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DIVERSIFYING WITHOUT DISCRIMINATING: COMPLYING WITH THE MANDATES OF THE TRIPS AGREEMENT

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Since the Patent Act was revised in 1952, patent law has expanded to cover an array of novel endeavors—new fields of technology (notably computer science and business methods) as well as the activities of researchers engaged in fundamental scientific discovery. These changes have been accompanied by shifts in the organizational structure of the technological community, with smaller firms and universities emerging as important players in the patent system, and by new marketplace expectations arising from consumer demand for interoperable technology and converging functionality. As a result of these developments, structural flaws in the legal order have become evident. Although the technological community was once fairly united in its needs, the recent debate over patent reform has made it clear that this is no longer the case. The broad patents available for basic science present different problems from those associated with the thickets of narrow rights awarded in fields where advances are incremental. Boutique firms with shifting alliances and universities with their spin-off enterprises rely on patents for reasons that are inapplicable to vertically integrated companies that bring research, development, and distribution under one roof. In some cases, a patent acquires value through technical superiority; in others, it does so because it covers a product that is incorporated into a standard or is subject to network effects, market tipping, or lock-in. There are also vast disparities in patent-to-product ratios. In some fields, like pharmaceuticals, the ratio is close to one (one patent covers one product). But in other areas, that ratio can be vastly higher or lower: for

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example, a single electronic product can require a multiplicity of patent licenses to bring to market;[1] at the same time, a gene patent can potentially give rise to a multitude of products.[2] In the last few years, it has become increasingly difficult to believe that a one-size-fits-all approach to patent law can survive.

There is no shortage of suggestions for making the legal environment responsive to the diverse experiences and demands of the technological community. Some suggestions rely on adjudication to accommodate such diversity. For example, Dan Burk and Mark Lemley have highlighted various policy levers that the courts could use to create a better fit between U.S. patent law and the technologies for which protection is sought.[3] Thus, they suggest that the standard of the person having ordinary skill in the art (PHOSITA) should be deployed more discerningly; they suggest that this approach could, for example, distinguish between emerging and mature technologies.

Other proposals depend on legislative initiatives tied directly to the features of innovation markets that warrant differential treatment. Drawing on Wes Cohen's work on discrete and complex product industries,[4] one can imagine law that differentiates on the basis of the patent-to-product ratio. Thus, where the ratio is high, and potential holdouts are a serious concern, special rules on remedies and compulsory licensing may be appropriate.[5] Where the ratio is extremely low, there may be a need to prevent patentees from dominating more of a field than they can efficiently exploit. Similarly, when a market is characterized by network effects, compulsory licensing may be necessary to assure that all competitors and potential entrants have access to the patented technology at fair and reasonable rates.[6]

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1. CLARK, J. ET AL., U.S. PATENT & TRADEMARK OFFICE, PATENT POOLS: A SOLUTION TO THE PROBLEM OF ACCESS IN BIOTECHNOLOGY PATENTS? 14–15 (2000).

2. *See, e.g.*, Helen M. Berman & Rochelle C. Dreyfuss, *Reflections on the Science and Law of Structural Biology, Genomics, and Drug Development*, 53 UCLA L. REV. 871 (2006).

3. *See* Dan L. Burk & Mark A. Lemley, *Is Patent Law Technology-Specific?*, 17 BERKELEY TECH. L.J. 1155 (2002); Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 VA. L. REV. 1575 (2003). In turn, of course, the Patent and Trademark Office (PTO) would be expected to apply the differentiated standards articulated by the courts.

4. Wesley M. Cohen, Richard Nelson, & John P. Walsh, *Protecting Their Intellectual Assets: Appropriability Conditions and Why U.S. Manufacturing Firms Patent (or Not)*, Nat'l Bureau of Econ. Research, Working Paper No. 7552, 2000; Wesley M. Cohen et al., *R&D Spillovers, Patents and the Incentives to Innovate in Japan and the United States*, 31 RESEARCH POLICY 1349 (2002).

5. Carl Shapiro, *Navigating the Patent Thicket: Cross Licenses, Patent Pools, and Standard-Setting*, *in* 1 INNOVATION POLICY AND THE ECONOMY 119 (Adam B. Jaffe et. al. eds., 2001).

6. *See, e.g.*, Rochelle Dreyfuss, *Unique Works/Unique Challenges at the Intellectual Property/Competition Law Interface*, *in* EUROPEAN COMPETITION LAW ANNUAL 2005—THE INTERACTION BETWEEN COMPETITION LAW AND INTELLECTUAL PROPERTY LAW (Claus-

There are also suggestions for intervention along administrative lines, through the laws and agencies that regulate industrial sectors where a one-size system causes special problems. For instance, Rebecca Eisenberg has suggested that the data-exclusivity regime administered by the Food and Drug Administration (FDA) might be used as a substitute for patent protection.[7] Using a separate institutional device for different industrial sectors could help break the impasse in patent reform caused by the widening gap between the needs of the pharmaceutical industry and the demands of the information technology sector.

The ability of national courts, legislators, or administrators to tailor patent protection to reflect the differing concerns of different industries is, however, circumscribed by international intellectual property obligations, most notably by the TRIPS Agreement.[8] In previous articles, we have urged an interpretation of the TRIPS Agreement that recognizes that the demands of innovation policy vary among countries and over time, and suggested that WTO dispute settlement panels offer broad latitude to member states to implement their core TRIPS patent obligations in ways that optimize protection as circumstances change.[9] In many cases, we see the compliance issue as not *whether* industry-specific patent laws can be adopted, but *the ways* in which these rules are structured.

We begin with some background. The TRIPS Agreement contains two types of provisions that constrain national choices. First, it articulates a series of substantive minimum levels of patent protection that WTO members are obliged to provide. For example, the term of patents must endure for at least twenty years from the date an application is filed.[10] Even these provisions are not, however, absolute; rather, they offer several opportunities for tailoring. For instance, there are provisions that allow member states to reflect order public, or deal specially with

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Dieter Ehlermann & Isabela Atanasiu, eds., 2006), *available at* http://papers.ssrn.com/sol3/papers.cfm?abstract_id=763688.

7. Rebecca S. Eisenberg, *The Shifting Functional Balance of Patents and Drug Regulation*, 20 HEALTH AFFAIRS 119 (2001).

8. Agreement on Trade-Related Aspects of Intellectual Property Rights vol. 31, Apr. 15, 1994, 33 I.L.M. 81 [hereinafter TRIPS Agreement].

9. *See* Graeme B. Dinwoodie & Rochelle C. Dreyfuss, *Patenting Science: Protecting the Domain of Accessible Knowledge*, *in* THE FUTURE OF THE PUBLIC DOMAIN IN INTELLECTUAL PROPERTY (Lucie Guibault & P. Bernt Hugenholtz eds., 2006); Graeme B. Dinwoodie & Rochelle C. Dreyfuss, *TRIPS and the Dynamics of Intellectual Property Lawmaking*, 36 CASE W. RES. J. INT'L L. 95 (2005); Graeme B. Dinwoodie & Rochelle C. Dreyfuss, *WTO Dispute Resolution and the Preservation of the Public Domain of Science Under International Law*, *in* INTERNATIONAL PUBLIC GOODS AND TRANSFER OF TECHNOLOGY UNDER GLOBALIZED INTELLECTUAL PROPERTY REGIME, (Keith E. Maskus and Jerome H. Reichman eds., 2006); Graeme B. Dinwoodie & Rochelle C. Dreyfuss, *International Intellectual Property Law and the Public Domain of Science*, 7 J. INT'L ECON. L. 431 (2004).

10. TRIPS Agreement, *supra* note 8, art. 33.

therapies, microorganisms, and plants.[11] Indeed, the scope of the patent section of the Agreement as a whole provides members with some flexibility in that it applies only to inventions "capable of industrial application."[12] Second, TRIPS constrains national lawmakers through a series of structural provisions that appear to cut across the entire patent system. For example, under Article 3, protection must be offered on a national treatment basis, and Article 4 requires that member states provide protection on a most-favored nation basis. These structural provisions are essentially provisions prohibiting discrimination.[13]

Unfortunately, Article 27 of the TRIPS Agreement appears to destroy this nice dichotomy. Its requirement that "patents shall be available and patent rights enjoyable without discrimination as to the . . . field of technology," does not fall neatly into either category. The travaux préparatoires of the TRIPS Agreement emphasize that the provision was intended to guarantee protection for a variety of subject matter previously unprotected by patent rights in many countries.[14] In this regard, it looks like a substantive minimum provision relating to subject matter. But because the provision is cast in terms of nondiscrimination, it can also be interpreted as structural. This ambiguity came to a head in Canada–Protection of Pharmaceuticals Patents,[15] when a dispute settlement panel of the WTO gave Article 27 broad structural effect, and required exceptions to patent protection in Canadian law to comply not only with the demands of Article 30, which explicitly regulates permissible exceptions from patent protection, but also with Article 27's protection against technology-based discrimination.

To be sure, there are normative reasons to support this interpretation. It essentially turns Article 27 into a pre-commitment strategy, binding members to trans-substantive patent law as a way to prevent industries

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11. TRIPS Agreement, *supra* note 8, art. 27(2).

12. TRIPS Agreement, *supra* note 8, art. 27(1).

13. *See, e.g.*, Panel Report, *European Communities—Protection of Trademarks and Geographic Indication for Agricultural Products and Foodstuffs*, WT/DS174/R (Mar. 15, 2005) [hereinafter EC–GI]. In the EC–GI case, the issue was whether the EC discriminated against non-EC nationals by making recognition of geographic indications contingent on receiving a domestic certification from the home country of the non-EC national. Although it would be difficult to obtain a certification in a nation that lacks the investigatory machinery required by the EC regulation, the EC argued that the condition for protection was not discrimination against *nationals* because anyone seeking a geographical indication that references an EC locality can utilize the EC system. Nonetheless, the Panel found the system discriminatory, reasoning that the TRIPS Agreement requires "effective equality of opportunities" and focuses on "actual effects of the contested provisions in the marketplace."

14. Report of WTO Dispute Settlement Panel, *Canada–Patent Protection of Pharmaceutical Products*, ¶ 4.6 n. 27, WT/DS114/R (March 17, 2000) [hereinafter Canada–Pharmaceuticals].

15. *Id.*

from dissipating resources by demanding special forms of protection. While such an objective has much to recommend it and a panel has noted with some approval the notion of TRIPS as a check on certain domestic political pressures (such as anti-foreigner legislation),[16] it is far from clear that the TRIPS Agreement was actually meant to protect the structure of any particular domestic political economy. Indeed, the effect that TRIPS might have on domestic political structures is quite complex. The combined effect of giving strict international scrutiny to legislation impinging on producer interests while leaving domestic legislatures with considerable discretion over abrogating user interests is that legislative deals tend to unravel, and to do so in only one direction: a direction that favors the owners of intellectual property. The best example here is one drawn from copyright, where the United States lengthened the copyright term and at the same time, added new exemptions for playing music in Irish (and other) bars. The Irish bar provision was struck down by the WTO in the US–110(5) case,[17] but the term extension was upheld in *Eldred v. Ashcroft*.[18] International rules that give members more flexibility would at least avoid the unidirectional unraveling problem. Furthermore, a "light" ban on de facto discrimination—one that permits a member to justify its actions—may be enough to prevent the more egregious forms of rent seeking while still allowing states to tailor their law effectively.

Additionally, requiring exemptions to be available for all forms of technology as a matter of international law could distort domestic law by inducing national legislators to adopt exemptions that are broader than necessary. This outcome would also conflict with the basic thrust of Article 30, which expressly requires any given exemption to be "limited." A targeted exemption that differentiated between different types of invention would limit a patentee's rights only in areas where there was a perceived imbalance between public and private rights.[19] A formalist over-commitment to technological neutrality is inconsistent with this purposive reading of the TRIPS Agreement. In the end then, for these and a series of other reasons that we have written about at length, we think the Panel was wrong to subject exemptions to the technological neutrality condition.

But even if one were to accept the possibility that the Canada–Pharmaceuticals panel reached the right conclusion and that Article 27 is in some respects structural, strong arguments can be made that there is

16. *Id.*

17. Panel Report, *United States – Section 110(5) of the US Copyright Act*, WT/DS160/R (Jun. 15, 2001).

18. 537 U.S. 186 (2003). *See generally*, Dinwoodie & Dreyfuss, *TRIPS and the Dynamics of Intellectual Property Lawmaking*, *supra* note 9.

19. *See* Dinwoodie & Dreyfuss, *WTO Dispute Resolution*, *supra* note 9, at 876–877.

still considerable room for tailoring. Thus, the language of the provision itself may contain latitude to create some level of differentiation. Over the past ten years, arguments grounded in text have proved to have immense attraction to the WTO dispute settlement body in TRIPS cases. Thus, attention to text may, for example, support Brian Kahin's suggestion that the "availability" of patent rights should be regarded as subject to more stringent anti-discrimination scrutiny than the "enjoyment" of patent rights.[20] Certainly, the basic purpose of Article 27 was focused on wholesale exclusions, which seems to suggest that its "availability" provisions should receive more serious international examination. We, however, do not think it is plausible to parse Article 27 in this way: from a grammatical standpoint (if nothing else), it is difficult to have confidence that the legal effect of "availability" and "enjoyment" can be separated.

Instead, we propose that any interpretation of Article 27 should require greater attention to the term "discrimination."[21] Discrimination is not the same as differential treatment.[22] The Canada–Pharmaceuticals panel acknowledged that "Article 27 does not prohibit bona fide exemptions to deal with problems that may exist only in certain product areas."[23] We see at least three arguments that support such differential treatment. First, as suggested earlier and as the pieces in this volume attest, different sectors experience different problems within the current patent system. Under a normal meaning of the term "discrimination," treating different cases differently is not discrimination. For example, it may not be discrimination to create exceptions to broad patents out of the concern that they dominate too broad a swath of the technological frontier, while giving the holder of a narrow patent the right to exploit the entire domain of his claim. At the end of the day, the value of the exclusivity offered to different technologies is similar.

Second, we note that many of the proposals for tailoring are not aimed at the nominal legal rights created by patent law, but rather at the economic effects of these patents: for example, the transactional costs

20. Brian Kahin, *Patents and Diversity in Innovation*, 13 MICH. TELECOMM. TECH. L. REV. 389 (2007).

21. The panel almost invites this line of analysis in Canada–Patent Pharmaceuticals, when it declined to provide a comprehensive definition of "discrimination" within the meaning of art. 27, but instead sought to "define the concept of discrimination to the extent necessary to resolve [the issued raised before the panel.]" Canada–Pharmaceuticals, *supra* note 14, at ¶ 7.98.

22. *Cf. id.* at ¶ 7.94 (noting the dangers of assimilating "discrimination" and "differential treatment" while suggesting that discrimination can result from nominally identical treatment, and differential treatment might be justified). *See also id.* at ¶ 7.101 (listing issues arising in cases of de facto discrimination).

23. Canada–Pharmaceuticals, *supra* note 14, at ¶ 7.92.

associated with patent thickets or the holdouts possible when many patents are required to bring a product to market. Differentiation targeted at such effects arguably finds explicit support in the Canada–Pharmaceuticals report.[24] In that case, the EU argued that Canada was interfering with the internationally guaranteed rights of patentees by intruding upon the ability of pharmaceutical companies to retain a measure of exclusivity after patent expiration. Specifically, the EU claimed that generic manufacturers should not be permitted to conduct the tests necessary for regulatory review during the patent term because those activities allowed the generics to come to market as soon as the patent expired, thus destroying the lead time advantage the (ex-) patent holder would otherwise enjoy. The panel rejected the argument. Post-term exclusivity was not the "natural or normal consequence" of enforcing patent rights. Rather, it was a product of the combination of patent law and regulatory approval that the panel saw as a commercial or economic effect, instead of a legal effect, and thus not the type of exploitation TRIPS was intended to protect.

Admittedly, rejecting the relevance of effects in assessing compliance with international patent obligations could—if extended too broadly as an interpretive device—undermine our own efforts in certain circumstances to assess and justify discrimination by reference to marketplace effects.[25] On the other hand, if we read the report more narrowly and confine it to its core holding, it can be understood simply as saying that benefits flowing from non-patent law realities (such as alterations in industry structure or changing relationships between science and technology) cannot be the basis for a claim of guaranteed rights. This latter interpretation, which is more favorable to our argument that we can look at the overall and net effects of a tailored system, is consistent with the idea that the TRIPS Agreement is aimed primarily at ensuring minimum rights.

A third argument allowing for the development of industry specific laws focuses on the nature of the discrimination. In the Canada–Pharmaceuticals report, the panel rejected the argument that Canada's regulatory review exception was technology-specific.[26] Any patent in an industry that was subject to marketing approval would be subject to the challenged exception. Thus, the Canadian exception was not regarded as

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24. Canada–Pharmaceuticals, *supra* note 14, at ¶ 7.57–58 (discussing normal exploitation under Article 30).

25. *Cf.* Dinwoodie & Dreyfuss, *TRIPS and the Dynamics of Intellectual Property Lawmaking*, *supra* note 9, at 112–113 (arguing "that adjudicators should take into account how changing social practices and new technological opportunities alter the balance of protection accorded to innovative works").

26. Canada–Pharmaceuticals, *supra* note 14, at ¶ 7.102.

effecting a de iure discrimination. Of course, the analysis did not stop there; the panel's report must also be read as prohibiting de facto discrimination.[27] However, it does so only in specific circumstances—when the claim includes some additional element, such as an allegation of intent to discriminate.[28] We think it is entirely appropriate that those claiming de facto discrimination should be required to demonstrate some element over and above those required to establish de iure cases of discrimination.

But what is the extra element? The Canada–Pharmaceuticals panel does not give us a definitive answer. The panel clearly thought that purpose was relevant. In some passages, the panel imposed a burden on the complainant to demonstrate that the application of a law in a facially neutral manner was a sham.[29] Were that the sole means of proving de facto discrimination, the various forms of tailoring discussed in this conference would likely survive scrutiny. However, the panel also suggested that the complainant could show that "objective indications of purpose demonstrated a purpose to impose disadvantages on [particular industries]".[30] Whatever that formulation means, a broad reading appears to endanger all forms of tailoring since they are all intended to effects different industries differently. Further, such an approach appears to collapse de iure and de facto claims.

We suggest that those defending an exclusion as compliant with Article 27 should be permitted to rebut a showing of disparate treatment by demonstrating a legitimate purpose.[31] We think that this is consistent with Article 1(1) of the TRIPS Agreement, which gives countries deference as to the means by which they implement the general purposes of the TRIPS Agreement. As has been suggested, TRIPS to some extent assumes the character of a "constitutional" international law or a "basic law." In a number of countries, constitutional law has developed a vari-

27. This interpretation of TRIPS Article 3 does not dictate that panels take the same approach to *technological* discrimination in the context of Article 27. National treatment implicates foundational aspects of the WTO system, and any derogation from it is inherently suspect. This is not true of Article 27; technological differentiation can in fact effectuate the purposes of the Agreement. To put this another way, the EC–GI panel was trying to avoid protectionism, but the goal of tailoring is not to protect local markets from foreign competition: it is intended to make local marketplaces work more efficiently for everyone. Thus, it is by no means clear that nondiscrimination among peoples (certainly a goal of public international law and the focus of the EC–GI case) and nondiscrimination among technologies (per the panel's interpretation of Article 27) are objectives of equal importance to the international intellectual property system.

28. Canada–Pharmaceuticals, *supra* note 14, at ¶ 7.105.

29. *Id.* at ¶ 7.104.

30. *Id.* at ¶ 7.105.

31. *Cf id.* at ¶ 7.94 (noting that the "standards by which the justification for differential treatment is measured are a subject of infinite complexity").

ety of tests to assess whether there is a sufficient means-ends nexus to support a statute. For example, one could consider whether the stated objectives behind the law were in any way furthered by the legislative means chosen, or whether it was a rational means, or a particularly appropriate means, or a well-tailored means, or the least burdensome means, of pursuing these objectives.

At the very least, we believe that panels may need a way to evaluate the relation between the stated purpose and the means chosen.[32] Thus, differentiation might be satisfied by, for example, demonstrating a close linkage between the exclusion and the particular change in organizational or institutional structure in the country in question. An example might be a law tailored to deal with the problems created by the decision to extend patenting to fundamental research, or the unique problems encountered when patents serve functions other than protection from free-riding.[33] Developing this type of analysis would also open up space to incorporate the economic and empirical work described in this volume, furthering Brian Kahin's call for patent law to expand its horizons in developing policy.[34]

Given that analysis, it is evident that the TRIPS Agreement leaves ample room for a member state to adopt most of the initiatives discussed at the outset. Lemley and Burk's legally neutral rules, applied though adjudication, certainly appear to survive challenge. Legislatively constructed industry-specific rules could also be sustained if they were framed in a similarly neutral manner. For example, rules that changed the remedies available for infringement could past muster if proxies for the targeted technologies, such as "discrete product industries" and "complex product industries," were utilized. Indeed, the Canada–Pharmaceuticals panel implicitly permitted use of such a conceptual proxy when it was willing to analyze the Canadian law as being about inventions "subject to marketing approval."[35] The pharmaceutical industry was what Canada meant, but that is not what the statute said, and the panel approved it on that basis.

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32. Of course, it might be argued that had such an assessment been expected, the drafters would have written the standard into the Agreement. *Cf.* Agreement on Technical Barriers to Trade, art. 2(2), Apr. 15, 1994, WTO Agreement, Annex 1A, Legal Instruments–Results of the Uruguay Round, vol. 27 (1994), http://www.wto.org/English/docs_e/legal_e/17-tbt.pdf (requiring a member state to show that the measure in question was the least trade–restrictive possible, etc.).

33. This would include the so-called trolling problem, *see* Carol M. Nielsen & Michael R. Samardzija, *Compulsory Patent Licensing: Is It a Viable Solution in the United States*, 13 MICH. TELECOMM. TECH. L. REV. 509 (2007).

34. Kahin, *supra* note 20.

35. *Cf.* Canada–Pharmaceuticals, *supra* note 14, at ¶ 7.99.

Nor is this merely semantics. Thus, it has been suggested that the differentiation between complex and discrete product industries is artificial because even pharmaceuticals (the quintessential discrete products) are susceptible to multiple claiming strategies.[36] To be sure, this move would turn the pharmaceutical industry into a complex product industry.[37] But if that happened, then presumably the pharmaceutical industry would begin to experience the transaction costs and holdout problems that currently plague information technologies. If so, then a conceptually neutral rule would prove its value: there would be no need to plead for special legislation when a readily available solution is already on the books.[38]

By the same token, special rules for industries subject to network effects, standard setting, or lock-in should be acceptable. If the special rule were intended to limit the exclusivity that is derived from the network effect—the tipping of the market in favor of the patented product—then what the Canada–Pharmaceuticals panel had to say about disregarding commercial effects that do not arise solely from the patent would presumably be relevant. After all, the value derived from a tipped market (from being included in a standard or a network) is not a predictable part of the marketing opportunities produced by the patent. Since it would not be a legal effect (not a part of the patentee's "normal" market), there may be ways in which members are free to cut it back.[39]

Initiatives to deal with the industries in which the patent/product ratio is less than one could presumably be analyzed in the same way. Here is an area where there is a live example: Germany recently enacted a special rule to deal with the broad scope of gene patents. Under the new provision, a gene patent creates an exclusive right over the uses recited in the application, but permits the public to otherwise utilize the gene

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36. Robert A. Armitage, Comment, *The Myth of Inherent and Inevitable "Industry Differences": "Diversity" As Artifact in the Quest for Patent Reforms*, 13 MICH. TELECOMM. TECH. L. REV. 401 (2007).

37. *Cf.* Cohen et al., *R&D Spillovers*, *supra* note 4 (describing how a discrete product industry in the United States can be complex in Japan because of differences in claiming norms).

38. The public choice effects of different interpretations of TRIPS are hard to assess. *See* Dinwoodie & Dreyfuss, *TRIPS and the Dynamics of Intellectual Property Lawmaking*, *supra* note 9. But the Canada–Pharmaceuticals panel was receptive to the idea that some of the provisions of the Agreement were designed to bolster domestic political structures in ways that minimize counterproductive pressures that public choice theory could predict in a global system still largely effectuated through national political institutions. *See* Canada–Pharmaceuticals, *supra* note 14, at ¶ 7.92 (noting the plausibility of the EC's argument that some of the provisions of TRIPS might have been intended to "ensure that governments do not succumb to [certain] domestic pressures").

39. Members would not have complete discretion. For example, we doubt that they could curtail the term of a patent. Article 33 makes the required term crystal clear. *See* TRIPS Agreement, *supra* note 8, art. 33.

free of the patentee's control.[40] As framed, this provision clearly carves out biotechnology inventions for special treatment. If challenged, Germany is likely to have a difficult time defending this law.[41] Nonetheless, the problems associated with a patent-to-product ratio far below one are arguable severe: the patentee acquires rights out of proportion to what it invented.[42] Further, the patent can dominate a range of applications far broader than it has the knowledge to exploit. Framing a statute so that it is neutrally applied in every case in which the ratio is less than one (a term like "discrete" or "complex" has yet to be invented) could pass muster, if it is sufficiently limited.

A harder case is presented by proposals to deal with the special needs of a particular industry through administrative agencies (such as the FDA) that regulate the industry in question. First, it is not always the case that the desirable variations in the patent system will be coextensive with a particular industrial sector. For example, product-to-patent ratios can be high for some products in an industry, but not for others. Using the scope of regulatory authority over an industry as the proxy for differentiation may fail to effectuate the domestic patent objective; it may be both under- and over-inclusive and thus could weaken the nexus between ends and means. Second, surely a measure cannot evade review by the simple expedient of placing it in nonpatent legislation (for example, by burying it somewhere in the U.S. code other than title 35). Indeed, the trademark measures challenged in the so-called Havana Club case were not part of the U.S. intellectual property statutes, but the WTO nonetheless analyzed the restrictions on Cuban marks under the TRIPS Agreement.[43] Furthermore, it may be significant that the TRIPS Agreement specifically provides leeway for antitrust authorities, but not for other administrative agencies, to pursue their regulatory objectives notwithstanding intrusion upon the rights otherwise guaranteed by the TRIPS Agreement.[44] Nonetheless, it seems to us that the presence of a regulation within a broader regulatory scheme, such as food and drug

40. Patentgesetz [PatG] [Patent Law] May 5, 1936, Reichsgesetzblatt [RGBl II], 117, as amended, § 1a, ¶ 4.

41. The German law, which bars the patentee from controlling any use other than those found at the time of the application, may be too broad to qualify under Article 30, even if it can survive Article 27's technological neutrality requirement. *Id.*

42. *See* NUFFIELD COUNCIL ON BIOETHICS, THE ETHICS OF PATENTING DNA 13 (2002), *available at* http://www.nuffieldbioethics.org/fileLibrary/pdf/ theethicsofpatenting-dna.pdf (last visited Oct. 31, 2005) (suggesting that the returns from genomic patents far exceed the technical contribution made by the patentees).

43. Panel Report, *United States–Section 211 of the Omnibus Appropriation Act of 1998*, WT/DS176/R (Aug. 6, 2001).

44. *See, e.g.*, TRIPS Agreement, *supra* note 8, art. 31(k).

law, can furnish powerful support for a claim of a rational relationship to legitimate purposes.

CONCLUSION

Certainly, there are many valid critiques of international lawmaking: there are issues of both transparency and institutional capture. Nonetheless, we take seriously and give weight to the normative claims of the TRIPS Agreement to facilitate and enhance free trade. But we think that industry-specific patent laws are fully consistent with the comparative advantage philosophy that undergirds the modern trade regime. After all, national patent laws reflect local technological capacity. For example, a nation whose comparative advantage lies in upstream research may want to patent fundamental discoveries, but one that specializes in manufactured products may wish to put fundamental discoveries in the public domain while providing strong protection to end products. By the same token, a nation that excels in complex product industries will want to fashion law that deals with the problems that complexity creates. A rigid requirement that each member treat all fields alike potentially interferes with a nation's ability to fully develop its own technological possibilities.

Admittedly, it could be argued that the TRIPS Agreement is designed to prevent nations from instantiating advantages through their patent laws. However, wide-ranging legal advantages persist under the WTO. For example, banking and securities laws make it easier for entrepreneurs to attract capital, and labor laws make it easier for employers to keep prices down. Until all the laws relevant to trade are harmonized, it is anomalous to read such inflexibility into the TRIPS Agreement, especially when it has such strong potential to undermine the WTO's capacity to increase social welfare. A better approach is to view TRIPS as an effort to create an efficient marketplace and to treat its minimum substantive requirements as safeguards against one country using its patent law to undermine the industrial policy of another. If TRIPS needs an overarching goal and an interpretive principle to identify the limits on tailoring, then efficiency-of-trade recommends itself as the right focus.