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INTERNATIONAL INTELLECTUAL PROPERTY LAW AND THE PUBLIC DOMAIN OF SCIENCE*

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ABSTRACT

The TRIPS Agreement can be read to reflect a static view of the structure of intellectual property law. In this paper, we address whether – and how – the TRIPS Agreement can, on the other hand, be read with more fluidity, and thus to allow adjustments in national intellectual property regimes designed to reflect the dynamic nature of information production. To focus that inquiry, we concentrate on efforts to ensure a broader public domain for 'upstream' inventions by modifying various elements of US patent law. The paper considers three stylized examples and asks whether each approach could be adopted by the United States without falling afoul of the TRIPS Agreement as it is currently understood. Our purpose is to identify interpretive approaches that allow member states to keep their laws attuned to the developments and needs of science. But in so doing, we also raise broader questions regarding the level of formalism generated by the WTO dispute settlement system, and the extent to which the TRIPS Agreement allocates power between supranational and national institutions, and between international and national laws.

INTRODUCTION

The size and content of a rich public domain are affected by a constellation of national intellectual property rules. Since 1995, these domestic rules have, in WTO-member states, been subject to the requirements of the Agreement on

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Trade Related Aspects of Intellectual Property (the TRIPS Agreement),[1] which thus serves to regulate on an international level the ways in which member states can shape the content of the public domain. At the time the TRIPS Agreement was negotiated, the main focus of attention was on codifying then agreed-upon norms of protection. As a result, the Agreement can be read to reflect a static view of the structure of intellectual property law. In this article, we address whether – and how – the TRIPS Agreement can be read with more fluidity, in order to allow adjustments in national regimes designed to reflect the dynamic nature of information production.

To focus that inquiry, we concentrate on efforts in United States patent law to ensure a broader public domain for 'upstream' inventions, that is, for discoveries so directly related to fundamental principles that they dominate broad swathes of inventive opportunities. The expansion of patentable subject matter to include upstream inventions has led concerned observers to suggest that other elements of patent law must be modified in order to re-create public-domain space in which work can be undertaken in accordance with traditional scientific norms.[2] *Expanding* the categories or the scope of protectable subject matter in domestic law comports with a basic premise of the TRIPS Agreement, which leaves considerable discretion to member states to provide protection in excess of mandated minimum levels.[3] But these proposed modifications, by *contracting* protection, would arguably raise TRIPS-compliance concerns, and bring into question the resilience of the Agreement.

Evaluating a broad range of possible modifications in domestic law would allow us to fully probe the provisions of the TRIPS Agreement to see which are most hospitable to protecting the public domain of science. At this point, however, we look at only three stylized examples. These are: (1) excluding certain discoveries from the subject matter of eligible patent protection; (2) creating a statutory exemption that gave courts discretion to permit unauthorized uses of sufficient social significance; and (3) varying the right to relief. This article asks whether each approach could be adopted by the United States without falling afoul of the TRIPS Agreement as it is currently construed. Our purpose is not to predict the outcome of future disputes – there are far too few precedents for that. Rather, our goal is to identify interpretive approaches that allow members to keep their laws attuned to the developments and needs of science.

[1] Agreement on Trade-Related Aspects of Intellectual Property Rights, 15 April 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, Legal Instruments – Results of the Uruguay Round, vol. 31, 33 I.L.M. 81 (1994).

[2] See below text accompanying nn 4–7.

[3] See Pamela Samuelson, 'Intellectual Property Arbitrage: How Foreign Rules Can Affect Domestic Protection', in *International Public Goods*, above n *.

I. UPSTREAM PATENTING AND ITS RELATIONSHIP TO TECHNOLOGICAL PROGRESS

At one time, science was considered distinct from technology, and intellectual property law was predicated on the existence of an analogous doctrinal boundary between basic and applied research.[4] Increasingly, however, United States patent law recognizes private claims to core principles of knowledge that are of special significance to basic research. This may simply reflect the science-intensive nature of modern technology, which makes recent advances inherently dual in character, or changes in the organization of science, including the emergence of research organizations (such as universities) that look to patent rights to support fundamental research. Whatever the cause, patent protection has moved upstream.[5]

The net result is troublesome. Patents may now confer power not only in *product* markets,[6] but also in *innovation* markets. As such, these patents can have broad significance. Because second comers can often invent around end-use inventions, patents rarely monopolized product markets. In contrast, a patent on, say, the structural information of a protein, or on a metabolic pathway, or a computer operating system, could give the patentee control over all work involving that protein or pathway, or all opportunities to create applications of that system. As a result, there is growing evidence suggesting that – at least in the United States – patent rights over research opportunities have begun to hinder progress by chilling innovation and impeding the production of new knowledge.[7]

II. HYPOTHETICAL SOLUTIONS AND THEIR INTERNATIONAL IMPLICATIONS

These developments give rise to many difficult questions for patent policymakers. In this article, however, we ask a very specific question: what can national legislators who perceive a problem do to fix it, consistent with their countries' international obligations under the TRIPS Agreement?

[4] See *Funk Bros. Seed Co.* v *Kalo Inoculant Co.*, 333 U.S. 127, 131 (1948) (holding that packets containing mixtures of bacteria were 'no more than the discovery of some of the handiwork of nature' and hence unpatentable); *Brenner* v *Manson*, 383 U.S. 519 (1966) (defining the utility required for patent protection as end-use rather than research-use utility). See also *O'Reilly* v *Morse,* 56 U.S. (15 How.) 62 (1853) (holding that abstract principles are not statutory subject matter).

[5] See, e.g., *Diamond* v *Chakrabarty*, 447 U.S. 303 (1980); *State Street Bank & Trust Co.* v *Signature Financial Group, Inc.*, 149 F.3d 1368 (Fed. Cir. 1998), *cert. denied*, 119 S.Ct. 851 (1999).

[6] In this context, product market means the market for products, processes, and the products of processes.

[7] See, e.g., Rebecca S. Eisenberg, 'Bargaining over the Transfer of Proprietary Research Tools: Is This Market Failing or Emerging?', in Rochelle Dreyfuss, Diane L. Zimmerman, and Harry First (eds), *Expanding the Boundaries of Intellectual Property: Innovation Policy for the Knowledge Society* (2001); Carlos M. Correa, 'Internationalization of the Patent System and New Technologies', 20 Wis. Int'l L.J. (2002) 523, 528.

A. Subject matter exclusions

The most direct way to deal with the problem of upstream patenting might be to define patentable subject matter in a way that excludes inventions with significant upstream applications from eligibility for protection. This approach could be implemented across the board, or limited to areas where evidence suggests that the chill to research is potentially great. For example, Richard Epstein has suggested that the 'use value' of patents – their value in product markets – should be compared to their 'blocking' value – their upstream significance in innovation markets. When the blocking value exceeds the use value, inventions within the subject area should not be considered patentable.[8] He gives the example of expressed sequence tags (ESTs), short sequences of coding DNA, noting that while the useful applications of ESTs barely meet the utility standard of current patent law, '[e]ach EST is a gateway to some gene on which useful work could be done.' Since the primary use of a patent on an EST would thus be to block others from entering that gateway, Epstein argues that such patents should not be issued.

John Barton takes a different approach. He would exclude specific subject areas where this problem becomes acute. An example is proteomics – information about the shape of the body's protein molecules that is crucial to understanding and predicting how the body will respond to pharmaceutical interventions.[9]

We ask whether such carve-outs would meet the requirements of Article 27.1 of the TRIPS Agreement, which provides that, subject to defined exceptions, 'patents shall be available and patent rights enjoyable without discrimination as to the ... field of technology?'[10] To analyze that question, one can usefully distinguish between *de iure* and *de facto* forms of discrimination. In the former situation, specific fields of technology are carved out for special treatment; in the latter, rules that are facially neutral have disparate effects on particular subject areas.

The language of Article 27 is clearly aimed at prohibiting *de iure* discrimination with respect to the availability and enjoyment of patent rights. The drafting history of the Agreement is replete with indications that a primary concern of the negotiators was to eliminate blanket exclusions of certain types of patentable subject matter (most notably drugs, agrochemicals and foodstuffs).[11] A subject matter exclusion directed at biotechnology generally, or at specific areas within biotechnology, such as proteomics, would thus almost certainly run afoul of the Agreement.

[8] Richard A. Epstein, 'Steady the Course: Property Rights in Genetic Material', in F. Scott Kieff (ed), *Perspectives on Properties of the Human Genome Project* (2003) at 153, 168–88.

[9] John H. Barton, 'United States Law of Genomic and Post-Genomic Patents', 33 Int'l Review of Indus. Prop. & Copr. L. (IIC) (2002) 779–910.

[10] TRIPS Agreement, above n 1, art. 27.1.

[11] See Canada – Patent Protection of Pharmaceutical Products, WT/DS114/R (Report of WTO Dispute Settlement Panel, 2000) ('*Canada – Pharmaceutical Products*'), at ¶ 4.6 n 27.

An approach that comes conceptually closer to Richard Epstein's suggestion is, however, more difficult to analyze. Facially, the provision is neutrally drawn – it would bar patents on discoveries of predominantly upstream significance in every field of technology. Nonetheless, it would more profoundly affect biotechnology and computer science than, say, chemistry or mechanical engineering. While this effort to define patentable subject matter so as to exclude protection for inventions with significant upstream applications does not directly implicate the motivating rationale for Article 27.1, its potentially disparate effect on different fields could conceivably fall afoul of the literal text of Article 27.

Thus far, there have been no decisions directly addressing subject matter exclusions under Article 27, but we inform our analysis with the observation that WTO panels tend to hew closely to text when resolving disputes.[12] The panel in *Canada – Pharmaceutical Products* considered Article 27 in the course of reviewing the TRIPS consistency of two exemptions that Canada had enacted in its patent law. One of these, the so-called regulatory review exemption, permitted use or manufacture of a patented invention solely for purposes of obtaining regulatory approval. The intent was apparently aimed at promoting competition between generic and proprietary pharmaceuticals by facilitating market entry by generics at the moment of patent expiration. While the exemption was expressed in technologically neutral language, the European Union argued that its impact on the pharmaceutical industry violated Article 27.1 under, essentially, a disparate impact theory.

The WTO panel rejected the EU's specific contention, but only after Canada assured it that the exemption was indeed neutral in the sense that it was legally available to every product subject to marketing approval requirements. In fact, the panel agreed with the EU's larger point, that the Agreement barred both *de iure* and *de facto* discrimination. In other words, it appears that under this decision, the mere lack of a textual limitation to particular fields will not immunize a provision from challenge.

Still, it may be possible to salvage Epstein's approach. Patent laws tend to apply differently across industrial sectors, depending on such factors as the level of skill in particular fields,[13] and it is difficult to believe that members of the WTO would have readily committed themselves to altering this approach to their domestic lawmaking. Indeed, the panel acknowledged as much, stating, 'Article 27 does not prohibit bona fide exemptions to deal with problems that may exist only in certain product areas.'[14]

[12] See Graeme B. Dinwoodie, 'The Architecture of the International Intellectual Property System', 77 Chi.-Kent L. Rev. (2002) 993, 1005–06 ('Webster's has become an essential research tool in WTO TRIPS litigation').

[13] See Dan L. Burk and Mark A. Lemley, 'Policy Levers in Patent Law', 89 Va. L. Rev. (2003) 1575; Dan L. Burk and Mark A. Lemley, 'Is Patent-Law Technology-Specific?', 17 Berk. Tech. L.J. (2002) 1155.

[14] *Canada – Pharmaceutical Products*, above n 11, at ¶ 7.92.

In fact, the panel's report can be read as prohibiting *de facto* discrimination only when the claim includes some additional element, such as an allegation of an intent to discriminate. Thus, the panel stated, 'it was not proved . . . that the objective indications of purpose demonstrated *a purpose to impose disadvantages* on pharmaceutical patents in particular, as is often required to raise a claim of de facto discrimination.'[15] While panels, both in the TRIPS[16] and broader WTO contexts,[17] have acknowledged the difficulty of identifying (and scrutinizing) the purposes behind particular national laws, we find it entirely appropriate that those claiming *de facto* discrimination should be required to demonstrate some element – like intent – over and above those required to establish *de iure* cases of discrimination. At the very least, those defending an exclusion should be permitted to rebut a showing of disparate treatment by demonstrating a legitimate purpose. What these demonstrations might entail, we leave to another day, but they might be satisfied by, for example, demonstrating a close linkage between the exclusion and the particular organizational or institutional structure (such as a bifurcated generic and proprietary drug industry – or a decision to rely on patents to support fundamental research) in the country in question.

The foregoing suggests that variations in result must be evaluated carefully when determining whether national law violates the technological-neutrality principle. Discrimination is not the same as differential treatment. This is not to foreclose the possibility that a claim for *de facto* discrimination under Article 27.1 could succeed, but this reading does suggest that nations retain power to modify their notions of statutory subject matter along the lines of the Epstein proposal in order to deal with changes in the relationship between basic science and end-use technologies.

Arguably even more targeted carve-outs of the sort proposed by Barton should be permissible. Although we recognize that such a conclusion runs headlong into the literalism that panels have exhibited in interpreting TRIPS and which would likely inform any reading of Article 27.1, if a legitimate policy objective can be effectuated by a narrow, technology-specific exclusion, we fail to see why Article 27.1's commitment to formal neutrality should force WTO Members to adopt exclusions that are broader than necessary. Such an approach would appear to run counter to the underlying thrust of the TRIPS Agreement toward enhanced protection. We address this paradox below in connection with our discussion of Article 30.

[15] Id, at ¶ 7.105 (emphasis added).

[16] See United States – Section 110(5) of the US Copyright Act, WTR/DS/160/R (Report of WTO Dispute Settlement Panel, 2000).

[17] See generally Robert E. Hudec, 'GATT/WTO Constraints on National Regulation: Requiem for an "Aim and Effects' Test"', 32 Int. Law. (1998) 619, 626–33.

B. Exemptions

To the extent that the problem with upstream patents is their capacity to block pure research, another solution would be to permit certain activities to be undertaken without a patentee's authorization, in return for payment of a nonmarket-based rent (or for free). For example, Maureen O'Rourke would create a patent law exception, analogous to the fair use defense of copyright law, one that could be tailored to the unique concerns of particular sectors of the patent industry. Her analysis would consider (i) the nature of the advance represented by the infringement; (ii) the purpose of the infringing use; (iii) the nature and strength of the market failure that prevents a license from being concluded; (iv) the impact of the use on the patentee's incentives and overall social welfare; and (v) the nature of the patented invention.[18] A court would use these factors to determine whether a patented invention could be used without authorization, and also to assess royalties.

Professor O'Rourke's proposal, if enacted into domestic law, could indeed solve the upstream patent problem by freeing patented inventions for use in fundamental research. However, Articles 27 and 30 of the TRIPS Agreement each present problems for this approach.

1. Article 30's 'three-part test'

Article 30 provides that exceptions from liability for patent infringement are permissible if they (1) are limited, (2) do not unreasonably conflict with a normal exploitation of a patent, and (3) do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties. O'Rourke's proposal appears to accommodate these criteria by requiring courts to consider similar parameters. This conclusion, however, is not without doubt. There is a question about what WTO adjudicators will make of the discretion that this exemption gives courts. Certainly, the parameters that courts use in exercising that discretion would become critical to a finding of TRIPS-compatibility.

Our analysis of factors that courts should consider is informed by two panel reports, *Canada – Pharmaceutical Products* discussed above, and *United States – Section 110(5)*.[19] In the former, two exemptions were challenged: the regulatory review exemption described earlier, and a stockpiling exemption that enabled the generic industry to manufacture patented products within the last six months of a patent term (for sale upon expiry of the term). Two exemptions were also at issue in the *Section 110(5)* case, both of which permitted the playing of transmissions of recorded copyrighted music in commercial establishments. In each case, it was claimed that the exemptions

[18] See Maureen A. O'Rourke, *Toward a Doctrine of Fair Use in Patent Law*, 100 Col. L. Rev. (2000) 1177, 1205.

[19] See *Canada – Pharmaceutical Products*, above n 11; *United States – Section 110(5)*, above n 16.

at issue satisfied each of the cumulative three steps of the applicable test for permissible exceptions (Article 30 for patents, Article 13 for copyright).[20]

2. Scope of uses: 'limited' exceptions

The *Canada – Pharmaceutical Products* panel stated that the term 'limited', which is found only in Article 30,[21] required that the exemption be a narrow one, which the panel measured by reference to the extent to which the rights of the patentee were curtailed.[22] The stockpiling exemption was found not to be limited because, during the last six months of the statutory term, it negated all protection under three of the patentee's five guaranteed rights (make, use, or sell) with no limitations on the quantities produced or the market destination of the products.[23] In contrast, the regulatory review exemption was considered 'limited' because it narrowly curtailed the patentee's exclusive rights. The extent of the acts permitted (i.e., those that were necessary to comply with the regulatory approval process) was small and narrowly bounded.[24]

On its face, O'Rourke's proposed exemption resembles the invalid stockpiling exemption in that it would appear to curtail *all* of a patentee's exclusive rights. One could certainly argue that if a provision was facially unlimited, then it should be doomed. However, the Appellate Body has cautioned that panels should not assume that a member state would act inconsistently with its international obligations.[25] If, in fact, courts were to develop principles that limit the broad language of O'Rourke's proposal to bring it closer to the approved regulatory review exception, then it should satisfy the first step of the three-step test in Article 30

3. Economic impact: conflict with normal exploitation

The *Canada – Pharmaceutical Products* panel concluded that the normal practice of exploitation was 'to exclude all forms of competition that could

[20] See TRIPS Agreement, above n 1, arts. 13, 30.

[21] The first step of the copyright test confines copyright exceptions to 'certain special cases', which the panel interpreted to require, among other things, that the exception be limited and clearly defined. *United States – Section 110(5)*, above n 16 at ¶ 6.107-6.110.

[22] The panel concluded that the first step in the three-step test does not require consideration of the economic impact of the exemption because that concern was taken up by the second and third step of the test. Id, at ¶ 7.49. Thus, even if the adoption of the proposed fair use or an experimental use exemption did give rise to substantial economic impact (because, for example, protecting research opportunities represents a large part of the patentee's return at present) that would not of itself prevent the exemption being regarded as limited.

[23] In certain respects, the panel appeared to be incorporating some of the considerations relevant to analysis under Article 31, which governs the grant of compulsory licenses, into Article 30 analysis. The conditions in Article 31 are discussed briefly below in the context of discussing the interpretation of Article 44.

[24] *Canada – Pharmaceutical Products*, above n 11, at ¶ 7.45.

[25] United States – Section 211 of the Omnibus Appropriations Act of 1998, ¶ 259, WT/DS176/AB/R (WTO Appellate Body, 2001) (citing *Chile – Taxes on Alcoholic Beverages*, ¶ 74, WT/DS87/AB/R, WT/DS110/AB/R (WTO Appellate Body, 2000)).

detract significantly from the economic returns anticipated from a patent's grant of market exclusivity'.[26] Courts could ensure compliance with this standard most directly by considering whether a challenged domestic provision compromised significant economic opportunities.[27] Yet, the defense might survive challenge even if it were to render non-infringing certain uses or acts for which patentees currently extracted payment. The notion of normalcy should not be static but should evolve through successive interpretations of Article 30 by panels, the Appellate Body, the TRIPS Council, and future ministerial negotiations.[28] As the two panels acknowledged, while this understanding should take account of national practices, especially with regard to typical means of exploiting the patent and the source of that commercial capacity, normalcy is ultimately a normative question – it depends on a vision of the just balance between proprietary rights and public access interests, and not purely on past practices. We suggest that the factors mentioned by the panels should be considered, but that the normative question should permeate the entire analysis.[29]

(a) *National practices.* In part, the *Canada – Pharmaceutical Products* panel treated the ability to exploit the invention exclusively after patent expiration as normal because it was *typical*, by which the panel may have meant that several members had pre-market clearance procedures that had the effect of prolonging the period of exclusivity beyond the time of patent expiration.[30] Although state practice is clearly relevant to the creation of customary international law, existing national laws should not of themselves be permitted to entrench an international norm. Such an approach exalts national laws inappropriately. Furthermore, because states are generally free to exceed internationally mandated minima, there is a baseline issue: a denial of exclusivity may be from a level of exploitation that exceeds the internationally mandated standard. No rule of international intellectual property law should prevent a state that enacts higher levels of protection from reassessing the appropriate balance and offering protection that more

[26] *Canada – Pharmaceutical Products*, above n 11, at ¶ 7.55.

[27] Such an approach might appear unduly internationalist in the current political climate. Thus, we would rest on the canon of statutory construction that instructs judges to interpret domestic law, where possible, in accordance with international obligations.

[28] Cf. WTO Ministerial Conference, Declaration on the TRIPS Agreement and Public Health, ¶ 5, WT/MIN(01)/DEC/2 (14 November 2001) ('while maintaining our commitments in the TRIPS Agreement, we recognize … flexibilities'). The traditional sources of customary international law (including member state institutions) might also supply meaning to the concept.

[29] These factors are not meant to be exclusive; in other cases, additional considerations may be relevant.

[30] *Canada – Pharmaceutical Products*, above n 11, at ¶ 7.56. In fact, it is possible that the panel was referring to the fact that such exploitation was typical of patents in all fields of invention or that it was employed by 'most patent owners'. Moreover, in *United States – Section 110(5)*, the panel declined to address the EU's contention that 'comparative references to other countries with a similar level of socio-economic development could be relevant to corroborate or contradict data from the country primarily concerned', see ¶ 6.189.

closely hews to the minimum level.[31] To suggest otherwise would create a perverse result where states might be reluctant to expand intellectual property rights lest that precluded them from readjusting levels of protection downward through grants of specific exemptions.

Moreover, barring reform would be inconsistent with the notion that members' economic and social circumstances will change over time, and that states should be free to adjust national laws to accommodate those changes. From an institutional political perspective, it would validate the refrain of many critics of recent international intellectual property developments that the system operates as a one-way ratchet.

(b) *Typical means of exploiting the patent*. In determining normalcy for purposes of Article 30, the *Canada – Pharmaceutical Products* panel may alternatively have been considering what right holders regard as typical exploitation practices. However, it was clearly unwilling to rely on that ground alone. Likewise, the *United States – Section 110(5)* panel held that the extent to which rights holders actually exercised their rights could not be 'fully indicative of normal exploitation'.[32] Indeed, both panels offered a definition of 'normal' that explicitly encompassed a normative assessment as well as an empirical analysis of what was 'regular, usual, typical or ordinary'.[33]

We are concerned, however, that despite this language, neither panel took the normative dimension seriously; neither went so far as to articulate a normative vision of exploitation. Instead, as Jane Ginsburg has commented, the analysis in *Section 110(5)* sought only to 'anticipate what the empirical situation [would] be, [rather] than [provide] an explanation of what the right holder's markets *should* cover'.[34] The intellectual property literature includes a rich body of intellectual property theory, and the opening for normative assessment provides a vehicle for panels to use this scholarship to develop international law. Of course, a commitment to a broader approach would inevitably draw panels into more intrusive assessments of national legislative

[31] The *Canada – Pharmaceutical Products* panel noted that '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,' id, ¶ 7.55. This language appears largely directed at efforts to expand forms of exploitation but the general proposition holds true.

[32] *United States – Section 110(5)*, above n 16, at ¶ 6.196. The patent standard in article 30 (but not the copyright equivalent in art. 13) allows conflicts with normal exploitation provided they are reasonable. It would thus appear to afford member states greater latitude on the second leg of the patent exemptions test. But in both provisions, the permissible conflict is measured against the same norm, that is 'normal exploitation'.

[33] See *United States – Section 110(5)*, above n 16, at ¶ 6.166 ('dynamic, approach, i.e., conforming to a type or standard'); *Canada – Pharmaceutical Products*, above n 11, at ¶ 7.54 ('The term ["normal"] can be understood to refer to an empirical conclusion about what is common within a relevant community, or to a normative standard of entitlement.' The panel concluded that the word 'normal' was being used in Article 30 in a sense that combined the two meanings.).

[34] Jane C. Ginsburg, 'Toward Supranational Copyright Law? The WTO Panel Decision and the 'Three Step Test' for Copyright Exemptions', 187 Revue Internationale Du Droit D'Auteur (2001) 3, 17.

values. But, as the Appellate Body recognized in its first TRIPS report,[35] and as the *United States – Section 110(5)* panel hints in its discussion of 'normal', it is the responsibility of panels to make critical assessments of national law.[36]

(c) *Source of commercial capacity*. The *Canada – Pharmaceutical Products* panel declined to treat as normal the 'additional period of de facto market exclusivity created by using patent rights to preclude submissions for regulatory authorization' because it was 'not a natural or normal consequence of enforcing patent rights'.[37] It was the product of a combination of patent laws and the regulatory approval scheme – a commercial rather than a legal effect.

We agree that a rigorous inquiry into the nature and source of control should inform the analysis. Enhanced commercial exploitation may arise from the availability of technological protection measures that reinforce statutory rights; from contracts that parties enter on account of industry structure or because the costs of challenging an exclusive right outweighs the benefits of cooperation; or more darkly, from market power and undue commercial leverage. Absent such inquiry, invalid assertions of rights and the flexing of market muscle may be elevated to international law.

Applying this multi-factored approach to O'Rourke's proposal produces a mixed picture. Many states afford exemptions for socially significant uses, but these exemptions do not give courts the kind of case-by-case discretion envisioned by O'Rourke.[38] But to the extent that US courts developed permissible uses that parallel such exemptions, *national practices* should support a finding of compliance.[39] On *typicality*, unauthorized uses that stem

[35] *India – Patent Protection for Pharmaceutical and Agricultural Chemical Products*, WT/D550/AB/R (Report of the Appellate Body, 1997).

[36] Determining the contexts in which international norms should trump national determinations will obviously depend on both the substantive intellectual property values and systemic values underlying the international system. The Appellate Body seems to have left room for deference to national welfare considerations if not in direct conflict with the literal text. See TRIPS Agreement, above n 1, Preamble; J. H. Reichman, 'Securing Compliance with the TRIPS Agreement after *U.S.* v *India*, 1 JIEL (1998) 585, 597.

[37] *Canada – Pharmaceutical Products*, above n 11, at ¶ 7.57.

[38] Research exemptions are fairly common to domestic law, and pending EU proposals for a Community Patent would exempt 'acts done privately for non-commercial purposes', and 'acts done for experimental purposes relating to the subject-matter of the patented invention'. G. B. Dinwoodie and R. C. Dreyfuss, 'WTO Dispute Resolution and the Preservation of the Public Domain of Science under International Law', in K. E. Maskus and J. H. Reichman (eds), *International Public Goods* above n * (citing sources).

[39] Moreover, once we are free to infuse the term 'normal' with normative and not merely empirical meaning, one further argument that might be used to defend an exemption under Article 30 would be to cast the exemption as an effort to restore patent protection to levels that reinstate the 'normal' exploitation that existed before the recent developments that have motivated concern. In so doing, empirical evidence of practice might plausibly be relevant, but it is hard to see how practices in 2003 have any greater claim to determine normalcy than practices in 1993.

from market failure present the strongest case because the patentee could not exploit that market. Further, the normative analysis is key here. From a theoretical perspective, states need the ability to calibrate the degree of freedom given to second-comers according to the needs and maturity of particular industries. The proposal is weakest when analyzed in terms of the *source of the capacity to exploit* because in most cases it will stem from patent rights. Two points should be kept in mind. First, the conclusion on normalcy depends on an interaction of relevant factors, not a cumulative satisfaction of each. Second, the entire analysis must be infused with normative content. To the extent that O'Rourke is preserving a competitive research (as opposed to end-use) market, her proposal furthers the goals of intellectual property law.

4. Types of uses: unreasonable prejudice to legitimate interests

Both components of the third step of Article 30 clearly involve a normative assessment, as the *Canada – Pharmaceutical Products* panel acknowledged.[40] Thus, much of what we said above is relevant here. However, there is no international norm to deal with the problem of preserving a robust research market in the face of upstream patenting. When the *Canada – Pharmaceutical Products* panel found that there was no controlling international norm in that case, it suggested deference to local autonomy,[41] and that approach may well support the O'Rourke proposal.

The validity of the exemption is bolstered by the last clause of the third step in Article 30, which (unlike its copyright counterpart in Article 13) explicitly calls for a panel to 'take account of the legitimate interests of third parties'. The panel hinted that considerations such as society's interest in promoting progress, and scientists' interest in free inquiry, might be considered 'legitimate' within the meaning of Article 30.[42] Further, although the panel cautioned that Articles 7 and 8, which speak of promoting technological innovation to the mutual advantage of producers and users, and of protecting public health and promoting the public interest, cannot be used to reargue the balance struck in Article 30 of the TRIPS Agreement, they can shed light on the meaning of 'legitimate interests'. Thus, if the availability of the exemption

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If normal exploitation is judged from the ways in which patentees have traditionally captured returns from their discoveries, the proposal should be consistent with TRIPS. As noted earlier, the traditional market for patented works is a *product market*; the right to control research is, in most fields, slim. Professor O'Rourke's proposal will, in many cases, merely free up usages that were not enjoyed previously; normal forms of exploitation will continue to be recognized. Members of the WTO should be free to realign the components in their constellation of patent law rules and to restore the stable universe that they thought existed.

[40] *Canada – Pharmaceutical Products*, above n 11, at ¶ 7.73.

[41] Id, at ¶ 7.82. Cf. *India – Patent Protection for Pharmaceuticals*, above n 35, at ¶¶ 46, 59. This approach illustrates that pro-public goods arguments might flow either from substantive intellectual property preferences embedded in the TRIPS Agreement, or from neo-federalist principles found in the international intellectual property system.

[42] *Canada – Pharmaceutical Products*, above n 11, id, at ¶ 7.69.

depends, as O'Rourke contemplates, on market failures that preclude contracts that would advance overall social welfare, a panel might accept the argument that the exemption was TRIPS-consistent.

5. Article 27's technological neutrality

Another possible challenge to O'Rourke's approach is rooted in the technological neutrality principle of Article 27, which the *Canada – Pharmaceutical Products* panel read as imposing an additional hurdle for member states seeking to invoke Article 30 to justify domestic exemptions to the exclusive rights required by international patent law. The panel appeared to regard Article 27.1 as a structural provision, part of the fabric of the Agreement as a whole, which can be transposed to the analysis of other provisions.

If Article 27 does apply to exemptions within Article 30, the O'Rourke proposal appears vulnerable to challenge. Although this 'fair use' exemption would not be aimed at specific subject matters of invention, it is likely that the factors would play out differently in different fields. Indeed, the fifth factor in the O'Rourke analysis – the nature of the patented invention – makes this possibility explicit. We believe, however, that the O'Rourke approach remains appropriate because the policy concerns that underlie her analysis tend to become more acute in some fields than others. Thus, we think the panel was wrong in applying Article 27.1 to exemptions. As noted earlier, there are good reasons why different technologies or different uses may require different judicial or legislative treatment. It seems counterproductive to require socially desirable exemptive solutions to extend to all technologies when technology-specific problems require technology-specific solutions.[43]

Indeed, requiring exemptions to be technologically neutral appears particularly anomalous in that it tends to make a broader than necessary exemption more sustainable under international law than a narrow exemption. This outcome conflicts with the norm contained in Article 30 that expressly requires the availability of exemptions to be evaluated in terms of whether any given exemption is '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. Regardless of whether a panel might be more sympathetic to an exemption that is cast in general terms, the policies underlying the TRIPS Agreement favor exemptions that are either targeted or, though framed broadly, evolve to permit particular limited uses. A formalist commitment to technology neutrality is inconsistent with a purposive reading of the TRIPS Agreement.

[43] If the approach of the *Canada – Pharmaceutical Products* panel prevails, we could present this argument under the rubric that, as explained above, a mere difference in treatment of different technologies might not amount to discrimination in violation of art. 27. See above text accompanying nn 13–17.

C. Remedies

A third way to protect the public domain of science is to vary the terms of relief so as to immunize upstream researchers from liability for patent infringement. One idea, proposed by one of us and modified by Richard Nelson, would benefit non-commercial research organizations, especially universities and their employees, if 1) the patented materials they wished to utilize were not made available on reasonable terms; 2) the investigators agreed to publish their research results; and 3) the investigators agreed either to refrain from patenting the research results or to patent and then license the result on a nonexclusive basis and on reasonable terms.[44]

The compatibility of this solution with TRIPS obligations is difficult to gauge in light of the disputes resolved so far.[45] Immunizing certain users from liability could be categorized as an exemption to the right conferred and analyzed under Article 30.[46] If so, then the argument would be similar to the one set out above, with the added observations that this approach curbs the judicial discretion that engendered some ambivalence in our analysis of the open-ended exemption. It also seems unlikely to intrude seriously on the patentee's own interests. While it could reduce markets for research tools, only those markets that the patentee refused to supply would be affected. Some opportunities may also be lost in the innovation market, but because these opportunities would likely be non-commercial, fundamental research opportunities, they are likely to be rather low on a commerce-minded patentee's own priority list.

We are not, however, convinced that Article 30, standing alone, should, provide the appropriate framework of analysis. While Article 30 imposes well-established strictures of international law on what member states can do, the TRIPS Agreement as a whole appears to envision far more latitude at the remedial phase. The flexibility that the TRIPS Agreement preserves is most evident in Article 41, which sets out WTO Member's enforcement obligations.[47] Subsection 5 explicitly provides that Members are not required to enforce intellectual property law in a manner different from how they enforce their laws in general. This deference constitutes a structural value.

[44] See Rochelle Dreyfuss, 'Varying the Course in Patenting Genetic Material: A Counter-Proposal to Richard Epstein's Steady Course', in *Perspectives on Properties of the Human Genome Project,* above n 8, at 204–5; Richard Nelson, 'The Market Economy and the Scientific Commons', Research Policy (forthcoming 2004). An analogue to this approach has been adopted in US law to limit liability for certain uses of patented surgical and medical processes, where there was also a fear (albeit on different grounds) that important developments would be inadequately licensed and used. See 35 U.S.C. § 287(c)(2). See generally Gerald J. Mossinghoff, 'Remedies under Patents on Medical and Surgical Procedures', 78 J. Pat. & Trade. Off. Soc'y (1996) 789.

[45] *United States – Section 211*, above n 25, discusses remedies, but not in ways that would substantially influence our analysis here.

[46] Cf. Mossinghoff, above n 44, at 796 (examining the surgical immunity provision under art. 30).

[47] TRIPS Agreement, above n 1, art. 41.

Members need discretion to choose the means by which they satisfy effective enforcement obligations because enforcement implicates questions of resources and institutional priorities that go to the heart of national political ordering in ways that far transcend intellectual property law.

Other more specific remedies provisions also create substantial flexibility. Article 45 requires member states to give judicial authorities power 'to order the infringer to pay the right holder damages adequate to compensate'.[48] However, when a court exercises that authority, adequacy is measured entirely by local conditions. In markets where demand for the product – or ability to pay – is low and in markets that have price controls in place, the compensatory award will be low.[49] The award will, in other words, reflect local conditions, desires, and needs. This is as it should be: a patent is a right to exclude, not a right to exploit. Even the provisions that protect the right to exclude can be read as creating substantial space for sovereign interests. Although Article 44.1 requires member states to give judicial authorities *power* to order injunctive relief, nothing in the provision expressly *require*s courts to enter such orders. United States law reads the same way in that it is interpreted to give courts considerable discretion to tailor injunctions to specific (local) conditions.[50]

Given this degree of flexibility, an approach based on remedial immunity should be considered consistent with the TRIPS Agreement. Monetary rewards could be reduced to zero for the same reasons that monetary relief is traditionally low in some situations: the relevant user groups – in this case, non-commercial research institutions – lack resources to pay for the inputs they need. Moreover, the economic value of the use – in this case, basic research – is highly speculative, and courts do not generally award speculative damages.[51] Injunctive relief is also denied for familiar reasons, sounding in the need to deal with important social problems. In this case, that might include an organizational structure for science in which fundamental and applied scientific research are conducted in different institutions, coupled with a cultural aversion to entering into binding transactions with strangers in the face of scientific and business uncertainty. Admittedly, relief under this proposal is withheld across the board, rather than on the typical case-by-case basis. Yet, efficiency or other values often require the articulation of a rule that constrains equitable discretion and reduces reliance on case-by-case

[48] Id, art. 45.

[49] TRIPS does not apparently proscribe price controls, although some effort to do so has reportedly been made in bilateral negotiations.

[50] 35 U.S.C. § 283; Burk and Lemley, 'Policy Levers', above n 13. See, e.g., *Foster* v *American Mach. & Foundry Co.*, 492 F.2d 1317 (2d Cir. 1974) (preserving the market for an invention the patentee was not practicing). The provisions on government uses take a similar case-by-case approach, see TRIPS Agreement, above n 1, arts. 44(2) and 31(h).

[51] In United States contract law, speculative damages are not available, see e.g., American Law Institute, Restatement (Second) of Contracts § 352 ('damages are not recoverable for loss beyond the amount that the evidence permits to be established with reasonable certainty').

analysis.[52] An approach to the enforcement provisions of TRIPS that prevents a member from choosing between a case-by-case or a rule-based approach might be thought to impose on such a state the obligation to enforce intellectual property law in a manner different from the enforcement of laws generally. Indeed, where TRIPS negotiators thought that members had to be constrained in permitting a broad rule-based approach to adjudication, they included a provision to that effect.[53] Finally, the requirement of 'effective remedies' in Article 41.1 is preserved in that the patent remains valuable for many purposes. For example, it can be used to extract remuneration in other markets, and it retains its value as a signal to potential collaborators and investors.

As a matter of policy, it makes sense that the net result should be that member states retain authority to control the terms on which basic research is conducted. Given that members appear free to hold down the profits that innovators can earn by such actions as permitting parallel imports, or imposing compulsory licenses or price controls,[54] it is important that they remain equally free to control the costs that innovators face. Otherwise, price could, in theory, fall to the worldwide demand price (or to the price set by the government with the most stringent price controls), while the costs of research and development would be entrenched by the Agreement.[55]

CONCLUDING OBSERVATIONS

Our case studies demonstrate that a country that perceives a problem with the patenting of upstream research has a variety of ameliorative approaches at its disposal, each with different pay-offs as a matter of domestic policy. These approaches are also likely to provoke different responses at the international level. Unless Article 27 of the TRIPS Agreement is read narrowly, subject matter exclusions may be impermissible; an open-ended exemption could be heavily dependent upon a domestic interpretation that tracks international standards; and the immunity approach may violate remedies obligations, even for patented technologies that are principally utilized in basic research.

Should the TRIPS Agreement be read to constrain national choices in this formalistic way? Consider, for example, the provision of current United States law on which the immunity defense outlined above was based. It immunizes a

[52] For example, in intellectual property cases it is presumed that irreparable harm will ensue if the plaintiff with a likelihood of success on the merits could not obtain preliminary injunctive relief.

[53] See TRIPS Agreement, art. 31(a); see also Daniel Gervais, *The TRIPS Agreement: Drafting History and Analysis* (1998) 165.

[54] TRIPS Agreement, arts. 6, 31.

[55] Arguably, the immunity approach could be viewed as a government subsidy that violates other provisions of the General Agreement on Tariffs and Trade. However, subsidization of basic (as opposed to applied) work has long been regarded as permissible. See e.g., Mary Lowe Good. 'Technology and Trade', 27 Law & Pol'y Int'l Bus. (1996) 853, 857–58.

'medical practitioner's performance of a medical activity' that would otherwise constitute infringement. If the analyses of Articles 30 and 44 that we put forward are rejected, then this provision could also be found to violate the TRIPS Agreement. Yet, a subject matter approach to surgical method patents would clearly be upheld under Article 27.3(a), which permits members to exclude surgical methods from patentability.[56] It is difficult to see why WTO panels should adhere strictly to this formalistic approach, which requires these choices to be analyzed separately.

Of course, formalism may have a role to play. Our analysis also raises the question whether any provisions of the TRIPS Agreement are what we have called structural or horizontal in nature, part of the fabric of the Agreement as a whole, which should be transposed to the analysis of other provisions. The *Canada – Pharmaceutical Products* panel appeared to regard Article 27.1 as one such provision and superimposed its technological neutrality principle on Article 30. Although the Agreement no doubt contains some provisions (such as national treatment) that possess this structural character, panels should be cautious before elevating any particular provisions to this status, especially when these are ostensibly directed at specific issues rather than delineated in that part of the Agreement that addresses General Provisions and Basic Principles.[57]

In its latest TRIPS report, *United States – Section 211,* the Appellate Body attached great weight to the characterization of the law being challenged.[58] Such formalism may be necessary in the early stages of a lawmaking enterprise. However, characterization must be performed with attention to substantive goals. In multistate private litigation where choice of law is an issue, courts have long used a similar process. In those cases, the forum does not regard itself as bound by the characterization of the state that enacted the rule, but instead it makes its own assessment based on the state interests that underlie the law.[59] In our present context, panels should do likewise, especially in the early years when they are considering state laws that were not formulated with TRIPS categories in mind. The appearance of arbitrariness will best be avoided by a process of characterization that is alert to the substantive purposes of intellectual property law.

It is also important for panels to keep what might be called the 'neo-federalist' underpinnings of the TRIPS Agreement in mind. The Agreement, as an instrument of intellectual property law, must strike a balance between sufficient levels of protection to stimulate the desired social and commercial

[56] See TRIPS Agreement, above n 1, art. 27.3(a).

[57] See TRIPS Agreement, above n 1, arts. 1–8.

[58] *United States – Section 211*, above n 25, at ¶ 105.

[59] See Restatement (Second) of Conflict of Laws § 7. Cf. Lawrence Collins *et al.*, *Dicey & Morris*, *The Conflict of Laws* ¶ 2.034-035 (13th edn, 2000) (noting that it is 'pointless' to look for the true or inherent meaning of legal categories and suggesting that courts avoid such 'mere conceptualism' by examining the purposes of the substantive rule at issue).

activity undertaken by first-comers, and sufficient limits on those rights to ensure the maximum socially useful exploitation of that activity. It partly achieves this balance substantively by allocating rights as between private and public interests, that is, between producers and users of intellectual property. But TRIPS, like any international agreement, must also deal with issues such as sovereignty, diversity, and legitimacy that pervade international relations. It must accordingly allocate power between supranational and national institutions, between national and international laws. In the TRIPS context, that allocation has the additional effect of giving member states an important role in striking the producer/user balance of intellectual property law.[60]

In the discussion above, much of our argument rested on recognizing the importance of this neo-federalist structure. Thus, a decision to allow WTO Members to create a larger public domain by one method or another may be a product not of an intellectual property balance that the TRIPS Agreement mandated, but rather a consequence of the conferral of autonomy on national governments. For our case study, it seems to follow that the United States can enact a particular regime not because it embodies a balance between public and private interests that was struck in the TRIPS Agreement, but rather because that Agreement allows its members to make a range of determinations, of which the one adopted by the United States is a permissible option.

To put it another way, because the TRIPS Agreement was negotiated with the goal of promoting international trade, the goals of substantive balance common to domestic intellectual property systems are barely discernible in its provisions. Nevertheless, panels must take seriously the autonomy interests implicit in the structure of the international intellectual property system, and they must allow sovereigns to respond to changes in science, to the structure of their patent industries, or to other social needs. Otherwise, a series of worldwide disutilities will result.

In passing, we have suggested various systemic values that are crucial to this approach to analyzing TRIPS obligations: the incentives likely to optimize social utility may vary widely from country to country; permitting some diversity of approach allows nation states to act as laboratories in the development of international rules; affording space for the self-determination of sovereign states encourages voluntary and ultimately more effective compliance with international norms; and, universality may have costs, whether measured in economic or non-economic terms. We plan to develop these systemic values at greater length in another article. Fully articulating the latitude afforded WTO Members under international intellectual property law will provide scholars and national policymakers with a sense of the boundaries within which these domestic debates can then occur.

[60] Characterization will also be a tool for implementing the principles of neo-federalism that we discuss above. Cf. *Dicey & Morris*, above n 59, at 2–039 (noting that in private multinational litigation, characterization by a forum is simply the refinement or redefinition of the forum's conflicts rule).