Merrill *Patents in the Knowledge-Based Economy* (2003) The National Academies Press (Washington D.C.).

³⁹ See JAFFE & LERNER (n 10).

considerable political will to respond to local needs by adopting the lowest level of protectionism⁴⁰ that TRIPS allows. Working through the TRIPS flexibilities is not, however, an easy task. Countries, such as India, that were at the cusp of development at the time of the Uruguay Round, may be in a good position to accomplish it,⁴¹ but many WTO members lack the incentive to put intellectual property lawmaking at the top of their legislative agendas. For those new to an intellectual property regime, there may also be inadequate legal infrastructure to accomplish the task effectively. To be sure, TRIPS promised developing countries technical assistance.⁴² But some countries have complained that what they mainly receive is advice to adopt the same laws found in the country providing the help.⁴³

In developed countries, the situation is somewhat reversed. Legal talent is readily available and there is adequate legislative interest; however, the political economy is vastly more complicated. Traditionally, intellectual property users have been badly organized and, relative to rights holders, poorly financed.⁴⁴ Technology producers are in an almost equally bad position to institute needed legal revisions. The impact of change is far from uniform across fields.⁴⁵ Accordingly, while some sectors (e.g. information technology) feel strongly that patent reform is necessary, others (the pharmaceutical industry) rigorously defend the current system. Although a mixed system is the obvious solution, TRIPS includes a ban on discrimination by field of technology,⁴⁶ and high protectionists claim that any deviation from a “one size fits all” patent system would violate that provision.⁴⁷ Even at the theoretical level, there is sharp disagreement. For example, the EPO recently published a report projecting future developments in the patent industries. It came in the form of four Scenarios that reflect the uncertainty in how recent trends will play out and disagreement about what legal actions are needed to ameliorate the problems that are likely to emerge.⁴⁸

The United States has also experienced a problem that other democracies may well encounter. Intellectual property legislation tends to proceed through a series of compromises. In a challenge (if one is possible at all), domestic courts will tend to review the resulting legislation

⁴⁰ One of the many clashes between trade and intellectual property is the use of the term “protectionism.” In trade talk, protectionism is bad—the idea is to roll back barriers by reducing protectionist measures. However, to TRIPS negotiators, intellectual property protection is good because it commodifies information and makes it tradeable. In this article “protectionism” is used in the intellectual property sense of the term.

⁴¹ See, for example, P Drahos *An Alternative Framework for the Global Regulation of Intellectual Property Rights* (2005) 10-13 (forthcoming, Austrian Journal of Development Studies), available at <http://cgkd.anu.edu.au/menus/PDFs/DrahosAustrian%20JDS%20-%20Alternative%20IPv2.pdf> (noting India’s long experience shaping intellectual property law to suit its domestic needs).

⁴² Article 67 of TRIPS.

⁴³ D J Halbert ‘The World Intellectual Property Organization: Past, Present and Future’ (2007) 54 *J. Copyright Soc’y USA* 253 at 263-64; G Shaffer ‘Can WTO Technical Assistance and Capacity Building Serve Developing Countries?’ (2005) 23 *Wis. Int’l L.J.* 643 at 646.

⁴⁴ Cf. Barfield (n 2) 73-77 (suggesting that major US corporations exert significant influence on trade negotiators). Attempts are, however, being made to better organize user groups, see, for example, J Boyle ‘The Second Enclosure Movement and the Construction of the Public Domain’ (2003) 66 *Law & Contemp. Probs.* 33.

⁴⁵ See, for example, J R Allison & M A Lemley ‘The Growing Complexity of the United States Patent System’ (2002) 82 *B.U. L. Rev.* 77.

⁴⁶ TRIPS, art. 27.

⁴⁷ See, for example, B Kahin ‘Patents and Diversity in Innovation’ (2007) 13 *Mich. Telecomm. Tech. L. Rev.* 389 at 392 (2007).

⁴⁸ EPO Scenarios (n 14).

on a deferential standard. In the WTO, however, impingements on exclusive rights receive fairly strict scrutiny. Because of the dichotomous standard of review, deals are vulnerable to unraveling—always in the direction of stronger protection. For example, in 1998 US copyright holders succeeded in extending the term of copyright protection, but at the same time, relinquished the right to control musical performances in certain settings (the so-called “Irish bar” exemption, named after one of the locations covered by the measure). Both parts of the legislation were challenged: term extension went to the Supreme Court, which upheld the statute, while a WTO panel decided that the Irish bar exemption violated the TRIPS Agreement.⁴⁹ Were the United States to comply with the panel report, the effect would be to increase the level of protection and upset the legislatively-set balance between right holders and the public.

2. International stage

To some extent, the problems encountered at the national stage might be solved at the international level. Indeed, the WTO system has been described as democracy-enhancing because it operates as a pre-commitment strategy that reduces rent seeking by powerful interest groups.⁵⁰ In the context of TRIPS, the argument is that by reducing the force of short-term concerns about the availability of intellectual goods for both consumption and production, the Agreement allows members to capture the long-term benefits of fostering the discovery of new knowledge.⁵¹

If there is anything to this argument, then one way to overcome legal infrastructure deficits in the South and political economy problems in the North would be to revise the TRIPS Agreement to better reflect the need for balance and to impose balancing obligations (or obligations that achieve balance) on member states. At the very least, the DSU could be producing interpretations of the Agreement that lay out the normative options and clarify the scope of existing flexibilities. Armed with a better understanding of permissible alternatives, reformers would have an easier time in the domestic arena.

a. Revision of TRIPS

Somewhat paradoxically, it is likely that the problems of developing countries are more amenable to accommodation through TRIPS revision than are the difficulties encountered in developed countries. One development issue—access to essential medicines—is well understood and has attracted both attention and sympathy. Although it took rather longer than expected, the TRIPS Agreement is being amended to permit nations that lack manufacturing capacity to look elsewhere for the products they need.⁵² This is not to say that in the patent area, all development problems have been solved. Medicines are not the only patented products where access is an issue and copyrighted goods can raise equally strong concerns. Moreover, as India

⁴⁹ See *Eldred v Ashcroft* 2003 (537) U.S. 186; *Panel Report United States - Section 110(5) of the US Copyright Act* (15 June 2000) WT/DS160/R [hereinafter *US-110(5)*]. See generally, G B Dinwoodie & R C Dreyfuss ‘TRIPS and the Dynamics of International Property Lawmaking’ (2004) 36 *Case W. Res. J. Int’l L.* 95.

⁵⁰ See, for example, J O McGinnis & M L Movsesian ‘The World Trade Constitution’ (2000) 114 *Harv. L. Rev.* 511.

⁵¹ Cf. Esty (n 2) 1502 (suggesting that global-scale policymaking reduces the “all-or-nothing nature of national politics.”)

⁵² See Doha Declaration and Declaration on the TRIPS agreement and public health (n 4).

is demonstrating, the road to technological capability passes through a stage of “fair following,” where skills are learned by adapting the work of others.⁵³ To accommodate that kind of activity, nations must be permitted to set the scope of infringement liability low enough to allow adaptation or the standard of patentability high enough to put some inventions that are commercially worth fair-following into the public domain. Alternatively, they need authority to award compulsory licenses to local industry.

Developing nations appear to have some capacity to instigate these sorts of changes. Individually, they may have less leverage in international intellectual property negotiations than developed countries, but their clear preferences for low levels of protection allow them to take unified positions. In WIPO, for example, they succeeded in diminishing the protectionist bite of various intellectual property instruments and in promoting a development agenda.⁵⁴ Indeed, as Susan Sell tells it, one reason international intellectual property lawmaking shifted from its traditional home at WIPO to the GATT negotiations (and then to the WTO) was because attempts to raise the level of international protection in WIPO had, essentially, stalled.⁵⁵ At the WTO, however, consensus decisionmaking allows each side to veto the other’s initiatives.

Refashioning TRIPS to accommodate the new needs of developed countries is likely to prove even more difficult. Those who are interested in revising the terms of protection must contend with the same highly organized and well-heeled rent seeking forces that pushed intellectual property negotiations to the WTO. Furthermore, governments in the North have reasons of their own to prefer strong worldwide protection: intellectual property exports bring in revenue, furnish a basis for income taxation, and offset trade deficits. For example, knowledge goods is a key contributor to the U.S. balance of trade.⁵⁶

⁵³ “Fair following” refers to utilization of prior advances in ways that do not entail free riding, and which therefore do not threaten incentives to innovate. See generally J H Reichman ‘From Free Riders to Fair Followers: Global Competition under the TRIPS Agreement’ (1997) 29 *N.Y.U. J. Int’l L. & Pol.* 11; Drahos (n 41) (emphasizing the importance of giving nations the “freedom to design” intellectual property law consistent with their interests). See also Dreyfuss & Lowenfeld (n 5); CIPR Report (n 27) 26-30 (suggesting the importance of imitation to developing economies).

⁵⁴ See, for example, P Samuelson ‘The U.S. Digital Agenda at WIPO’ (1997) 37 *Va. J. Int’l L.* 369 at 389-90. The 1971 Appendix to the Paris Act Revision of the Berne Convention (also known as the Berne Appendix) is an example of international lawmaking specifically directed at problems of development. The development agenda is discussed *infra*, text at notes 112-119.

⁵⁵ S K Sell *Private Power, Public Law: The Globalization of Intellectual Property Rights* (2003) Cambridge University Press 181; L R Helfer ‘Regime Shifting: The TRIPS Agreement and New Dynamics of International Intellectual Property Lawmaking’ (2004) 29 *Yale J. Int’l L.* 1 at 20-22.

⁵⁶ See, for example, C L Mann *Accelerating the Globalization of America* (2006) Peterson Institute 176; Statement by Brad Smith (Microsoft) to Senate Foreign Relations Committee re: software piracy (April 29, 1999), available at <http://library.law.columbia.edu/urlmirror/CVLAJLA/24CVLAJLA47/19990429bs.htm>. See also P McCalman ‘Reaping What You Sow: An Empirical Analysis of International Patent Harmonization’ (2001) 55 *J. Int’l Econ.* 161 (showing that the US, Germany, France, Italy, Sweden, and Switzerland are the only beneficiaries of the TRIPS Agreement and that significant losers include Canada, Brazil, UK, India, Mexico, Japan, Spain, and Korea), available at http://www.sciencedirect.com/science?_ob=ArticleURL&_udi=B6V6D-43F70T3-8&_user=30681&_coverDate=10%2F31%2F2001&_rdoc=1&_fmt=full&_orig=na&_cdi=5812&_docanchor=&_acct=C000000333&_version=1&_urlVersion=0&_userid=30681&md5=3055d43b997a8827179a8fd862d103f6&artImpPref=F. See also CIPR Report (n 27) 24 (“Between 1991 and 2001, the net US surplus of royalties and fees (which mainly relate to IP transactions) increased from \$14 billion to over \$22 billion.”).

Even if developed countries were to recognize that the problems they are experiencing in fostering creative production require amendment of the TRIPS Agreement, it would be difficult to implement the insight. True, the technological neutrality principle, which is complicating domestic negotiations in the newly-complex patent sector, could be modified. However, the critical problem for developed economies is the Agreement's failure to balance the interests of the first generation of producers against those of follow-on creators. Rectifying this problem would require the addition of "substantive maxima" or "user rights" that would prevent members from raising the level of protection to the point where it threatens robust creative development.⁵⁷ But much as such a system would add a pleasing symmetry to the Agreement, a working group at the Max Planck Institute has identified a key structural problem. TRIPS is formulated to safeguard the interests of foreign traders; it does not protect domestic consumers and creative users from their own governments. Thus, while user rights might be useful *indirectly* to inform the scope of members' flexibilities,⁵⁸ they could not be enforced *directly*.⁵⁹

b. Interpretive guidance through the DSU

Given the remote prospect of TRIPS revision, a more likely vehicle for accommodating emerging concerns is through dispute settlement. If DSU panels and the Appellate Body were to clarify the choices available through the TRIPS flexibilities, members would understand their options. For countries where legal advice is deficient, a roadmap would be highly desirable. In countries with complex political economies, clarification might simplify the political debate. It would make it clear where TRIPS roadblocks lie, eliminate rhetorical appeals to supposed TRIPS prohibitions, and provide some assurance that political compromises will not unravel.⁶⁰

In fact, the TRIPS Agreement would appear to leave members in both the South and the North with sufficient room to respond to domestic concerns. As noted earlier, the Objectives and Principles that introduce TRIPS obligations explicitly acknowledge the trade-offs inherent in

⁵⁷ See G B Dinwoodie 'The International Intellectual Property Law System: New Actors, New Institutions, New Sources' (2004) 8 *Am. Soc'y Int'l L. Proc.* 213 at 219; R C Dreyfuss 'TRIPS—Round II: Should Users Strike Back?' (2004) 71 *U. Chi. L. Rev.* 21.

⁵⁸ For an example of indirect enforcement, see, for example, text at note 77, *infra*.

⁵⁹ M Levin & A Kur *Special Session at the Annual Meeting of the International Association for the Advancement of Teaching and Research in Intellectual Property: Towards More Balanced, User-Friendly Paradigms in IP Law: A Project Reform of TRIPS* (Sept. 5, 2006) (spearheading a proposal to amend the TRIPS Agreement). To see the problem, consider, for example an amendment to the Agreement requiring members to recognize an experimental use defense permitting universities to conduct research on patented materials without authorization. Xandia (a WTO member) refuses to enact such a provision and Xandian research universities are successfully sued for infringement. What would be their remedy? TRIPS is not generally interpreted as self-executing, see, for example, TRIPS, art. 1 ("Members shall give effect to the provisions of this Agreement"). Since the universities' quarrel is with Xandia, there is nothing in the DSU portion of the WTO Agreement that provides it with recourse. Other nations may complain that they are deprived of the fruits of the Xandian research. While a slowdown in world-wide innovation is certainly a global concern, it would likely be considered too speculative (or insufficiently related to trade) to furnish the basis for a complaint in the WTO.

Of course, the DSU could be amended to allow non-government entities in WTO countries to bring challenges. However, scholars who have studied the idea tend to reject it, in part because it would exacerbate the asymmetry between the lawmaking capacity of the dispute settlement procedure and the legislative capacity of the WTO, see Barfield (n 2) 108-110; R O Keohane, A Moravcsik & A Slaughter 'Legalized Dispute Resolution: Interstate and Transnational' (2000) 54 *Int'l Organization* 457.

⁶⁰ Cf. Drahos (n 41) 20 (suggesting the development of "best practices" to guide national courts and legislatures).

protecting intellectual property.⁶¹ For example, the patent provisions in the Agreement include a host of flexibilities. The size of the inventive step is not set;⁶² presumably countries (such as India) with an interest in fair following can define the step to be quite high. Similarly, the Agreement does not specify what it means by “making, using, offering for sale, selling or importing,”⁶³ which should give nations some leeway in defining the scope of infringement. Members can also exclude from patentability specific classes of inventions,⁶⁴ as well as any advance that is needed to protect public order or morality.⁶⁵ Under highly specified circumstances, including blocking patent problems, members can permit unauthorized (but usually, compensated) uses.⁶⁶ And most important, a three-part “exceptions” provision permits members to enact (1) “limited” exemptions so long as they (2) “do not unreasonably conflict with a normal exploitation,” and (3) “do not unreasonably prejudice the legitimate interest of the patent owner, taking account of the legitimate interests of third parties.”⁶⁷

Unfortunately, however, the prospects for jurisprudential development do not appear encouraging. Graeme Dinwoodie and I studied the six intellectual property disputes that have been taken as far as a panel decision (half ultimately resolved by the Appellate Body)⁶⁸ and we found little sensitivity to the need for balance, for law that reflects the dynamics of intellectual production, or for the demands of the political process in which national lawmaking proceeds.⁶⁹

The three panel reports interpreting the “exceptions” tests are by far the most troubling. These include *US-110(5)*, the above-mentioned “Irish bar” case, which interpreted the copyright analogue to the three-part patent provision; *Canada-Pharmaceuticals*, which applied the patent test to a Canadian law permitting generic drug manufacturers to test drugs for regulatory review purposes and to stockpile inventory prior to patent expiration; and *EC-GI*, which applied a somewhat different trademark “exceptions” test to an EC law recognizing geographic indications (GIs) that impinge on trademark exclusivity. Of the three challenged statutes, only the EC’s was found fully compliant with the restrictions in an exceptions provision. In the other two cases, the panels appeared to see the issues through the lens that TRIPS creates—as purely a problem of commodification.

⁶¹ Articles 7-8 of TRIPS.

⁶² Article 27.1 of TRIPS.

⁶³ Article 28 of TRIPS.

⁶⁴ Article 27.3 of TRIPS (these include surgical and diagnostic methods, and certain plants and animals).

⁶⁵ Article 27.2 of TRIPS.

⁶⁶ Articles 31 & 31(l) of TRIPS.

⁶⁷ Article 30 of TRIPS.

⁶⁸ The six are India—Patent Protection for Pharmaceutical and Agricultural Chemical Products, WT/DS50/AB/R (5 September 1997) [hereinafter *India-Pharmaceuticals*] (ultimately decided by the Appellate Body); Canada—Term of Patent Protection, WT/DS170/AB/R (18 September 2000) (Appellate Body); Canada—Patent Protection of Pharmaceutical Products, WT/DS114/R (17 March 2000) [hereinafter *Canada-Pharmaceuticals*] (panel decision); *US-100(5)* (n 49) (panel decision); United States—Section 211 Omnibus Appropriations Act of 1998, WT/DS176/AB/R (6 August 2001) [hereinafter *Havana Club*] (Appellate Body); European Communities--Protection of Trademarks and Geographic Indication for Agricultural Products and Foodstuffs, WT/DS174/R (15 March 2005) [hereinafter *EC-GI*] (panel decision). Technically, there were seven disputes as both the United States and the European Communities brought an *India-Pharmaceuticals* challenge.

⁶⁹ Dinwoodie & Dreyfuss (n 8 & 49); G B Dinwoodie & R C Dreyfuss ‘Diversifying Without Discriminating: Complying with the Mandates of the TRIPS Agreement’ (2007) 13 *Mich. Telecomm’n & Tech’y L. Rev.* 445.

To start, the panels essentially decided that the reasons underlying the challenged legislation are of little relevance. On the copyright side, the three-part test refers to “special cases,” which suggests that a member could defend its action with a compelling justification. But the *US-110(5)* panel did not see things that way: it held that “special” means “clearly defined.”⁷⁰ Under that view, even the US fair use defense,⁷¹ which has strong constitutional underpinnings, may not be defensible: free speech may feel special to the United States, but it is hardly clearly defined. For patents and trademarks, the situation may appear somewhat better because the exceptions tests make express reference to the interests of third parties—presumably, in the case of patents, these would include user groups such as patients interested in therapeutic use of medical inventions and research scientists interested in experimentation involving patented inventions.⁷² The panels, however, held that the individual parts of the test were to be considered cumulatively.⁷³ For patents, this means that if a measure runs afoul of part (1) (“limited” exemption) or part (2) (“unreasonably conflict with normal exploitation”), the user-based justification will never come into play. In *Canada-Pharmaceuticals*, for example, the panel did not reach the question whether patients would benefit from the stockpiling exemption. Rather, it held the provision, which permitted stockpiling for only the last six months of the patent term, was nonetheless not “limited” because during that time, three of the five exclusive rights associated with a patent were affected.

Admittedly, this interpretation of the exceptions tests would not be critical if adjudicators looked at the concepts “limited,” “normal exploitation,” “legitimate interest,” and “unreasonable prejudice” in a nuanced way. After all, these terms appear to lend themselves to normative interpretation. Adjudicators could construe them in light of the core WTO goal of maintaining an international trading system for intellectual products or in view of the stated objectives of the TRIPS Agreement.⁷⁴ But the panels have not been willing to venture beyond the literal wording of the tests. Indeed, the *Canada-Pharmaceuticals* panel was wary of considering the Objectives of the Agreement, arguing that it amounted to renegotiating TRIPS’ “basic balance.”⁷⁵

Mostly, the panels interpreted the terms by counting the number of rights within the patent or copyright bundle affected by the challenged provision, by considering the number of situations where the exception was applicable, and by examining potential economic losses. Every right received equal weight, no matter how small the impact on the right holders’ market; markets the right holder had never utilized were counted equivalently to those that it had. Monetary estimates were extremely generous.⁷⁶ On this approach, only two provisions passed muster. In *EC-GI*, where the trademark exceptions provision gave a specific example of an

⁷⁰ *US-110(5)*, ¶¶ 6.107-6.110.

⁷¹ Section 107 of 17 U.S.C.

⁷² *Canada-Pharmaceuticals*, ¶ 7.69.

⁷³ See, for example, *ibid* at ¶ 7.20.

⁷⁴ See, for example, J C Ginsburg ‘Toward Supranational Copyright Law? The WTO Panel Decision and the “Three Step Test” for Copyright Exemptions’ (2001) 187 *Revue Internationale du Droit d’Auteur* 17.

⁷⁵ *Canada-Pharmaceuticals*, ¶ 7.26.

⁷⁶ For example, the *US-110(5)* panel found that EC copyright holders could lose as much as \$53.65 million per year. When the United States failed to conform its law to the panel report, the case went to arbitration and the arbitral award was only €1,219,900 per year (this at a time when a dollar and a euro were close to parity), *Recourse to Arbitration Under Article 25 of the DSU, Award of the Arbitrators, United States – Section 110(5) of the US Copyright Act, 5.1, WT/DS160/ARB25/1* (11 November 2001).

acceptable exemption (“fair use of descriptive terms”), the panel found for the EC.⁷⁷ The Canadian law permitting generic drug testing for regulatory review purposes was upheld, largely because the effect of that exemption was to reduce the amount of lead time that patent holders would otherwise enjoy after patent expiration, and the panel considered lead-time exclusivity peripheral to the patent rights secured by TRIPS.⁷⁸

The rigorous review of these exemptions leaves nations with little room to accommodate their varied interests. The cumulative nature of the tests poses a high bar, hampering legal evolution. Safeguarding public interests will be difficult because it is the rare case where there is room to maneuver at the periphery of the patent right.⁷⁹ Developing countries cannot defend exemptions that intrude upon a substantial number of protected rights, no matter how little profit the right holder could hope to extract from their limited markets. Nor can they use the compelling nature of their justifications to offset intrusions into intellectual property prerogatives.

The patent case added yet another constraint on members’ freedom of action. As noted earlier, patents are also subject to a requirement of nondiscrimination by field of technology.⁸⁰ While it could be argued that a member enacting a technology-specific measure can rely on the exceptions provision to defend against a TRIPS challenge, the *Canada-Pharmaceuticals* panel treated nondiscrimination as structural, as an issue that is not subject to exceptions.⁸¹ In other words, it interpreted the provision—which is only found in the patent section of TRIPS—as equivalent of the commitments to most favored nation and national treatment, which infuse the entire WTO framework. This interpretation is especially problematical because a law that is broad enough to encompass all fields of technology is unlikely to simultaneously meet the “limited” requirement of the exceptions test. Accordingly, it may be difficult to devise patent regimes that solve complicated domestic economy issues or meet the needs of both traditional and emerging technologies.⁸²

The TRIPS cases are also troubling for things the TRIPS adjudicators did not do. They gave no consideration to the political dimension of the problem of complying with TRIPS. For example, members in transition were required to assure that pharmaceuticals invented after TRIPS went into force would be protected once compliant patent law was enacted.⁸³ To circumvent problems associated with adopting protectionist legislation in a low-protectionist climate, India fulfilled this obligation with an administrative (“municipal”), rather than a legislative, scheme. In *India-Pharmaceuticals*, however, that approach was successfully

⁷⁷ *EC-GI*, ¶ 7.654.

⁷⁸ *Canada-Pharmaceuticals*, ¶ 7.57 (“The additional period of market exclusivity in this situation is not a natural or normal consequence of enforcing patent rights.”).

⁷⁹ In this regard, there is irony in the *Canada-Pharmaceuticals* decision. While the panel failed to understand members’ need to accommodate future developments, it stressed the need of patent holders to alter their strategies to evolving market conditions, see ¶ 7.55 (“The specific forms of patent exploitation are not static, of course, for to be effective exploitation must adapt to changing forms of competition due to technological development and the evolution of marketing practices.”).

⁸⁰ Article 27.1

⁸¹ *Canada-Pharmaceuticals*, ¶¶ 7.88-7.93.

⁸² But see Dinwoodie & Dreyfuss (n 69) (arguing that differential treatment could be achieved by drafting law to treat specific problems rather than to apply to specific technologies).

⁸³ Article 70.8 of TRIPS (the so-called “mailbox” rule).

challenged. Although the Appellate Body acknowledged that members are permitted to choose their methods of compliance, it nonetheless retained the power to make the ultimate decision and held that India's method fell short.⁸⁴ As noted earlier, *US-110(5)* case displayed a similar disregard to the political compromise that enabled Congress to extend the copyright term.⁸⁵

The adjudicators were equally unwilling to consider the trade implications of the challenged legislation. Thus, while some of the challenged national measures could have undermined international trade in intellectual goods because they presented strong arbitrage possibilities, others were so purely consumptive, their threat to trade was minimal. Yet none of the reports drew this distinction. For example, because the drugs stockpiled in Canada could have been exported and affected pharmaceutical prices across the WTO, the *Canada-Pharmaceuticals* result makes sense as a matter of protecting the trading environment. In contrast, musical performances in US Irish bars are entirely consumptive and thus pose much less danger to trade. Certainly, they potentially reduce the rewards that EC right holders can expect in the US market and could therefore erode the comparative advantage that the EC enjoys in producing music; the EC was not wrong to challenge the US measure. But the *US-110(5)* panel failed to even note that the harm was confined to US territory. This omission suggests that the South could not enact laws that, say, permit translations of copyrighted materials into local dialects, and defend the legislation on the ground that it has minimal implications for international trade.

The adjudicators also failed to notice important differences between TRIPS and the rest of the WTO Agreement. In the GATT, members benefit from cushioning provisions that permit them to deal specially with issues of overarching national importance,⁸⁶ reduce trade concessions in certain circumstances,⁸⁷ and suspend obligations or withdraw concessions on a temporary basis.⁸⁸ Had adjudicators considered the inapplicability of these provisions to TRIPS, they might have taken a more generous view of the flexibilities that TRIPS does provide. Admittedly, the GATT measures have less significance now that the GATT portion of the Agreement is firmly established. But TRIPS is not established, at least not in developing countries. And as we have seen, the dynamic nature of intellectual property production means that its obligations will raise continuous problems even in developed economies.⁸⁹

As the locus of international intellectual property lawmaking, dispute settlement has other limitations. Despite its "legalization," there is still a diplomatic flavor to the proceedings that is somewhat inconsistent with the notion of expounding law. For example, aside from *India-*

⁸⁴ International relations are also not considered, see, for example, *Havana Club* (requiring the United States to extend national treatment to Cuban trademark holders).

⁸⁵ *Canada-Pharmaceuticals* had elements of this problem as well, see Dinwoodie & Dreyfuss (n 49).

⁸⁶ Article XX of GATT. See P Lamy 'The Place of the WTO and its Law in the International Legal Order' (2006) 17 *Eur. J. Int'l L.* 969, 978 (noting that art. XX permits nations to set aside market access regulations when "considerations other than those of trade must prevail").

⁸⁷ Article XXVII of GATT.

⁸⁸ Article XIX of GATT and its associated Agreement on Safeguards.

⁸⁹ Esty suggests that nations are cushioned because they can pay compensation in lieu of compliance, Esty (n 2) 1536. Indeed, the *US-110(5)* case ended in exactly this way, with the US paying the EC yearly to compensate for unauthorized performances. However, this approach works only for countries that have the means to pay. Thus, it tends to exacerbate tension among countries at different stages of development.

Pharmaceuticals, all of the intellectual property cases decided to date were, in a sense, a draw: the complainant won on one issue and the respondent won on another. To produce these outcomes, the reports took some fairly far-fetched positions. In *US-110(5)*, for example, the EC had also challenged an exemption on musical performances that pre-dated the Irish bar provision. That exemption was upheld on the ground that it was confined to performances of dramatic musical works (for example, opera).⁹⁰ Yet there is nothing in US copyright law suggesting this limitation; indeed, the provision was regarded in the United States as so open-ended, the Irish bar exemption was arguably added to provide the establishments it covers with a safe harbor. Similarly, at the same time that the *EC-GI* panel found the conflict between geographic indications and trademarks acceptable, it invalidated a part of the GI legislation on national treatment grounds; in order to decide for the EC on the trademark issue, it interpreted the scope of the GI right far more narrowly than EC lawmakers likely envisioned.⁹¹ Because diplomacy-oriented decisions are highly contingent on framing, they cannot offer domestic policymakers the kind of guidance they need.⁹²

DSU adjudication also suffers from a problem of participation. As Eyal Benvenisti has noted, WTO adjudicators have been diligent about developing administrative law that assures fair process.⁹³ In one way, the intellectual property cases are no exception. In *EC-GI*, the panel found that the EC violated its national treatment obligations because it did not provide a registration system for foreign geographic indications that is as easily utilized as the one set up for registering European indications. Similarly, in *Havana Club*, the Appellate Body acknowledged that *ownership* of trademarks was not covered by the TRIPS Agreement, yet it required the United States to furnish holders of Cuban marks with the same *procedural advantages* that other right holders enjoy.

At the same time, however, the cumulative effect of the DSU process is to truncate participation. In all of the cases decided to date with the exception of *India-Pharmaceuticals*, the respondent has been a developed country and the complainants were all developed countries. Developing countries (particularly members that are still in the transitional phase) have, in short, played a very limited role in developing TRIPS jurisprudence. Although the DSU permits nonparty members to make their views known,⁹⁴ and the Appellate Body famously permitted NGOs to file amicus briefs in *US-Shrimp-Turtle*,⁹⁵ the role of nonparties is highly circumscribed. Reduced participation by nations and entities with strong user-sympathies makes it more likely that decisionmakers will interpret the Agreement with right holders' interests at the fore. While DSU reports do not strictly speaking, have stare decisis effect,⁹⁶ they are regularly cited as

⁹⁰ *US-110(5)*, ¶ 2.8.

⁹¹ *EC-GI*, ¶ 7.659 (“the positive right to use the GI extends only to the linguistic versions that have been entered in the register and not to other names or signs which have not been registered.”).

⁹² A cynic might also wonder whether panels produce split reports to avoid appeals to the Appellate Body.

⁹³ E Benvenisti ‘The Interplay Between Actors as a Determinant of the Evolution of Administrative Law in International Institutions’ (2005) 68 *Law & Contemp. Probs.* 319 at 332.

⁹⁴ Articles 10 & 17.5 of DSU.

⁹⁵ *Report of the Appellate Body, United States—Import Prohibition on Certain Shrimp and Shrimp Turtle Products* (12 October 1998) WT/DS58/AB/R.

⁹⁶ Cf. Article 3.2 of DSU; Article IX Section 2 of WTO Agreement (noting that DSU cannot change obligations of the parties and only Ministerial Conference and General Council can render authoritative interpretations of the agreements).

precedent (which, indeed, is why there are concerns about the legitimacy of WTO lawmaking).⁹⁷ Furthermore, to the extent these decisions are *not* precedential (except with respect to the parties in the dispute), their force in domestic political debates is diminished.

Of course, it may be wrong to draw pessimistic conclusions from only six cases, half of which were not appealed. Much would be learned if, for example, the Appellate Body were to consider a challenge to India's position on the patentability of new uses of known substances because that legislation raises an issue concerning follow-on invention in the context of a patent law crafted to promote both innovation and development.⁹⁸ But the paucity of cases raises another significant question: will DSU jurisprudence be varied enough to provide sufficient guidance? There is a continuing moratorium on nonviolation complaints regarding intellectual property, which means that none of the subtler international intellectual property issues raised by TRIPS will be expounded upon in the near future.⁹⁹ Because the dispute settlement system lacks an analogue to declaratory judgment actions, a member interested in responding to an emerging problem in a pioneering way cannot get an advanced read on whether the proposed approach is compatible with TRIPS. Most important, the number of intellectual property cases reaching disposition is declining. This phenomenon is particularly troubling, for it speaks not only to the sufficiency of interpretive guidance; it also suggests that the WTO may no longer occupy a central role in international intellectual property lawmaking. Unless the WTO system can become more responsive to members' interests, problems will be increasingly settled in other fora or bilaterally. Given the current tendency of bilateral agreements to increase levels of intellectual property protection,¹⁰⁰ the latter approach bodes poorly for the development of a well-functioning multilateral mechanism for regulating rights in knowledge products.

II. Alternative Regulatory Approaches

In some ways, the TRIPS story is a classic example of a regime in need of administration: a treaty with unanticipated consequences, entered into by nations with widely diverse needs,

⁹⁷ See R H Steinberg 'Judicial Lawmaking at the WTO: Discursive, Constitutional, and Political Constraints' (2004) 98 *Am. J. Int'l L.* 247 at 254.

⁹⁸ See Section 3(d) of Indian Patents Act (barring a patent on "the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant"). India's denial of a patent on Novartis' drug Glivec (Gleevec) may set the stage for such a challenge, see R Daniel *Novartis: India High Court denies a Glivec-related challenge* (Aug 6, 2007) Market Watch available at <http://www.marketwatch.com/news/story/novartis-india-high-court-denies/story.aspx?guid=%7B28DBBD2F-95A0-434B-B73A-E2066046C3D7%7D>.

⁹⁹ TRIPS, art. 64.2; Ministerial Declaration, WT/MIN(05)/DEC, art. 45 (18 December 2005)(directing the TRIPS Council to consider the conditions for lifting the moratorium). The issue remains on the agenda of the TRIPS Council, see Annual Report (2006) of the Council for TRIPS, IP/C/44 (Dec. 4, 2006), but as of mid-year 2007 no further action on this issue had been undertaken. For a discussion of the role non-violation complaints could play in TRIPS, see Dinwoodie & Dreyfuss (n 49). Nonviolation complaints arise when a member asserts that an objective of the Agreement is being impeded as the result of any measure applied by another member state. In contrast, in a violation complaint, the claim is that a measure taken by another member nullifies or impairs a benefit accruing under the Agreement.

¹⁰⁰ See, for example, P K.Yu 'Currents and Crosscurrents in the International Intellectual Property Regime' (2004) 38 *Loy. L.A. L. Rev.* 323 at 392-400. A new plurilateral instrument is also under consideration, the Global Congress on Combating Counterfeiting (GCCC), <http://www.dfat.gov.au/trade/acta/discussion-paper.html>.

affecting groups whose interests are not always aligned with those of their governments, and without an effective legislative capacity.¹⁰¹ It has been suggested that in the WTO system as a whole, the Appellate Body is taking on the role of mediating among different interests, constraining the range of outcomes, and providing interpretive guidance.¹⁰² But as the last section suggests, the DSU system (whatever one may think of its legitimacy) has so far proved ineffectual at overcoming the deficiencies in TRIPS. The drafters of the TRIPS Agreement incompletely theorized the functioning of exclusive rights regimes and, at the end of the day, created an instrument that can impair consumer access to knowledge products and impede dynamic innovation.¹⁰³ It does not even convey a sense of what *Trade Related Aspects of Intellectual Property Rights* might mean.¹⁰⁴ It is no surprise, then, that adjudicators cannot effectively delineate the space in which WTO members may operate—the Agreement does not contain judicially-manageable standards relevant to the question. Nor can much insight be expected from the adjudicators themselves: although intellectual property expertise qualifies a candidate for an appointment on the Appellate Body, none of the current members of the Appellate Body have experience in intellectual property law.¹⁰⁵ Further, many cases are decided by panels and few individuals versed in intellectual property have been chosen to serve.¹⁰⁶

TRIPS does, however, include two notable features. It contemplates close cooperation with WIPO, which has considerable experience administering intellectual property instruments. Furthermore, the Agreement sets up a Council to oversee compliance, conduct negotiations on issues left open at the end of the Uruguay Round, and “carry out such other responsibilities as assigned to it by the Members.”¹⁰⁷ The issues, then, are whether and under what conditions the expertise of either (or both) of these organizations could be exploited to rectify the deficits in TRIPS.

A. The World Intellectual Property Organization

The problem of administering international intellectual property instruments is not of recent vintage. The earliest multinational agreements, the Paris Convention (on patents and trademarks) and the Berne Convention (on copyright), were negotiated in the late nineteenth century. Each began as a separately administered “Union” of its members, but it soon became clear that there was enough overlap of issues (or gaps in the coverage of the conventions) to make joint administration desirable. To that end, the United International Bureaux for the Protection of Intellectual Property (BIRPI) was founded in 1893. As international intellectual

¹⁰¹ Cf. Benvenisti (n 93); Trachtman (n 25).

¹⁰² Ibid. See also Ehlerman & Ehring, *Authoritative Interpretation* (n 2); Steinberg (n 97) 251.

¹⁰³ Even the overview section on the WTO website discusses only short term costs and long term benefits—there is virtually no recognition that costs can also be an issue in the long term, see http://www.wto.org/english/thewto_e/whatis_e/tif_e/agrm7_e.htm.

¹⁰⁴ Indeed, it is not clear that the drafters meant to limit the Agreement to trade-related matters, see Croome (n 25) at 215.

¹⁰⁵ Article 17.3 of the DSU (the qualifications for service include expertise in any of the covered agreements). For the biographies of Appellate Body members, see http://www.wto.org/english/tratop_e/dispu_e/ab_members_bio_e.htm#abi_saab.

¹⁰⁶ Indeed, under DSU, art. 8.1, the only individuals who are eligible to serve on panels are GATT hands, ex-Council representatives, and people who have “taught or published on international trade law or policy or served as a senior trade policy official of a member.”

¹⁰⁷ Article 68 of TRIPS.

property instruments and inter-government organizations interested in intellectual property proliferated during the course of the next century, BIRPI eventually found itself in a situation not too different from the Paris and Berne Unions. In 1967, it decided that a struggle for supremacy could be avoided by affiliating with the United Nations. In 1970, WIPO was established as a specialized agency of the United Nations and charged with the responsibility of administering multilateral intellectual property instruments.¹⁰⁸ Composed of members of the conventions it administers, other UN members that care to join, and invitees, WIPO operates through a General Assembly; a Conference consisting of all of the members of the WIPO Convention; a Coordination Committee composed of the Executive Committees of the principal conventions; an International Bureau, which functions as the secretariat; and a series of provisional, special, expert, and standing committees. In 1995, pursuant to provisions in the TRIPS Agreement, WIPO entered into an agreement with the WTO “to establish a mutually supportive relationship.”¹⁰⁹

In some ways, WIPO is an ideal locus of international intellectual property lawmaking. Putting aside TRIPS, it now administers virtually all of the major intellectual property conventions (upwards of 20 instruments), which gives it considerable expertise in every facet of knowledge production and protection. More important, it regularly grapples with the kinds of problems the intellectual property community is facing. In response to technological changes, WIPO presided over the successful completion of two new agreements, the WIPO Performances and Phonograms Treaty (WPPT), and the WIPO Copyright Treaty (WCT),¹¹⁰ both of which enable the creators of various intellectual goods to benefit from distribution in the markets that modern technologies make possible. Furthermore, its standing committees routinely monitor the creative environment, identify emerging issues, and make concrete proposals. For instance, soon after the Internet went into wide use, the WIPO Standing Committee on the Law of Trademarks, Industrial Designs and Geographical Indications began to consider the problem of localizing trademark infringements and eventually proposed criteria helpful in deciding jurisdictional and choice of law issues in the digital environment.¹¹¹

WIPO is also an appropriate forum for considering the needs of developing countries. As Debora Halbert puts it, “WIPO was born into the controversy of how intellectual property would impact the developing world:” at the time of the 1967 Stockholm Conference at which the WIPO Convention was approved, a Protocol Regarding Developing Countries was adopted to broker the deal.¹¹² In exchange for agreeing to WIPO control, the South was assured access to

¹⁰⁸ Convention Establishing the World Intellectual Property Organization (July 14, 1967) 21 U.S.T. 1749 and 848 U.N.T.S. 3 available at http://www.wipo.int/export/sites/www/treaties/en/convention/pdf/trtdocs_wo029.pdf [hereinafter WIPO Convention]. For a history of international intellectual property lawmaking and WIPO, see Halbert (n 43).

¹⁰⁹ Articles 63 & 68 of TRIPS; Preamble of the Agreement Between the World Intellectual Property Organization and the World Trade Organization (n 17).

¹¹⁰ WIPO Performances and Phonograms Treaty, adopted on May 20, 2002, 36 I.L.M. 76; WIPO Copyright Treaty, adopted on Mar. 6, 2002, 36 I.L.M. 65.

¹¹¹ Standing Committee on The Law of Trademarks, Industrial Designs and Geographical Indications, Use of Trademarks on The Internet: Issues Paper (3d Sess.), Sct/3/4, available at http://www.wipo.int/edocs/mdocs/sct/en/sct_3/sct_3_4.pdf. For discussion, see American Law Institute, Project on Intellectual Property: Principles Governing Jurisdiction, Choice of Law, and Judgments in Transnational Disputes.

¹¹² Halbert (n 43) at 262.

educational and cultural materials.¹¹³ Furthermore, because WIPO's concern is limited to intellectual property, its negotiations are dramatically different from negotiations within the WTO. Developed countries are unable to use the leverage of large markets to force the adoption of intellectual property measures that are not in the interest of developing countries. Since side payments cannot be easily offered to developing economies for enduring economic dislocations caused by high protection, the only way to make new arrangements acceptable is to take access interests into account. And because voting can be used in decisionmaking, countries in the North cannot regularly veto pro-development goals.¹¹⁴

Starting in 2004, WIPO has, in fact, been engaged in an ambitious "Development Agenda."¹¹⁵ As originally conceived, the plan was to consider the relationship between intellectual property protection and the UN Millennium Development Goals and to help implement the development-oriented provisions of the TRIPS Agreement, including operationalizing TRIPS' Objectives and Principles. To these ends, WIPO created a Provisional Committee on Proposals Related to a WIPO Development Agenda (PCDA). In its 2007 session, the PCDA recommended that the WIPO General Assembly set up a permanent committee, open to participation by WIPO member states as well as interested intergovernmental organizations and NGOs.¹¹⁶

Not surprisingly, many of the PCDA's proposals deal specifically with the problems of development: technical assistance to craft and implement intellectual property and competition law appropriate for developing economies; aid in developing scientific and cultural institutions; and facilitation of technology transfer (both direct and in the form of exchange programs). Significantly, however, the proposals also go one step further. Recognizing that the South and the North are not necessarily antagonists in debates over intellectual property, the PCDA also includes recommendations that deal with concerns about the quality of the creative environment. Thus, the proposals speak of "making national IP institutions more efficient" and promoting "fair balance between IP protection and the public interest"¹¹⁷—goals that could certainly include finding a better accommodation between first and later-generation innovators. The PCDA also recommends that WIPO undertake studies on the impact of strong intellectual property rights and the role of open collaborative projects in promoting innovation.¹¹⁸ Even more provocatively, it proposes "norm setting activities" that promote "the preservation of the public domain within WIPO's normative processes and deepen the analysis of the implications and benefits of a rich and accessible public domain."¹¹⁹

¹¹³ Ibid at 265-66.

¹¹⁴ That said, the preference (at least among some members) is for consensus, cf. Drahos (n 41) at 5.

¹¹⁵ See, for example, Proposal by Argentina and Brazil for the Establishment of a Development Agenda for WIPO, WO/GA/31/11 (August 27, 2004) available at

http://www.wipo.int/documents/en/document/govbody/wo_gb_ga/doc/wo_ga_31_11.doc. The proposal was supported by other developing states, including Bolivia, Cuba, the Dominican Republic, Ecuador, Iran, Kenya, Sierra Leone, South Africa, Republic of Tanzania and Venezuela.

¹¹⁶ Provisional Committee on Proposals Related to a WIPO Development Agenda (PCDA), Fourth Session (June 11 - 15, 2007) available at http://www.wipo.int/ip-development/en/agenda/pcda07_session4.html.

¹¹⁷ Ibid Annex at ¶ 10.

¹¹⁸ Ibid at ¶¶ 35 & 36.

¹¹⁹ Ibid at ¶ 16.

Admittedly, there is a great deal of room for skepticism regarding the future of this agenda. First, several of the items look eerily similar to the activities that WIPO undertook at the Stockholm Conference. As with the current Development Agenda, NGOs were permitted to attend the deliberations. However, many of the NGOs that participated in negotiating the Stockholm Protocol turned out to be high protectionists (broadcasting unions, industrial property organizations, publisher groups, confederations of authors and composers).¹²⁰ At the end of the day, the developed countries prevented the Protocol from becoming a part of the Berne Convention. A replacement was adopted, but it has proved too unwieldy for developing countries to utilize effectively.¹²¹ The three years that the current Development Agenda has been in the planning stage strongly suggests that it too may falter.

Second, some of the PCDA's "development" goals are, in reality, efforts to move to even higher levels of commodification. One agenda item talks about protecting developing countries' "domestic creations, innovations and inventions,"¹²² another calls for recognizing rights over wholly new classes of information, including genetic resources, traditional knowledge, and folklore.¹²³ Protecting local creativity and knowledge is, of course, an attractive idea in that it would allow the South to turn the tables and extract returns from the North. On the whole, however, these materials are not protected by existing regimes because they not new, inventive, or—in the case of genetic resources—the product of human ingenuity. Classifying them as intellectual property strongly suggests that WIPO's real commitment is to the complete commodification of the knowledge base. Recognizing these claims as intellectual property rights would also co-opt developing countries (or, in some cases, indigenous groups within these countries) to the protectionist cause and further increase the cost of the inputs that are needed to create the next generation of innovation.¹²⁴

Finally, interspersed among the promises to safeguard access interests and the public domain is a worrisome trope. The Convention establishing WIPO states that the organization's *primary* goal is to "promote the protection of intellectual property throughout the world."¹²⁵ Since WIPO was partially created to administer the Berne Convention, which was formed by authors and composers for the express purpose of safeguarding their rights,¹²⁶ it is to be expected that WIPO would start by conceptualizing its role in this manner. However, it is troubling that, despite its 40-year involvement in issues of development, WIPO continues to recommend that the South adopt laws similar to those found in the North¹²⁷ and that it persists in equating the human rights side of the intellectual property problem with the liberty interests of creators rather

¹²⁰ Halbert (n 43) at 263.

¹²¹ See note 54 (discussing the Berne Appendix); R L Okediji 'The International Relations of Intellectual Property: Narratives of Developing Country Participation in the Global Intellectual Property System' (2003) 7 *Sing. J. Int'l & Comp. L.* 315 at 327. See also Chon (n 29).

¹²² PCDA (n 116) Annex at ¶ 11.

¹²³ *Ibid* at ¶ 18.

¹²⁴ See, for example, S Safrin 'Hyperownership in a Time of Biotechnological Promise: The International Conflict to Control the Building Blocks of Life' (2004) 98 *Am. J. Int'l L.* 641.

¹²⁵ WIPO Convention (n 108), see especially Preamble & articles 3-4.

¹²⁶ Significantly, the French term for copyright is "droit d'auteur."

¹²⁷ See Halbert (n 43) 263-64 (citing US attempt impose its law); 270 (citing an argument the Swiss have made suggesting that in the absence of patent protection, technology transfer would be ineffectual because the information would be transferred without the know how to use it and noting that "transfer" appears to refer to the transfer of the protectionist legal system).

than users' interests in health, culture, education, or scientific progress.¹²⁸ The commitment to intellectual property promotion also influences WIPO's work in other arenas. For example, it encourages ever-stronger protection for well known trademarks,¹²⁹ it is working on a substantive patent law treaty (SPLT) that many observers fear will further complicate the innovation landscape,¹³⁰ and its initial impulse was to create an extraordinarily protective copyright regime for the digital environment.¹³¹

This skepticism is, however, likely unwarranted. It is misleading to compare WIPO now to its early incarnations. The shift in international intellectual property protection to the WTO has left WIPO somewhat bereft of purpose; embracing the Development Agenda can be understood as a search for a new role. More important, where developing countries were once largely alone in opposing strong protection, the changes in the patenting environment have led many in the patent sectors in the North to join their cause. This trend is equally evident on the copyright side. As the cost of creating and distributing intellectual goods decreases, activists increasingly question the need for strong copyright protection.¹³² Open collaboration and information exchange communities have proliferated (Wikipedia, the Creative Commons, and Linux furnish three examples).¹³³ Further, thanks (in part) to the aggressive enforcement tactics of the recording industry, there are now millions of consumers who have developed a visceral understanding of the problems associated with strong rights regimes.¹³⁴ The NGOs at the table are thus no longer just largely representatives of film companies, book publishers, and artists-rights groups; there are many low-protectionist advocates involved as well.¹³⁵ Finally, and perhaps most significantly, the stark dichotomy among members is changing: there are now emerging economies—a "Middle" composed of nations like India and Brazil—that are reaping benefits from protecting intellectual property, yet continue to deal with many of the problems strong protection poses to development.¹³⁶

¹²⁸ Halbert, *ibid* at 257. To be sure, authors' rights are also mentioned in such instruments as the Universal Declaration of Human Rights, art. 27(2). It is not, however clear that this view should be transferred to patent rights, or—more broadly—to instruments aimed at promoting the interests of developing economies.

¹²⁹ See, for example, WIPO and Assembly of the Paris Union for the Protection of Industrial Property *Joint Recommendation Concerning Provisions on the Protection of Well-Known Marks*, Pub'n 833 available at http://www.wipo.int/about-ip/en/development_iplaw/pub833.htm.

¹³⁰ See Reichman & Dreyfuss (n 29). Cf. J F Duffy 'Harmony and Diversity in Global Patent Law' (2002) 17 *Berkeley Tech. L.J.* 685 (suggesting that the costs of harmonizing patent norms outweigh the benefits).

¹³¹ See, for example, Samuelson (n 54).

¹³² See, for example, L Lessig 'Re-crafting a Public Domain' (2006) 18 *Yale J.L. & Human.* 56; Y Benkler *The Wealth of Networks: How Social Production Transforms Markets and Freedom* (2006) Yale University Press; Boyle (n 44).

¹³³ See, for example, E Von Hippel *Democratizing Innovation* (2005) MIT Press.

¹³⁴ There are many blogs devoted to the question of sharing music, see, for example, ITtoolbox Blogs, RIAA Lawsuits against Peer to Peer, available at <http://blogs.ittoolbox.com/security/dmorrill/archives/riaa-lawsuits-against-peer-to-peer-12967>

¹³⁵ Examples include Intellectual Property Watch, <http://ip-watch.org/index.php?res=1024&print=0>; Médecins Sans Frontières (MSF), Campaign for Access to Essential Medicines, <http://www.accessmed-msf.org/index.asp>; and Knowledge Ecology International (KEI), http://www.keionline.org/index.php?option=com_frontpage&Itemid=1.

¹³⁶ See, for example, D P Steger 'The Culture of the WTO: Why it Needs to Change' (2007) 10 *J. Int'l Econ. L.* 483 at 483 (describing China, Brazil, and India as converting the bi-polar North/South trading system into one that is multi-polar).

With a new coalition among the politically-solidified South, the technically-expert, legally-skilled low protectionist reformers in the North, and the emerging Middle, there is reason to believe that WIPO will actively engage in its new Agenda and that it will succeed in reconceiving intellectual property norms in light of development issues and an appreciation for the public domain. Indeed, the power of such an alignment is already evident. As Pamela Samuelson's account of the negotiations leading up to the WCT demonstrates, the high protectionist regime originally proposed by the United States and the EC to deal with the digital challenge was modified through the combined efforts of developing countries and low protectionist activists.¹³⁷

Given the WTO's failure to fully comprehend the impact of intellectual property on innovation and the unwillingness of adjudicators to utilize the Objectives and Principles of the TRIPS Agreement interpretively or to provide content for terms such as "limited," "normal exploitation," "legitimate interest," and "unreasonable prejudice," WIPO's new efforts could certainly be a significant help in fleshing out the TRIPS Agreement. Relying on WIPO's administrative guidance would also appear consistent with the approach taken in other WTO agreements, where principles set out by expert international bodies such as the Codex Alimentarius Commission or the International Standards Organization have been incorporated and utilized by DSU adjudicators.¹³⁸ Indeed, WIPO participation may, in the end, be the only way to cope with the dynamic and increasingly complex nature of the intellectual property sector.

There is, however, a question about the legitimacy of relying on standards generated by WIPO. The membership of the WTO and WIPO are not coextensive; if, for example, WIPO's Development Agenda were to result in a new convention, a separate vote in the WTO would be needed to make it a part of the TRIPS Agreement. Furthermore, TRIPS' references to WIPO are not on the same footing as references to non-WTO intergovernmental organizations found in other agreements. The WTO Agreement on Technical Barriers to Trade, for example, explicitly envisions the development of international standards by non-WTO bodies and even directs members to use them.¹³⁹ In contrast, the TRIPS Agreement is highly specific about which parts of the WIPO instruments are incorporated into the Agreement and which are subject to the DSU.¹⁴⁰ Significantly, the agreement between WIPO and the WTO is largely confined to securing transparency and providing technical assistance to WTO members. Although there may be instances in which WIPO developments would be considered illustrative of the terms of the TRIPS Agreement,¹⁴¹ wholesale adoption of WIPO interpretations could be thought to "diminish the rights and obligations provided in the covered agreements," in violation of the DSU.¹⁴²

¹³⁷ Samuelson (n 54); J H Reichman & P Samuelson 'Intellectual Property Rights in Data' (1997) 50 *Vand. L. Rev.* 51 at 99-100 & 100 n. 214.

¹³⁸ See Trachtman (n 25) 638-39 (citing the European Communities - Trade Description of Sardines, WT/DS231/AB/R (23 October 2002), adopting Codex Alimentarius rules in a case involving the Agreement on Technical Barriers to Trade, Apr. 15, 1994, Marrakesh Agreement, Annex 1A, Legal Instruments--Results of the Uruguay Round, vol. 27 (1994))[hereinafter TBT].

¹³⁹ Article 2.4 of TBT.

¹⁴⁰ See, for example, articles 9, 14, 16, 22 & 39 of TRIPS.

¹⁴¹ See, for example, ¶ 6.69 of *US-110(5)* ("[S]ubsequent developments [such as the WCT] may be of rather limited relevance in the light of the general rules of interpretation as embodied in the Vienna Convention. However, in our

Nonetheless, there are arguably several ways that WIPO interpretations could be interpolated into the TRIPS Agreement. One method was proposed by Neil Netanel in connection with the question of how subsequent interpretations of the Berne Convention would apply to TRIPS. He suggested that TRIPS ought to be viewed as continually evolving. According to Netanel:

TRIPS drafters must have been well aware [that] the Berne Convention is a dynamic instrument ... and [that] the rapid development of copyright-related technology require[s] an ongoing process of interpretation and reinterpretation within the framework that Berne sets forth.¹⁴³

Under his approach, WIPO's elucidations of the terms of the instruments it administers would be immediately incorporated into TRIPS, either because WTO members should be regarded as having agreed to an evolving interpretation of the Agreement, or because each new interpretation represents a "subsequent agreement between the parties" within the meaning of the Vienna Convention.¹⁴⁴

Of course, this approach can only go so far: it works fairly well in the context for which it was proposed because TRIPS largely incorporates the Berne Convention.¹⁴⁵ However, TRIPS obligations regarding patents, trade secrets, and trademarks go well beyond the provisions of the Paris Convention. Since the problems in all of the intellectual property regimes are somewhat similar, it will often be comparatively straightforward to take an approach WIPO suggests for copyright and apply it in the other areas. However, it would be hard to consider an interpretation developed in this way as representing a genuine agreement among WTO members (and especially not among members of the WTO who have not joined the WIPO conventions). Indeed, if the panel report in *Canada-Pharmaceuticals* case provides any guidance, adjudicators are likely to take a very hard line on what constitutes the negotiated understanding or a subsequent agreement.¹⁴⁶

An alternative approach would be to wait. WIPO identification of TRIPS flexibilities could be regarded as guidance to WTO members on what laws they can enact to accommodate

view, the wording of the WCT ... nonetheless supports ... that the Berne Union members are permitted to provide minor exceptions to the rights provided....").

¹⁴² Article 3.2 of DSU.

¹⁴³ N W Netanel 'The Next Round: The Impact of the WIPO Copyright Treaty on TRIPS Dispute Settlement' (1997) 37 *Va. J. Int'l L.* 441 at 471-72.

¹⁴⁴ Vienna Convention on the Law of Treaties, U.N. Doc. A/Conf. 39/27, 8 I.L.M. 679 (1969) (entered into force Jan. 27, 1980), art. 31(3)(a). The DSU is considered to implicitly adopt the Vienna Convention through its reference to "customary rules of interpretation of public international law," DSU, art. 3.2, see S P Croley & J H Jackson 'WTO Dispute Procedures, Standard of Review, and Deference to National Governments' (1996) 90 *Am. J. Int'l L.* 193 at 200. Cf. J E Alvarez & J P Trachtman 'Institutional Linkage: Transcending "Trade And..."' (2002) 96 *Am. J. Int'l L.* 77 at 88-89 (suggesting that the WTO treaty could be amended to incorporate other norms directly, along with other ways to apply norms across intergovernmental bodies).

¹⁴⁵ Article 9.1 of TRIPS ("Members shall comply with Articles 1 through 21 of the Berne Convention (1971)").

¹⁴⁶ *Canada-Pharmaceuticals*, ¶ 7.47 (requiring "documented evidence of the claimed negotiating understanding"). *India-Pharmaceuticals* similarly refused to consider side agreements that had not been embodied in text. See also note 149, *infra*.

their local situations.¹⁴⁷ Once members act on these recommendations, the legislation would arguably qualify as “a subsequent practice” that establishes the meaning of the Agreement.¹⁴⁸ *Canada-Pharmaceuticals* may, however, cast doubt on that argument as well, for the panel rejected Canada’s claim that other members’ exemptions for regulatory review drug testing constituted a subsequent practice for interpretive purposes.¹⁴⁹

Because the prospect for both of these approaches is dim, a more formal procedure for importing WIPO guidance into TRIPS is likely needed. One idea would be to amend TRIPS to expand WIPO’s role in interpreting the Agreement. The system as a whole would then retain its basic structure, but (so long as WIPO continues to utilize a majority vote procedure) it would be more capable of responding to changing circumstances. Adopting this approach would, however, be very much a decision from “behind the veil of ignorance”—as the discussion of WIPO suggests, it remains unclear whether WIPO will retain its traditional protectionist stance or become a venue for accommodating access interests. Since it is unlikely that WTO members will be willing to roll the dice and adopt such an open-ended approach, a less formal relationship would likely be found preferable. For example, the Agreement between WIPO and the TRIPS Council could be altered to expand the range of issues they consider jointly. The TRIPS Council could then be given the task of bringing desirable modifications to the attention of the WTO.¹⁵⁰

Indeed, some role for the TRIPS Council would be desirable in any event, for the interests of WTO and WIPO are imperfectly aligned. That is, there are some decisions about the creative environment that would also improve trade—for example, were WIPO to help developing countries commodify traditional knowledge, there would be even more trading chips to exchange. But some decisions about intellectual property could be inimical to trade. For instance, if the Development Agenda led WIPO to change course on the issue of well known marks, traders engaged in global advertising would suffer. By the same token, there are problems that could be solved in TRIPS without any need to alter the WIPO agreements. For example, the limitations imposed by the *US-110(5)* case is a TRIPS, not a Berne Convention, problem.¹⁵¹ If the WTO were to adopt the consumption/arbitrage distinction suggested earlier, there would be uses freed for public use by virtue of TRIPS that would not run afoul of any WIPO instrument. Similarly, the North might be more willing to relinquish strong rights in the South if WTO members reached an accord on parallel imports.¹⁵² In sum, there are problems in

¹⁴⁷ See, for example, WIPO *Advice on Flexibilities under the TRIPS Agreement* available at http://www.wipo.int/ip-development/en/legislative_assistance/advice_trips.html.

¹⁴⁸ Article 31(3)(b) of the Vienna Convention.

¹⁴⁹ *Canada-Pharmaceuticals*, ¶ 7.42 (“the subsequent acts by individual countries did not constitute ‘practice in the application of the treaty which establishes the agreement of the parties regarding its interpretation’ within the meaning of Article 31.3(b) of the Vienna Convention”).

¹⁵⁰ A similar suggestion was proposed by E Petersmann ‘Challenges to the Legitimacy and Efficiency of the World Trading System: Democratic Governance and Competition Culture in the WTO’ (2004) 7 *J. Int’l Econ. L.* 585 at 601.

¹⁵¹ The *US-110(5)* case interpreted art. 13 of TRIPS, which is based on art. 9 of the Berne Convention. However, the three-part test of art. 9 applies only to *reproductions* of protected works, not to *public performances*. Article 11 of Berne protects “public performances,” and leaves it to national law to decide such issues as whether performances in Irish bars are “public,” see S Ricketson & J C Ginsburg, *International Copyright and Neighboring Rights: The Berne Convention and Beyond* (2005) Oxford University Press § 12.02.

¹⁵² See article 6 of TRIPS. This is not to say that a total ban on parallel importation is required; an agreement could, for example, take the form of prohibiting parallel importations between countries when the patentee is obliged by

intellectual property where WIPO expertise would be useful, but there are also issues on which WIPO is likely to be insensitive or unlikely to opine. Building expertise in the WTO is therefore crucial.

B. The Council for TRIPS

The TRIPS Council was created when the Uruguay Round established the WTO.¹⁵³ Like the other WTO Councils, its functions are determined by the covered agreements as well as by special assignments from the General Council.¹⁵⁴ Under the TRIPS Agreement, the Council's duties include affording members "the opportunity of consulting on matters relating to the trade-related aspects of intellectual property rights," furnishing assistance in the context of dispute resolution, and setting up a cooperative arrangement with WIPO.¹⁵⁵ In addition, TRIPS requires the Council to accept notifications from members regarding their laws¹⁵⁶ and to periodically review the implementation of the Agreement.¹⁵⁷ At the conclusion of the Uruguay Round, several important issues were left open, and the Council was also charged with the responsibility of overseeing their continued consideration. These include added protection for geographic indications for wines and spirits,¹⁵⁸ questions concerning protection for living plants and animals,¹⁵⁹ the applicability of nonviolation complaints to the TRIPS Agreement,¹⁶⁰ and extra assistance for least-developed countries.¹⁶¹ In 1998, the Council was also asked to consider electronic commerce in information products.¹⁶²

In the Doha Round, the TRIPS Council was assigned several additional tasks, most significantly, embarking on a development agenda.¹⁶³ Thus, the Doha Declaration stressed the importance of interpreting TRIPS in a manner "supportive of public health," and asked the Council to explore the relationship between the TRIPS Agreement and the Convention on Biological Diversity (CBD)(which protects genetic resources)¹⁶⁴, to consider the protection of traditional knowledge and folklore, to study "relevant new developments raised by members pursuant to Article 71.1" (which requires periodic review of the Agreement), and—significantly—to "be guided by the objectives and principles set out in Articles 7 and 8 of the TRIPS Agreement." In a separate statement on public health, the Council was instructed to find

law in the country of export to offer its products at a price that is a specified percentage (say, 25%) below the market price in the country of import.

¹⁵³ Article IV(5) of the WTO Agreement.

¹⁵⁴ See generally, Broude (n 2) 130-32.

¹⁵⁵ Article 68 of TRIPS.

¹⁵⁶ Articles 1.3, 3.1, 4(d) & 63.2 of TRIPS.

¹⁵⁷ Article 71 of TRIPS.

¹⁵⁸ Articles 23 & 24 of TRIPS.

¹⁵⁹ Article 7(b)(3) of TRIPS. The charge concerning animals and plants has been expanded to include consideration of the patentability of living products produced by genetic manipulation, Pugatch (n 27) at 135.

¹⁶⁰ Article 64.3 of TRIPS.

¹⁶¹ Article 66 of TRIPS.

¹⁶² Ministerial Declaration on global electronic commerce, WT/MIN(98)/DEC/2, adopted on 20 May 1998; ¶ 34 of the Doha Declaration (n 4).

¹⁶³ ¶¶ 17-19 of the Doha Declaration (n 4).

¹⁶⁴ Article 15(1) of the Convention on Biological Diversity (June 5, 1992) 31 ILM 818, 823.

a solution to the essential medicines problem and to extend the transition periods for least-developed countries.¹⁶⁵

Membership in the Council is open to all WTO members and individual members (or, more often delegations of members) are free to bring an item up for the Council's consideration. The Council meets regularly throughout the year and its deliberations have a degree of both transparency and outside participation. Thus, it is required to issue Annual Reports and these, along with meeting minutes, working documents, and decisions are available on the WTO website.¹⁶⁶ The 2006 Annual Report indicates that the Council has granted regular observer status to the OECD, UNCTAD, WIPO, and to other intergovernmental organizations with expertise on the issues the Council has been asked to consider. In addition, the Council grants ad hoc observer status to intergovernmental organizations with special interest in the topics discussed at specific meetings.¹⁶⁷

The Council has made moderate headway on its assignments. As noted earlier, it has entered into a cooperative agreement with WIPO and the minutes of its meetings indicate that it has actively undertaken its oversight obligations. Notably, it has defined these obligations to include not only monitoring compliance with TRIPS' minimum standards, but also ensuring that that developed countries are fulfilling their technology transfer obligations.¹⁶⁸ It has supervised the negotiations for a solution to the essential medicines problem and extended the relevant times for compliance with the Agreement. Its other tasks—the matter of nonviolation complaints, the GI questions, life patenting, electronic commerce, and the broader issues in the development agenda—remain under consideration.¹⁶⁹

Although the Council has generally been viewed as, essentially, the WTO's agent for carrying out specifically assigned tasks, Kal Raustiala has made the interesting argument that it is, in fact, the ideal forum for generating the guiding principles that domestic policymakers and international adjudicators currently lack. Raustiala points out that during implementation reviews, members challenge one another's legislation, consider the problems challenged measures are intended to address, argue about the meaning of TRIPS obligations, and examine ambiguities and lacunae within the Agreement.¹⁷⁰ According to Raustiala:

Interactions like these are useful because they inform other member states about substantive national law, signal potential areas of conflict and dispute, alert the queried member states to weaknesses of their national laws vis-à-vis TRIPS, and begin to create the norms and standards that will guide the work of the TRIPS Council and subsequent disputes and settlements.¹⁷¹

¹⁶⁵ ¶¶ 6 & 7 of the Declaration on public health (n 4).

¹⁶⁶ http://www.wto.org/english/tratop_e/trips_e/intel6_e.htm.

¹⁶⁷ See, for example, Annual Report (2006) (n 99). See generally K Raustiala 'Compliance and Effectiveness in International Regulatory Cooperation' (2000) 32 *Case. W. Res. J. Int'l L.* 387 at 434-38.

¹⁶⁸ Council for Trade-Related Aspects of Intellectual Property Rights, Implementation of Article 66.2 of the TRIPS Agreement, IP/C/28 (20 February 2003).

¹⁶⁹ Gervais (n 25) at 43-45; 48-50; 358-59; WTO, Doha Development Agenda: Negotiations, Implementation and Development, http://www.wto.org/english/tratop_e/dda_e/dda_e.htm.

¹⁷⁰ Raustiala (n 167) 429-39.

¹⁷¹ *Ibid* at 436-37.

Raustiala's vision has many attractive features. The Council's monitoring obligations and other assignments give it an important perspective on intellectual property issues in general, and, in particular, on how they play out in trade. Its authority appears to be extensive enough to deal with many of the problems members are facing. For example, its charge to review implementation of the Agreement presumably includes the power to consider whether competition (antitrust) standards should be added to the WTO framework and to study the problem of parallel importation. Its obligation to consider nonviolation complaints could enable it to find ways to shield national accommodations from ready challenge while preserving an opportunity for clarification through dispute resolution.¹⁷² Council deliberations could also be used to compensate for the absence of declaratory judgment actions: a nation intent on adopting a new approach could vet it in the Council before paying the political price of enacting new legislation or suffering the political consequences of unraveled compromises. And as Raustiala stresses, if dispute were resolved in the Council through diplomacy, DSU adjudicators would less often be put into the position where they must create law. Concerns about legitimacy might then abate.

Attractive as this approach appears, it is not without its problems. Foremost is the question whether WTO members could rely on the norms and standards generated in the procedure Raustiala envisions. Raustiala is certainly right that issues of compliance are ironed out at TRIPS Council meetings. However, it is unclear whether an accommodation between two parties that avoids dispute resolution should be regarded as establishing a norm that binds other members. In many cases, it may be more in the nature of a waiver—an agreement not to bring a complaint and instead to await future developments. Of course, as accommodations regarding a particular issue accumulate, members may begin to perceive the accommodation as a new norm—as a reasonable interpretation of the TRIPS flexibilities (taking into account its Objectives and Principles), or as a subsequent agreement among the parties. Nevertheless, any member that incorporated the norm into legislation would be vulnerable to a challenge from a member that did not participate in the deliberations. The risks associated with defending the legislation could diminish the impact of these “norms” on the thinking of policymakers or the behavior of domestic legislatures.

Of course, the Council could reduce the risk of challenge by turning aggressive interpretations into recommendations for amending the Agreement. The problem here is that this would appear to require a vote of the TRIPS Council, followed by a vote of the General Council. Since under current procedures, both Councils operate by consensus,¹⁷³ protectionist members would presumably have ample opportunity to veto proposals the Council makes to accommodate the interests of the South or the creative community. Of course, the operative word here is “presumably.” As dissatisfaction with the current stalemate grows, there is increasing interest in moving away from consensus decisionmaking. Thus, Claus-Dieter Ehlermann and Loring Ehring suggest that attention be paid to other options envisioned by the WTO Agreement.¹⁷⁴ They point out that when consensus cannot be achieved, the Agreement permits voting and that

¹⁷² See Dinwoodie & Dreyfuss (n 49) at 103.

¹⁷³ Gervais (n 25) at 359 (noting that although the Council has the power to set its own internal rules, it generally operates by consensus); WTO Agreement, art. IX (setting out decisionmaking rules of the General Council).

¹⁷⁴ Ehlermann & Ehring, *Authoritative Interpretation* (n 2).

obligations can be waived by three-fourths vote of the Ministerial Conference.¹⁷⁵ Further, they note that upon recommendation of a Council, an interpretation can be adopted by a three-fourths vote of the members of the Ministerial Conference or the General Council.¹⁷⁶ The latter route—the so-called “authoritative” or “definitive” interpretation mechanism—is particularly interesting in the context of TRIPS, where one of the major problems is that members and adjudicators lack standards for engaging in interest-balancing.

The Ministerial Conference and the General Council’s authority to adopt authoritative interpretations is, however, limited. The WTO Agreement provides that this mechanism cannot be utilized in a manner that would undermine the amendment provisions of the Agreement.¹⁷⁷ Because the WTO has never pursued this route, it is unclear what this means: where interpretation ends and amendment begins, whether authoritative interpretations can alter the rights or obligations of the parties, and even whether these are questions the Appellate Body is empowered to decide.¹⁷⁸ Ehlermann and Ehring suggest that the better view is that an authoritative interpretation must “somehow be linked to the pre-existing rules and cannot create self-standing rules.”¹⁷⁹ If they are right, that should be more than sufficient for an agreement like TRIPS, which uses highly capacious terms like “legitimate,” “unreasonable” and “normal.” Indeed, much could be accomplished by simply clarifying the relationships between various provisions, such as the operation of the steps in the exceptions tests and the applicability of the patent exceptions test to the provision barring technological discrimination.

Nonetheless, questions would remain. The TRIPS Council’s shifting membership is unlikely to develop the kind of expertise necessary to fully grasp the complex technical questions that intellectual property presents, the distortions that were created when intellectual property was shoehorned into a trade agreement, or the complicated political economy in which the system currently operates. Nor is it presently situated to get the input it needs. An early draft of TRIPS contemplated the creation of an Expert Group to advise what was then called the “Committee on TRIPS.” However, that proposal was rejected.¹⁸⁰ Instead, the Agreement permits the Council to “consult with and seek information from any source it deems appropriate” to carry out its obligations.¹⁸¹ Ad hoc advice is not, however, as valuable as internal expertise because it is not available until the Council recognizes that advice is needed. Here, then, is a place where closer relations with WIPO could help. The agendas of the two organizations are similar: both are considering protection for the knowledge products of the South and putting teeth into the Objectives and Principles that introduce the TRIPS Agreement. As earlier noted, WIPO already has considerable experience regarding many of the key issues. At present,

¹⁷⁵ Article IX of the WTO Agreement.

¹⁷⁶ Article IX(2) of the WTO Agreement.

¹⁷⁷ *Ibid.*

¹⁷⁸ Ehlermann & Ehring, *Authoritative Interpretation* (n 2) (also pointing out some highly technical questions). There is also a question whether this route is any more practicable than the current method of decisionmaking. The usual consensus rule is, in reality, a negative consensus rule: because abstentions are permissible, a high level of participation is not required. In contrast, authoritative interpretations require positive action from three-quarters of the membership of the General Council or the Ministerial Conference.

¹⁷⁹ *Ibid.* at 812.

¹⁸⁰ Draft of July 23, 1990, W/76, Gervais (n 25) at 358.

¹⁸¹ Article 68 of TRIPS.

however, WIPO enjoys only observer status at Council meetings, except in the specific areas where it has entered into a working relationship with the Council.

But even with WIPO's participation, there will be lingering concerns about voice. The outcomes of TRIPS Council deliberations are reported, but the meetings are held in secret.¹⁸² Although the Council regularly gives *observer* status to intergovernmental organizations, none is permitted to participate in deliberations. And NGOs are not even allowed to attend meetings; they often learn from participants what will be covered and put their views into open letters, but that process is highly informal and episodic.¹⁸³ While it may be true that low protectionists can sometimes count on the South to pursue their interests, this is unlikely to be sufficient in all situations. Developing countries have complex motivations in WTO negotiations and those that lack creative sectors are unlikely to be familiar with the impact of strong protection on innovation or to have reason to fight for innovator-regarding safeguards. Again, some of these problems could be ameliorated by a carefully structured relationship with WIPO, where it appears that a more open process is developing and a coalition among low protectionists, developing countries, and emerging economies is building. But until WIPO actually acts on its ambitious new agenda, many observers will remain skeptical about the adequacy of its representation.

Possibly, dispute resolution could be a legitimating mechanism in this regard. After all, a case challenging a norm developed in the TRIPS Council or the legitimacy of an authoritative interpretation, would presumably raise these governance issues.¹⁸⁴ As previously suggested, adjudicators have been fairly attentive to issues of process.¹⁸⁵ Were the Appellate Body to decide that norm-creation and authoritative interpretations are valid only if they are arrived at through reasoned decisionmaking in the context of a procedure that is fair to all stakeholders, the TRIPS Council would have incentives to develop the appropriate procedures. Council-developed intellectual property norms and authoritative interpretations could, in short, not only bring the TRIPS Agreement into better alignment with the public interest, they could provide the WTO with an occasion to consider the institutions needed for effective global governance and the opportunity to promulgate administrative principles for these institutions to follow.

III. Intellectual Property and Global Governance

This account of developments in international intellectual property can be viewed as a case study in global governance. Centuries of trade in intellectual goods revealed a need for intergovernmental coordination of the worldwide marketplace—hence the Berne and Paris Unions, BIRPI, and WIPO. As trade increased, the value of minimum standards of protection also became apparent.¹⁸⁶ The WTO was an attractive option for continued international

¹⁸² Cf. Esty (n 2) at 1544 (noting that the WTO has been criticized for the secrecy of its operations).

¹⁸³ Sell has suggested that certain private-sector parties had special access to TRIPS negotiations, Sell (n 55) 96-120; it is unclear whether these groups continue to enjoy special attention.

¹⁸⁴ See, for example, Esty (n 2) at 1539.

¹⁸⁵ See text at note 93.

¹⁸⁶ The experience of the EC demonstrates this point. Although the Treaty of Rome did not (like the US Constitution) give central authorities power over intellectual property, it soon became clear that if intellectual goods were to move freely in the European market, members would need to harmonize aspects of protection. As a result, the EC has promulgated a series of copyright directives, created the Community Trademark, Council Regulation

lawmaking, first because a protectionist agenda could be more easily pursued in a context in which trade offs and side payments could be made, and second because its obligations are enforceable through the DSU.¹⁸⁷ But the shift to the WTO has taken its toll both substantively and procedurally.

Classically, the private returns from patenting represented only a portion of the social benefits of innovation.¹⁸⁸ Commodification was imperfect, so advances leaked into a publicly-accessible space, where they modulated the effect of supracompetitive pricing and nourished future generations of innovation. TRIPS facilitated world trade by expanding the geographic scope of commodification. However, it also went one step further: it generated a one-way ratchet. States cannot reduce protection below a minimum level, but they are free to increase protection. Furthermore, through the combined effect of most favored nation and national treatment, and (for patents) technological neutrality obligations, TRIPS is, in effect, an engine driving protection to ever-higher levels throughout the WTO.¹⁸⁹

Procedurally, the shift from WIPO to the WTO converted an informal system of rulemaking into a legalistic regime that tends to mute the voices of certain constituencies. The shift should have immediately raised concerns about legitimacy. However, as Daniel Esty has argued, for other kinds of trade—especially before the Uruguay Round—legitimacy concerns were easy to ignore. The interests of participants were fairly well aligned. Once the basic policy decision to engage in freer trade was made, the remaining tariff issues were largely technical and highly susceptible to resolution by expert regulators. Besides, members reaped strong benefits from coordinating their activity.¹⁹⁰ It may have appeared straightforward to amalgamate intellectual goods into the same regime. Once again, the issue appeared to be trade and history had already demonstrated the benefits of a single strong international organ that coordinates the global marketplace.

Events have, however, revealed this assessment of the relationship between intellectual property and trade to be almost entirely incorrect. For intellectual property, the hard questions are matters of policy: put into the vocabulary of trade, they concern the extent to which particular firms and nations should be permitted to enjoy the comparative advantages of technological superiority and lock their advantages in by preventing others from accessing their works and building on them.¹⁹¹ Nor are the benefits from coordination as large as might be supposed. Developing countries are incurring high costs and developed countries are finding that TRIPS makes it difficult to respond effectively to changes in the innovation landscape. Expertise in trade is unhelpful in dealing with these concerns, and yet the negotiators of the TRIPS

(EC) No 40/94 of 20 December 1993 on the Community trade mark, and is currently negotiating for a Community Patent, see, for example, Commission Proposal for a Council Regulation on the Community Patent, COM(00)412 final. For an example of a case where free movement revealed the need for substantive harmonization, see *Warner Bros. and Metronome Video v Christiansen* 1988 (Cae 158/86) E.C.R. 2605 (ECJ). See generally, G B Dinwoodie, W O Hennessey & S Perlmutter *International Intellectual Property Law and Policy* (2001) Matthew Bender & Co. 645-716.

¹⁸⁷ Cf. A T Guzman 'Global Governance and the WTO' (2004) 45 *Harv. Int'l L.J.* 303.

¹⁸⁸ See generally, Brett B M Frischmann & M A Lemley 'Spillovers' (2007) 107 *Colum. L. Rev.* 257.

¹⁸⁹ See, for example, Drahos (n 41) at 6.

¹⁹⁰ Esty (n 2).

¹⁹¹ Cf. Netanel (n 143) at 456-57 (noting the relationship between commodification and comparative advantage).

Agreement were largely trade, not intellectual property, specialists.¹⁹² Many developments since Uruguay have come about through dispute resolution, but adjudicators likewise tend to have trade, rather than intellectual property, experience.

The previous discussion proposed various mechanisms for bringing together the intellectual property expertise found in WIPO with the trade expertise developing in the Council for TRIPS. However, before any of these mechanism (or alternative procedures for making international intellectual property law responsive to changing needs¹⁹³) could be adopted, several issues of institutional design must be resolved. The first is a method for controlling forum shopping (“regime shifting”).¹⁹⁴ Any proposal that invokes the expertise of more than one “agency” must deal with the possibilities that the agencies will be played off against each other. Indeed, as the short history recounted above demonstrates, the creative community has long oscillated between multiple and consolidated administration of its international instruments. Currently, the situation is equally complex because WIPO and the WTO are only two of the international organizations with a colorable interest in intellectual property. Others include UPOV (which deals with protection for plants), UNAIDS and WHO (which have a strong interest in medicines), UNCTAD (which deals with development issues), and the Secretariat for the CBD (which deals with genetic resources).¹⁹⁵ Even the European Court of Human Rights has weighed in (surprisingly, on the side of right holders).¹⁹⁶ In addition, nations interested in finding a congenial forum have regional and bilateral possibilities.¹⁹⁷

Of course, there can be advantages to regulatory competition; overlapping agency authority can lead to better decisions; different mixes of expertise can produce fresh perspectives.¹⁹⁸ At the same time, however, shared responsibility duplicates work and can also lead to inconsistent regulations and redundant or incoherent obligations.¹⁹⁹ And for intellectual property, it can exacerbate the protectionist pull. For example, developing countries learned from watching the North shift negotiations from WIPO to the WTO: they have successfully pursued protection for knowledge about genetic resources in negotiations over the CBD. CBD obligations require participating states to recognize a whole new class of rights. Dealing with these new right holders is likely to raise transaction costs, increase the possibilities for holdouts,

¹⁹² See Halbert (n 43) at 280 (noting that WIPO was not invited to any of the substantive meetings on TRIPS); Gervais (n 25) at 13 (noting that the negotiators realized that because the subject matter was so different from that traditionally handled by the GATT, special information gathering efforts needed to be made, and that they periodically requested information from WIPO).

¹⁹³ See, for example, Drahos (n 41) 12-27 (suggesting the development of “best practices” and a new treaty on access to knowledge).

¹⁹⁴ See generally, For a thoughtful discussion of this issue, see Helfer (n 55).

¹⁹⁵ See, for example, Annual Report (2006) (n 99) at ¶ 3 (listing organizations granted observer status).

¹⁹⁶ See, for example, *Anheuser-Busch, Inc. v Portugal* Oct. 10 2005 (App. No. 73049/01) (Eur. Ct. H.R.) available at <http://cmiskp.echr.coe.int/tkp197/view.asp?action=html&documentId=787908&portal=hbkm&source=externalbydoctrnumber&table=1132746FF1FE2A468ACCBCD1763D4D8149>; see generally, L R Helfer ‘Toward a Human Rights Framework for Intellectual Property’ (2007) 40 *U.C. Davis L. Rev.* 971.

¹⁹⁷ See note 100.

¹⁹⁸ See, for example, Esty (n 2) at 1538.

¹⁹⁹ See, for example, S K Sell ‘The Quest for Global Governance in Intellectual Property and Public Health: Structural, Discursive, and Institutional Dimensions’ (2004) 77 *Temp. L. Rev.* 363. See also E Benvenisti & George W. Downs ‘The Empire's New Clothes: Political Economy and the Fragmentation of International Law’ (2007) 60 *Stan. L. Rev.* 595.

and at the end of the day, slow innovation. And CBD obligations do not even have the same user flexibilities available in TRIPS.²⁰⁰

Control over forum shopping is straightforward in domestic administrative contexts because all of the potentially relevant agencies are created by the same authority and that authority can, presumably, also definitively allocate responsibility. As important, there are courts to enforce the allocation chosen.²⁰¹ But analogous mechanisms have yet to be developed at the international level. There are, however, several possibilities. One is for nations creating a new intergovernmental organization to make the scope of that organization's exclusive authority a part of their negotiations and agree to bring all matters within that scope only to that forum. Other intergovernmental organizations would presumably have an incentive to honor these allocations as a matter of institutional comity—that is, in the expectation that their primary jurisdictional authority will also be protected from similar maneuvers. Alternatively, an international norm akin to *res judicata* might be developed so that once an issue is resolved in one forum, inconsistent obligations imposed by another intergovernmental organization will not be enforced (or can be ignored). In either case, however, compliance will remain a significant problem—especially in situations, where heavy-handed unilateral action or bilateral negotiation is possible.²⁰² A third option is to incorporate the work of one organization into the lawmaking of others. As noted earlier, the WTO already does this in connection with the Codex Alimentarius and standards set by the International Standards Organization; it has similar arrangements with other intergovernmental organizations.²⁰³ Joint consideration of overlapping issues prevents forum shopping and, at the same time, improves decisionmaking without sacrificing consistency.

A second concern relates to sovereignty. In order for the WTO to make active use of the capabilities of WIPO and the Council for TRIPS, members must abandon consensus decisionmaking and reconceive the decision to rely on agency action as an expression of—rather than a derogation from—sovereign authority. At a minimum, that would likely require a mechanism for assuring members that WIPO or TRIPS Council decisions will be implemented only when they are within the scope of the authority that members chose to delegate. As suggested earlier, one possibility is to rely on disputes over legislation that integrates new norms or authoritative interpretations—that is, to put the Appellate Body in charge of enforcing the limits on delegation by giving it jurisdiction to decide when the norm or authoritative interpretation is a construction of the Agreement or an amendment to it. Even with that check, the “agencies” would retain a wide area in which to work out accommodations of various interests. After all, TRIPS leaves many terms (“technology,” “inventive step,” “selling”) undefined and the flexibilities provide considerable additional leeway.

Another constellation of issues relates to questions of competence, participation, and accountability. While it is attractive to bring together the intellectual property expertise of

²⁰⁰ See generally, Safrin (n 124).

²⁰¹ See, for example, *Ricci v Chicago Mercantile Exchange* 1973 (409) U.S. 289; *United States v Western Pacific R.Co.* 1956 (352) U.S. 59; *Texas & Pacific R.R. v Abilene Cotton Oil Co.* 1907 (204) U.S. 426 (applying a theory of “primary jurisdiction.”).

²⁰² For examples regarding intellectual property, see note 27.

²⁰³ See text at note 138; Esty (n 1) at 1538 & n. 168 (giving the example of WTO reliance on the International Monetary Fund).

WIPO and the trade expertise of the TRIPS Council, it is necessary to take a closer look at the source of these institutions' knowledge bases. In both cases, there has been considerable suspicion that information is acquired selectively and mainly from strong protectionists. Both organizations tend to act in secret and neither has formal procedures for insuring broad stakeholder input. If international intellectual property law is to be developed through entities akin to administrative agencies, it is imperative to develop global administrative norms and, as important, a mechanism for insuring their application.²⁰⁴ These issues could be addressed by the Appellate Body. Before permitting the incorporation of a new norm or an authoritative interpretation, adjudicators ought to consider the procedures that the Council (and/or WIPO) used to formulate it. The high level of confidence produced by interpretations of open questions that are arrived at by experts, based on a comprehensive study of the issues, subject to broad input, and carefully reasoned, may also compensate for the loss of formal control and thus also serve to assuage sovereignty concerns.²⁰⁵

In addition to these governance norms, which were largely developed in domestic settings, special attention needs to be paid to the international context, where member states at very different levels of sophistication are pitted against each other.²⁰⁶ For example, the TRIPS Council is currently responsible for assisting members engaged in dispute resolution;²⁰⁷ that obligation should be broadened to help members pursue their interests in Council deliberations—during what is, essentially, agency rulemaking. Indeed, because one effect of TRIPS is to keep countries at a comparative *disadvantage* disadvantaged, there may be a special obligation in the intellectual property portion of the WTO Agreement to reach out to developing countries to make sure that transparency and participation objectives are measured from their perspective.²⁰⁸

Conclusion

Although adding intellectual property to the Uruguay Round may have been key to the establishment of the WTO,²⁰⁹ forcing intellectual property into a regime designed to promote free trade had unfortunate consequences for both the consumers and producers of innovative materials. The GATT worked well because reducing trade barriers is an unalloyed benefit: if the principle of comparative advantage is correct, then an engine that exerts continual downward pressure on tariffs will steadily improve social welfare. But intellectual property protection is much more complex. Domestic regimes have never considered maximal protection to be the optimal. Instead, the level of protection has varied over time—depending on the needs of

²⁰⁴ See Kingsbury, et al. (n 21) at 48.

²⁰⁵ See also Esty (n 2) at 1517 (noting that in the United States, good outcomes compensated for questions about the legitimacy of the administrative state).

²⁰⁶ Cf. Kingsbury, et al. (n 21) at 52 (suggesting that global administrative law must take account of the “imperial” dimension of intergovernmental institutions).

²⁰⁷ Article 68 of TRIPS.

²⁰⁸ Similarly, procedures are needed to develop new norms of substantive fairness in a global intellectual property system, where the incentives available through international protection weaken the case for extracting maximum returns from every local market. See e.g., M Chon ‘Intellectual Property “From Below”: Copyright and Capability for Education’ (2007) 40 *UC Davis L. Rev.* 803 (advocating consideration of distributive justice as a goal of international intellectual property law); G B Dinwoodie ‘Private Ordering and the Creation of International Copyright Norms: The Role of Public Structuring’ (2004) 1 *J. Institutional & Theoretical Econ.* 160 (suggesting ways in which the international context might shape substantive copyright law).

²⁰⁹ See, for example, Dreyfuss & Lowenfeld (n 5) at 276.

emerging and maturing industries, and over place—depending on the levels of national sophistication, access to education, and wealth. The TRIPS Agreement complicates the balancing process. In part, it was drafted in a manner conducive to strict interpretation, in part, it is largely interpreted by trade—not intellectual property—specialists, and in part, the WTO utilizes decisionmaking procedures that are incapable of responding quickly to changing circumstances. At best, the TRIPS Agreement is not producing the level of welfare benefits its negotiators envisioned. But it might be doing much worse: slowing progress, fostering deadweight loss, and preventing the poor from benefiting from the world’s intellectual achievements.

WIPO and the TRIPS Council are currently embarked on development agendas that promise to reshape the relationships between intellectual property and the public domain, between generations of innovators, and between producers and users of knowledge products. However, importing these developments into TRIPS presents new challenges. Although WIPO and the Council have, or are in the process of, developing considerable expertise in intellectual property, deliberations have been less than transparent and interest groups have experienced differing levels of access. To some extent, this may be changing: low protectionists in the North are increasingly allying with the South to improve their leverage. Moreover, the emerging Middle is nicely situated to identify and pursue new approaches. For these developments to feed into TRIPS, however, new institutional mechanisms are needed to protect sovereign interests and assure procedural and substantive fairness. The story of TRIPS is, in other words, a demonstration of the need for global administrative norms.

It may be tempting to see the problems of adapting TRIPS to the WTO as unique (as an example of what some call “IP exceptionalism”²¹⁰). But it is not. TRIPS became a part of the WTO framework partly because intellectual property is traded in an international marketplace, but also because decisions that one country makes about protection spill over to other nations—if Canada allows generic drug manufacturers to stockpile pharmaceuticals prior to patent expiration, the patent holder loses lead time around the globe; if the Netherlands permits peer to peer file sharing, everyone else enjoys free music as well;²¹¹ consumers who see a trademark in Paris expect it to have the same meaning in New York.²¹² There are other fields where spillovers also exist and where minimum standards are similarly desirable. Some of these may, like trade, represent situations where there is an optimum result that does not vary greatly temporally or geographically. Labor law and civil rights are arguably examples. But there are many places where the issues are complex and both technologically and culturally contingent, and where continual monitoring and adjustments will be required. In these situations, there will inevitably be a similar move to depend on “functional relationships” with other international bodies to foster expertise,²¹³ and thus a congruent need for global norms to govern their interactions.

²¹⁰ J F Duffy ‘Intellectual Property Isolationism and the Average Cost Thesis’ (2005) 83 *Tex. L. Rev.* 1077 at 1089.

²¹¹ See *Buma/Sterma v Kazaa BV* 2003 (2004) *Europ. Copyright and Design Rep.* 16 (Netherlands) (permitting music files to be shared); *Metro-Goldwyn-Mayer Studios Inc. v Grokster, Ltd.* 2005 (125) S.Ct. 2764 (holding proprietor of file sharing site secondarily liable for copyright infringement).

²¹² *Vaudable v Montmartre, Inc.* 1959 (193) N.Y.S. 2d 332 (Sup. Ct.)(right to the mark “Maxim’s”).

²¹³ See, for example, Lamy (n 86) at 980 (“the WTO encourages Members to negotiate norms in other international forums, which they will then implement coherently in the context of the WTO”); S Cassese ‘Administrative Law Without the State? The Challenge of Global Regulation’ (2005) 37 *N.Y.U. J. Int’l L. & Pol’y* 663 at 674-77.