On Aiding Technological Development: The Max Planck Declaration on Patent Protection

Rochelle Dreyfuss* and Esteban Donoso**

The Declaration on Patent Protection is a welcome addition to the Max Planck Institute's work on the flexibilities available under the TRIPS Agreement. Like the previously published Copyright Declaration, it improves on the World Trade Organization's interpretations of the open-ended, three-part exceptions provisions of the TRIPS Agreement. Furthermore, it attempts to clarify the other regulatory options that are retained under TRIPS. Here, we contend, the Declaration makes three mistakes. First, its aggressive interpretations of certain provisions undermine its credibility, making it a less useful resource than a document prepared by such notable scholars might be. Second, the options, if adopted in toto, would significantly undermine incentives to invent. Yet the Declaration does not provide guidance on which options a state that is intent on encouraging innovation should adopt. Third, the Declaration's focus on the provisions in TRIPS that maintain sovereign regulatory authority misses the Agreement's failure to coordinate the global innovation enterprise. We argue that two dramatic revisions to TRIPS—a change in the term of patent protection and a rule on international exhaustion—would provide countries with more freedom to experiment with the flexibilities correctly identified by the Declaration. These changes would also ensure that each country contributes a proportionate share to the costs of global innovation. And they might also lead nations to entertain the idea of abandoning some of the flexibilities in order to provide better incentives to their domestic technology sector.

* Pauline Newman Professor of Law, New York University School of Law.
** LLM, New York University School of Law, Class of 2015. Magister, Universidad Andina Simón Bolívar, Class of 2009.

Publication of the *Declaration on Patent Protection: Regulatory Sovereignty under TRIPS*[1] was a highly welcome event. The Max Planck Institute for Innovation and Competition had previously issued a copyright declaration—*Declaration on a Balanced Interpretation of the "Three-Step Test" in Copyright Law*.[2] Written in the aftermath of two decisions by the Dispute Settlement Board (DSB) of the World Trade Organization (WTO) interpreting the three-part exceptions provisions of the TRIPS Agreement,[3] the *US-Section 110(5)* decision on copyright and the *Canada-Pharmaceuticals* decision on patents,[4] *Balanced Interpretation* rightly criticized the *110(5)* decision for its narrow view of available flexibilities.[5] As important, it suggested a new approach to the copyright exceptions test, one that would give member states more power to respond to the needs of local creators and their audiences.[6] In so doing, however, the Copyright Declaration conveyed a negative pregnant: by taking on only the *110(5)* decision, the Institute could be perceived as approving the way the *Canada-Pharmaceuticals* Panel interpreted the analogous patent provision.[7] The Declaration on Patent Protection corrects the problem, for it nicely transposes the critique of the copyright decision into the patent context.

The new Declaration also goes much further. It not only interprets the open-ended provision on exceptions to patent rights, it also "seeks to clarify some of the regulatory options states still retain under international law."[8] This too is an important development. As César Rodríguez-Garavito and Rochelle Dreyfuss

1. MAX PLANCK INST. FOR INNOVATION & COMPETITION, DECLARATION ON PATENT PROTECTION: REGULATORY SOVEREIGNTY UNDER TRIPS (2014) [hereinafter MAX PLANCK DECLARATION], https://www.mpg.de/8132986/Patent-Declaration.pdf [https://perma.cc/6MST-74NU].

2. Christophe Geiger et al., *Declaration on a Balanced Interpretation of the "Three-Step Test" in Copyright Law*, *reprinted in* 39 INT'L REV. INTELL. PROP. & COMPETITION L. 707 (2008).

3. Agreement on Trade-Related Aspects of Intellectual Property Rights, arts. 13, 30, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, LEGAL INSTRUMENTS—RESULTS OF THE URURGUAY ROUND, vol. 31, 33 I.L.M. 81 (1994) [hereinafter TRIPS Agreement].

4. Panel Report, *Canada—Patent Protection of Pharmaceutical Products*, WTO Doc. WT/DS114/R (Mar. 17, 2000); Panel Report, *United States—Section 110(5) of the US Copyright Act*, WTO Doc. WT/DS160/R (June 15, 2000).

5. Geiger, et al., *supra* note 2, at 709.

6. *Id.* at 710, 712.

7. *Id.* at 709.

8. MAX PLANCK DECLARATION, *supra* note 1.

found in their study of the impact of international intellectual property obligations on access to medicines in Latin America, many countries lack a firm understanding of how flexibly TRIPS can be read.[9] The Declaration could help such nations find TRIPS-compatible ways to accommodate their interests in lowering the cost of, and increasing access to, the fruits of technological innovation. The Declaration could also be viewed as the first step in developing an international *acquis* on intellectual property—something that Dreyfuss and Graeme Dinwoodie have argued is crucial to providing nations implementing these flexibilities with the grounding necessary to withstand attacks on their laws, be it in WTO dispute settlement, in later rounds of TRIPS negotiations, or through proposals for so-called "TRIPS-plus" obligations in subsequent bilateral and regional free trade agreements.[10]

Unfortunately, "could" is the operative word here. As we elaborate further below, the Declaration pushes the limits of TRIPS flexibilities so far, it loses credibility. As a result, countries following even its valid advice may not be able to use the Declaration effectively as a shield to later challenges. More critically, while the Declaration claims to provide a menu of "latitudes,"[11] it fails to include a basis for picking and choosing among them. The implication is that a country could—should—make use of them all. Combining all these minimalist provisions would, however, create a legal regime as bad for development as the maximalist notions championed by TRIPS-plus proponents. In a way, the two groups make opposing mistakes. Whereas advocates for strong international obligations tend to over-estimate the extent to which developing countries can benefit from laws that promote innovation, the minimalist view does the opposite: it under-estimates the inventive capacity of developing countries. In the name of promoting access, it suggests that countries divest themselves of a core mechanism for incentivizing local innovation and promoting the investment necessary to facilitate it. What many developing countries actually need is a set of incentives that would encourage the local population to innovate for itself immediately and move toward the technological frontier over time. In addition to clarifying the options countries have to minimize protection, it would therefore be useful for the Declaration to provide these countries with guidance on how to combine options in a manner that would genuinely "maintain a proper balance between the need for protection of knowledge goods in global markets . . . and public interest goals."[12]

---

9. Rochelle Dreyfuss & César Rodriguez-Garavito, *Conclusion: Balancing Wealth and Health in a Transnational Regulatory Framework, in* BALANCING WEALTH AND HEALTH: THE BATTLE OVER INTELLECTUAL PROPERTY AND ACCESS TO MEDICINES IN LATIN AMERICA 323, 324 (Rochelle Dreyfuss & César Rodríguez-Garavito eds., 2014).

10. GRAEME B. DINWOODIE & ROCHELLE C. DREYFUSS, A NEOFEDERALIST VISION OF TRIPS: THE RESILIENCE OF THE INTERNATIONAL INTELLECTUAL PROPERTY REGIME 173–203 (2012); *see also* Farida Shaheed (Special Rapporteur), *Rep. of the Special Rapporteur in the field of cultural rights*, U.N. Doc. A/70/279 (Aug. 4, 2015) (examining the relationship between human rights and patent rights).

11. *See* MAX PLANCK DECLARATION, *supra* note 1, at 14.

12. *Id.* at 2.

Once it is accepted that the goal for developing countries is not merely to gain access to foreign invention but to become innovative themselves, the question arises whether existing flexibilities offer the best options. To be sure, the Declaration does not purport to "think outside the box," but it does imply that the best way to deal with the heterogeneity among WTO members is to capitalize on their sovereign authority. However, as Esteban Donoso has previously argued, the real problem with TRIPS is insufficient coordination.[13] There is currently no mechanism that ensures that every country contributes a proportionate amount to the cost of developing the products from which it derives benefits.[14] Nor is there a way for developed countries to prevent any products made available at lower prices in developing countries from finding their way to world markets and depressing global returns.[15] As we will show, a better approach would be to allow states to alter the patent term to reflect their capacity to pay patent prices and to bar WTO members from recognizing a doctrine of international exhaustion (or, at least, limiting their options for considering right holder interests to be exhausted).[16] The first step, if accompanied by a reduction in the use of many of the flexibilities minimalists suggest, would increase local incentives to innovate. At the same time, they would guarantee a fair return to all patent holders. By preventing policy spillovers, the second step would diminish the pressure to adopt TRIPS-plus obligations. As important, it would permit differential pricing and reduce global deadweight loss.

This Article proceeds as follows. Part I provides examples of provisions in the Declaration that we believe exceed the flexibilities available in the TRIPS Agreement and thus cast doubt on its own integrity. Part II shows how countries could misunderstand the options set out in the Declaration and deprive their citizens of the incentives they need to meet even local innovation needs. Part III discusses Donoso's novel proposals for better coordinating the global innovation enterprise.

---

13. ESTEBAN DONOSO, A GLOBAL SOLUTION FOR THE PROTECTION OF INVENTIONS 38 (2013) [hereinafter DONOSO, GLOBAL SOLUTION]; *see also* Esteban Donoso, *Application of a Mechanism of Proportional Rewards Towards Innovation*, 4 N.Y.U. J. INTELL. PROP. & ENT. L. 105, 113 (2014) [hereinafter Donoso, *Proportional Rewards*] (arguing that regulation with optimal impact occurs when three different aspects of TRIPS, validity, effectiveness and justice, all overlap).

14. *See* Donoso, *Proportional Rewards, supra* note 13, at 106 (discussing the possibility of introducing a proportional reward system to the TRIPS Agreement where each country would contribute to technological development according to its economic capacity, seeing as no such system currently exists).

15. *Id.* at 124–25.

16. Currently, the TRIPS Agreement obliges all member states to protect inventions for twenty years. TRIPS Agreement, *supra* note 3, art. 33. Apart from national treatment and most favoured nation concerns, it is agnostic on international exhaustion. *Id.* art. 6. Not surprisingly, the Declaration encourages countries to make more use of the latitude provided by Article 6. MAX PLANCK DECLARATION, *supra* note 1, § 5.1 at 14.

I. INTERPRETIVE PROBLEMS

The Patent Declaration demonstrates the many ways in which a country can interpret the TRIPS Agreement to tailor its law to domestic conditions. We do not quarrel with the bulk of the recommendations. Countries have already implemented many of them and have done so to good effect. For example, the Declaration points out, "States have latitude to define what constitutes patentable inventions."[17] India has most famously used this option in § 3(d) of its Patent Act, which provides that the following is not eligible for protection:

> [T]he mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant.[18]

The statute has worked well for India: because it does not allow patent holders to protect minor variations of a product whose patent is about to expire and then use the patent on the variation to bar access to the version that was originally marketed, the bar on patents for incremental innovation minimizes evergreening—the practice of extending the effective life of drugs by successively patenting minor variants of them.[19] The provision has also meant that India's highly developed generic drug industries can continue to make medicines like Novartis's Gleevec, a treatment for leukemia that was developed from a known pharmaceutical formulation, available at low prices.[20]

Should a country (such as Switzerland, home of Novartis) challenge § 3(d), the Declaration could be extremely helpful.[21] Clearly, countries cannot consider *all* advances non-inventive or too obvious to be considered patentable. Accordingly, a DSB Panel confronting such a case would be required to draw a line between those advances that a country could, consistent with TRIPS, decide are not suitable for protection and those to which it must award patents.[22] As Dinwoodie and Dreyfuss

---

17. MAX PLANCK DECLARATION, *supra* note 1, § 3.1 at 14.

18. The Patents (Amendment) Act, 2005, No. 15, Acts of Parliament, 2005 (India).

19. Other countries try to prevent evergreening in other ways. *See, e.g.*, New York *ex rel.* Schneiderman v. Actavis, PLC, 787 F.3d 638, 654 (2d Cir. 2015) (finding coerced switching to a patented variant of a drug to be anticompetitive); Schering Corp. v. Geneva Pharm., Inc., 348 F.3d 992, 993 (Fed. Cir. 2003) (barring patent on a precursor to a drug whose patent was expiring). India's Patent Act, is, however, the most direct method of accomplishing this result.

20. *See* Novartis Ag v. Union of India (2013) 6 SCC 1.

21. *See Trade Policy Review: India*, WTO Doc. WT/TPR/M/313/Add.1, http://www.wto.org/english/tratop_e/tpr_e/tp_rep_e.htm; *see also* thiru, *WTO Trade Policy Review of India: Section 3(d) and* Compulsory Licensing under the Spotlight, KNOWLEDGE & ECOLOGY INT'L (Aug. 3, 2015), http://keionline.org/node/2305 [https://perma.cc/7FM5-FFX6] (summarizing questions and answers by WTO members, and noting that Switzerland propounded questions concerning § 3(d) of India's Patent Act as well as its use of compulsory licensing, and use of confidential test data).

22. *See* DINWOODIE & DREYFUSS, *supra* note 10, at 57 (discussing the DSB Panel's process in adjudicating claims and referring to local authority).

suggest, the Panel may well approach the line-drawing problem by canvassing what other jurisdictions have done, and defer to India in the absence of consensus.[23] Unfortunately for India, however, there are many countries where drugs like Gleevec—new forms of old molecules—are protectable if they display (as Gleevec did) greater bioavailability or other improved properties.[24] In such a case, the Declaration's notion of latitude and its differentiation between discoveries and inventions[25] could act as a tiebreaker. The Declaration is, after all, the considered opinion of an impressive array of specialists in intellectual property, competition, and international law, drawn from around the world. It was compiled over a period of several years, and in light of the TRIPS cases that had been decided up to its publication date.[26] Given that the WTO adjudicators picked to hear such a challenge would not necessarily include anyone with a background in patent law, the Declaration could be extraordinarily helpful to the Panel (and to India). Additionally, the Declaration could become invaluable as investor-state dispute settlement (ISDS) cases proliferate in the intellectual property arena.[27] As Joost Pauwelyn demonstrated, the arbitrators in these disputes are drawn from circles unlikely to be appreciative of the need for sovereign flexibilities.[28]

Whether the Declaration will function in this way depends, however, on its credibility—on whether it is perceived as thoughtful scholarship or as pure advocacy. Our concern is that some provisions push the line on flexibilities to the point where the Declaration is more likely to be viewed as the latter.

Most glaringly, the provision on patent scope states, "Articles 27 and 28 of the TRIPS Agreement do not prevent states from limiting the protection conferred by a patent to products or processes in relation only to the specific function(s) of the invention expressly claimed in the patent."[29] Article 27, which requires protection for advances that are "new, involve an inventive step and are capable of industrial application,"[30] is not related to scope, so it is only marginally relevant to this question (more on this below). However, Article 28 delineates the required scope of protection. Significantly, it differentiates between product and process patents. For products, Article 28 requires that the patent confer the exclusive rights "to prevent third parties not having the owner's consent from the acts of: making, using, offering for sale, selling, or importing for these purposes that product."[31] For

23. *Id.* at 81.

24. As the Indian Supreme Court noted, Gleevec was patented in the United States and under the European Patent Convention. Novartis Ag v. Union of India, (2013) 6 SCC 1, 90 ¶ 5 (India). *See also* Cynthia M. Ho, *Should All Drugs Be Patentable?: A Comparative Perspective*, 17 VAND. J. ENT. & TECH. L. 295, 326–27 (2015).

25. MAX PLANCK DECLARATION, *supra* note 1, at 5.

26. For a list of contributors, see *id.* at 19.

27. *See* Ho, *supra* note 24.

28. Joost Pauwelyn, *The Rule of Law without the Rule of Lawyers? Why Investment Arbitrators are from Mars, Trade Adjudicators are from Venus*, 109 AM. J. INT'L L. 761, 764, 798 (2015).

29. MAX PLANCK DECLARATION, *supra* note 1, § 4 at 14.

30. TRIPS Agreement, *supra* note 3, art. 27.1.

31. *Id.* art. 28.1(a).

processes, it requires that the patentee can "prevent third parties not having the owner's consent from the act of using the process, and from the acts of: using, offering for sale, selling, or importing for these purposes at least the product obtained directly by that process."[32]

It is difficult to square the notion that a nation can limit product patents to the disclosed functions with the fact that TRIPS makes this differentiation, for a product patent that is limited to only particular functions is essentially a patent on the processes for achieving those functions. The best way to see this is to consider enforcement. The holder of a true product patent (that is, a patent that covers the product itself) can monitor the market and sue anyone who appears to be making, using, selling, offering to sell, or importing the product without authorization. It is therefore relatively easy to stop unauthorized activity. The patentee must prove the defendant's product falls within the claims of the patent; it might also face a challenge to validity, but—importantly—it is not forced to prove what use the defendant is making of the product. In contrast, the holder of a product patent of the type envisioned by the Declaration must prove that the product is being used for one of the specified functions. In other words, the patentee would have to prove exactly what the holder of a process patent must prove: that the defendant is actually using the patented information in a specific way. Where the end-users are consumers, and in countries that offer little discovery, holders of process patents have found it difficult, if not impossible, to sustain the burden of making that sort of showing.[33]

Had TRIPS negotiators meant to require only this level of protection, they could have simply limited the patent obligation to the protection of processes. Or if they preferred to make distinctions, they might have eschewed the common terminology, which can be easily misunderstood, and instead required member nations to protect the right to make and the right to use (sometimes called "howtomake" and "howtouse" patents[34]). Presumably, they did not adopt either of these options because it is well recognized by innovation economists that process patents are much weaker than product patents.[35] Process patents may be all that an inventor can obtain in certain circumstances and, in those cases, they may be better than no protection at all. But a system that relies on nothing but species of process

32. *Id.* art. 28.1(b).

33. *Cf.* Dawson Chem. Co. v. Rohm & Haas Co., 448 U.S. 176, 206, 223 (1980) (holding it is not misuse to tie sales of a product to licensing the process for using it; noting the "practical difficulties" that patentees would otherwise encounter).

34. *See, e.g.*, Paul H. Eggert, *Uses, New Uses and Chemical Patents—A Proposal*, 51 J. PAT. & TRADEMARK OFF. SOC'Y 768, 784–5 (1969); Michael Risch, *Reinventing Usefulness*, 2010 BYU L. REV. 1195, 1233–34 (2010) (noting that courts could provide separate claims for making and using a product without ever protecting the product itself).

35. *See, e.g.*, Wesley M. Cohen & Steven Klepper, *Firm Size and the Nature of Innovation Within Industries: The Case of Process and Product R&D*, 78 REV. ECON. & STATS. 232, 233 (1996); Robert P. Merges & Richard R. Nelson, *On the Complex Economics of Patent Scope*, 90 COLUM. L. REV. 839, 851 (1990) ("because a product claim is typically broader than one simply on a particular way of making that product, patentees seek—and often obtain—product patents").

patents is in danger of not allowing investors to appropriate enough of a return to incentivize the optimum level of inventive activity.[36]

The patent system is also designed to encourage early patenting: all industrialized countries now award patents to the first to file an application.[37] Even before the United States adopted that position in 2011,[38] its law included a series of bars that pushed inventors to apply quickly.[39] Early patenting discloses inventions before others have devoted resources to re-discovering them and it immediately exposes any new underlying principles to others. Further, as John Duffy has argued, the earlier a patent is applied for, the sooner the protected invention falls into the public domain.[40] But if some countries were to limit product patents to the functions disclosed, they would undermine this system. It is not unusual to create a product for one purpose and then to find other applications.[41] Under the Declaration's approach, an inventor would tend to delay patenting until it discovered all the major functions of the product, for only then would it be able to recoup the full benefit of inventing it. Even if the inventor only cared to capture profits from one function, it might delay. After all, if new functions were found after the patent issued, the inventor would face the enforcement problem described above: it would be required to prove the defendant was using the product to perform the function described in the patent, not the one invented later. Because the world's patent application processes are, in a sense, tied together through the priority rules of the Paris Convention,[42] it is inconceivable that TRIPS negotiators would, without debate, have given countries "latitude" to adopt rules that encourage late patenting.

Admittedly, the Europeans have taken the position that product patents can be limited to the disclosed function, but they have done so only in the case of gene patents. For example, German and French patent laws include provisions that gene

36. *See, e.g.*, F.M. Scherer, *The Innovation Lottery: The Empirical Case for Copyright and Patents*, *in* EXPANDING THE BOUNDARIES OF INTELLECTUAL PROPERTY: INNOVATION POLICY FOR THE KNOWLEDGE SOCIETY 3, 20–21 (Rochelle C. Dreyfuss et al. eds., 2001).

37. Michael A. Shinall, *Priority and Disclosure: Challenges and Protections to Small Investors in a First-to-File World*, 94 J. PAT. & TRADEMARK OFF. SOC'Y 362, 363 (2012).

38. Leahy-Smith America Invents Act ("AIA"), Pub. L. No. 112-29, 125 Stat. 284 (2011) (codified in scattered sections of 35 U.S.C.).

39. *See* 35 U.S.C. §§ 102(b), (d), (g) (amended 2012).

40. John F. Duffy, *Rethinking the Prospect Theory of Patents*, 71 U. CHI. L. REV. 439, 444 (2004).

41. *See, e.g.*, Amarin Pharma, Inc. v. U.S. Food & Drug Admin., 119 F. Supp. 3d 196 (S.D.N.Y. 2015) (describing the widespread practice of using medications to treat conditions other than those for which the manufacturer sought FDA approval); Daniel S. Sem, *Repurposing—Finding New Uses for Old (and Patented) Drugs: Bridging the "Valley of Death," to Translate Academic Research into New Medicines*, 18 MARQ. INTELL. PROP. L. REV. 139 (2014); *Repurposing Drugs*, NAT'L CTR. FOR ADVANCING TRANSLATIONAL SCIS., http://www.ncats.nih.gov/research/reengineering/rescue-repurpose/rescue-repurpose.html [https://perma.cc/EM5P-7PGA] (last updated Jan. 14, 2016).

42. *See* Paris Convention for the Protection of Industrial Property, art. 4, March 20, 1883, as last revised at Stockhold July 14, 1967, 13 U.S.T. 1.

patents cover only the function of the gene described in the specification.[43] And the Court of Justice for the European Union has adopted a variation on the same theme, holding in *Monsanto v. Cefetra* that a product containing a protected gene is infringing only when the gene is functioning.[44]

But these actions do not suggest the Declaration's view of the scope of product patents is correct. First, this approach to gene patents has not been challenged in the WTO. Accordingly, there is nothing to say it is TRIPS compliant. Second, genes represent a very special case in that they have so many functions, giving patent holders rights over all of them would substantially impede scientific progress.[45] In addition, genes do not disappear as products are altered. For example, the patented gene in a plant will still exist when the plant is harvested, turned into feed, and given to cows that are later made into hamburger. The Europeans may, in short, be making a category error: the difficulty with gene patents isn't scope; it's subject matter. Genes are fundamental building blocks of nature; they are not "inventions" and should not, in their pure form, be the subject of patents.

That, indeed, is the position the United States Supreme Court took in *AMP v. Myriad*,[46] where it held that genomic DNA (gDNA) is not patentable subject matter (but that complementary DNA (cDNA), which is synthesized, is patentable). The High Court of Australia went even further. In *D'Arcy v. Myriad Genetics Inc.*,[47] where the Court held both cDNA and gDNA unpatentable, the Justices concluded as follows:

> When proper regard is paid to their emphasis on genetic information, the subject matter of the claims lies at the boundaries of the concept of "manner of manufacture". That it does lie at the boundaries is further evidenced by the odd consequence that if the claims are properly the subject of a patent, the patent could be infringed without the infringer being aware of that fact. That consequence coupled with the very large, indeed unquantified size of the relevant class of isolated nucleic acids, all of which bear the requisite information, raises the risk of a chilling effect upon legitimate innovative activity outside the formal boundaries of the monopoly and risks creating a penumbral de facto monopoly impeding the activities of legitimate improvers and inventors.[48]

In defense of what they have done, the Europeans might argue that because they could have excluded gene patents entirely, they are free to grant limited protection. That argument hinges on whether genes can be excluded from patenting

43. Gesetz zur Umsetzung der Richtlinie über den rechtlichen Schutz biotechnologischer Erfindungen [Statute Implementing the European Council's Biotechnology Directive], Jan. 21, 2005, BGBL I at 146, § 1a (4) (Ger.); CODE DE LA PROPRIÉTÉ INTELLECTUELLE art. L613-2-1 (Fr.).

44. Case C-428/08, Monsanto Tech. LLC v. Cefetra BV, 2010 E.C.R. 7.

45. Rochelle C. Dreyfuss & James P. Evans, *From Bilski Back to Benson: Preemption, Inventing Around, and the Case of Genetic Diagnostics*, 63 STAN. L. REV. 1349, 1350 (2011).

46. Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107, 2109 (2013).

47. *D'Arcy v Myriad Genetic Inc.* [2015] HCA 35 (Austl.).

48. *Id.* ¶ 93.

under Article 27 (i.e., on whether the *Myriad* cases are compatible with TRIPS)—perhaps that is why the Declaration included Article 27 in its statement about scope. But this argument works only in cases where a product could be excluded entirely. It would permit the exclusion of other natural phenomena and, per the Australian case, perhaps other technological platforms, such as basic molecular shapes (for example, buckminsterfullerenes or carbon nanotubes) and metabolic pathways, where patenting might similarly chill "legitimate innovative activity outside the formal boundaries of the monopoly."[49] But it does not support the general claim made in the Declaration that *all* product patents can be limited to the declared function. And even then, there is a question. TRIPS permits outright exclusion of advances that are not "inventions," but it does not state whether a country can take action less drastic than outright exclusion. While a reading that allows countries to adopt less radical options gives states more tools for tailoring law to their needs, Dinwoodie and Dreyfuss note that strong arguments can be made that the TRIPS Agreement should be read as putting states' feet to the fire. That is, if they decide a field presents a special problem, they must be willing to accept the political repercussions of entirely excluding that field from patenting.[50]

While the rule on scope provides the most obvious clue that the Declaration is somewhat less than balanced scholarship, other elements also undermine its credibility. Basic rules of evidence refrain from putting the burden on a litigant to prove the absence of a fact. Yet the recommendations on compulsory licensing instruct states that they can shift to the patentee the burden of proving the nonexistence of the conditions said to require a license.[51] In apparent contradiction to Article 31(g) of TRIPS, the Declaration takes the position that once awarded, a compulsory license can continue even if the circumstances for it have ended.[52] There is also convoluted language that may mean the states need not consider the effect of such licenses on investment in innovation.[53] Furthermore, the Declaration claims that the government can use patents without authorization for any purpose—presumably, including entirely private purposes for profit.[54] The measures on undisclosed information draw a distinction between "disclosing" undisclosed information and "relying" on undisclosed information.[55] While it is technically correct that these are two different actions, the history of Article 39.3 of TRIPS on trade secrets belies the notion that the provision was meant to permit generic drug companies to rely on the safety and efficacy information another firm

49. *Cf.* Ariad Pharm., Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1340 (Fed. Cir. 2010) (en banc) (invalidating claims essentially drawn to the operation of the NF-κB metabolic pathway on the ground that the patent failed to provide an adequate written description of the invention).

50. DINWOODIE & DREYFUSS, *supra* note 10, § 7.4 at 68–69.

51. MAX PLANCK DECLARATION, *supra* note 1, § 7.4 at 16.

52. *Id.* § 7.5 at 16.

53. *Id.* ("Article 31 of the TRIPS Agreement does not require the limitation of a compulsory licence to a degree that would unduly impede reasonable and good-faith investments of the licensee.").

54. *Id.* §§ 8.1–8.2 at 16.

55. *Id.* at 11, 17.

generated at great expense as long as the generics have not been granted the ability to physically view it.[56]

II. INCENTIVES TO INNOVATE

Even if the Declaration was correct in its interpretation of individual provisions of the TRIPS Agreement, it does less to "clarify regulatory options" than it might. The thrust of the document is that states can strike the appropriate balance by adopting all of the options the Declaration sets out. But that is true only if a state has absolutely no ambition to be inventive in its own right. Perhaps such states exist. Certainly, there are nations that are so lacking in universities, trained workers, laboratories, or even laws that facilitate the accumulation of capital or risk-taking that they are unlikely to reach the global technological frontier in the near future. Many states can, however, still invent in ways that can make important social contributions. Demand within the local market can encourage the establishment of a creative sector. Furthermore, successful early efforts to innovate for local consumption can lead to the development of needed infrastructure and, eventually, to the ability to generate innovations that appeal to broader markets. The copyright industries have already seen this progression (witness Bollywood) and with a judiciously crafted patent system, the same could easily happen on the technology side.

A truly minimalist approach of the type implied by the Declaration could, however, significantly hamper progress of this sort. Reconsider the first two examples set out in the previous section: the recommendation to refuse protection for incremental advances, such as finding a second use for a known product, and to limit patent protection on products to the functions disclosed in the specification. On its own, either option would provide a modicum of protection. Thus, in a country that denies patents on second uses but adopts the usual approach product patents, a second (sequential) use—if found during the period when the initial product is patented—will be protected by that patent.[57] If the second use is found by the holder of the product patent, the holder can capture the return on the new use for the remainder of the patent term on the original invention.[58] If the second use is found by someone else, the two inventors can enter into a contractual arrangement to share in the profits generated by the new function. Arguably, they

56. *See, e.g.*, Aaron Xavier Fellmeth, *Secrecy, Monopoly, and Access to Pharmaceuticals in International Trade Law: Protection of Marketing Approval Data Under the TRIPs Agreement*, 45 HARV. INT'L L.J. 443, 447 (2004); G. Lee Skillington & Eric M. Solovy, *The Protection of Test and Other Data Required by Article 39.3 of the TRIPS Agreement*, 24 NW. J. INT'L L. & BUS. 1, 15–22, 35 n.102 (2003).

57. *See, e.g.*, Jerry R. Green & Suzanne Scotchmer, *On the Division of Profit in Sequential Innovation*, 26 RAND J. ECON. 20 (1995) (analyzing the complex relationship between the original and sequential innovator); *see also* Bhaven N. Sampat & Kenneth C. Shadlin, *TRIPS Implementation and Secondary Pharmaceutical Patenting in Brazil and India*, 50 STUD. COMP, INT'L DEV. 228 (2015) (showing that the impact of § 3(d) would not have been as disastrous had India protected product patents when the original molecule was invented).

58. *See* Green & Scotchmer, *supra* note 57, at 21.

will allocate them in accordance with the relative value of the two uses. If the second inventor gets a patent of its own and refuses to license, states can adopt the provision in TRIPS permitting them to grant compulsory licenses in the case of blocking patents.[59] Again, the license fee would presumably reflect the added value of the second use. Alternatively, if the country adopts the Declaration's theory that a product patent covers only the disclosed function, but permits second use patents, then the patent on the first use protects the first inventor and the patent on the new use will permit the sequential inventor to capture a return on that invention. (There will be no blocking as the first patent would not extend to the second use).

But what if a country adopts both pieces of the Declaration's advice? The second use would not be covered by the first patent because it would not have been disclosed in the application. And it could not be covered by a new patent because such patents are barred. Yet incremental innovation is extremely important. In the pharmaceutical field, for instance, many significant therapies are found during the course of treating patients for other illnesses.[60] More generally, one reason disclosure is a crucial element of the patent regime (and experimental use provisions are important) is so that others can find applications the first inventor did not consider.[61] Perfecting these new advances can nonetheless be expensive. Accordingly, they too can require a system that encourages investment.

For developing countries, there is arguably a special reason to preserve a means for protecting incremental innovation, for many inventions require modification to local conditions. Seed companies, for example, may not optimize for soil and climate conditions in countries that do not farm on a commercial scale;[62] pharmaceuticals are not always developed to deal with the absence of refrigeration;[63] mechanical inventors may invent under the assumption that customers will enjoy a source of continuous energy. As David Opderbeck argued in the context of pharmaceuticals, firms in countries at the cusp of development, free from the expectation that they introduce "blockbuster" products, are particularly well situated to identify, and invent for, such niche markets.[64] Countries may thus be better off with a patent system that encourages adaptations of important breakthroughs to domestic needs than with one that reserves protection to the sort of leaps its own residents are unlikely to make. Whether it is better to adopt law that

59. TRIPS Agreement, *supra* note 3, art. 31(l).

60. *See* Sem, *supra* note 41, at 139.

61. *See, e.g.*, Merck KGAA v. Integra Lifesciences I, Ltd., 545 U.S. 193, 206 (2005) (recognizing the importance of research on known compounds). *See generally*, Merges & Nelson, *supra* note 35, at 845–48, 883.

62. *See, e.g.*, Ronald J. Herring, *Stealth Seeds: Bioproperty, Biosafety, Biopolitics*, 43 J. DEV. STUD. 130, 134 (2007).

63. See generally Brahmaiah Kommanaboyina & C. T. Rhodes, Trends in Stability Testing, with Emphasis on Stability During Distribution and Storage, Drug Development and Industrial Pharmacy, 25 DRUG DEV. & INDUS. PHARMACY 857, 864 (1999) (discussing the stability of pharmaceuticals in a variety of conditions).

64. David W. Opderbeck, *Patents, Essential Medicines, and the Innovation Game*, 58 VAND. L. REV. 501, 522 (2005).

frees second uses from patenting but permits patents on products, or vice versa, is a hard question and guidance would be helpful.

The Declaration raises many other issues of this sort. Is the approach it sets out for compulsory licensing the best way to encourage anyone (locals or foreigners) to develop the products for which a developing country might have a unique need? What of an open-ended provision on government use by for-profit subcontractors? Or the discretion to deny injunctive relief if "the legitimate interests of parties *may* be adversely affected" or if the injunction is "contrary to the public interest"?[65] As Alan Sykes has argued in the case of pharmaceutical research, the dearth of research in diseases of particular importance to developing countries may well come from the excessive willingness of developing countries to use exceptions, limitations, and flexibilities.[66] Ironically, the result of using these exceptions is that the more important and needed an innovation, the more likely exceptions and limitations will apply and the patent holder will be stripped of its ability to fully recoup costs. Such a situation can only discourage investors, both local and international, and exacerbate the problem nonmarket economies face in motivating research geared to their needs.

If the Declaration is truly aimed at clarifying options within the current framework, then it could do better than to set out minimalist options with no indications of their disadvantages, little guidance on which combinations work best and which are to be avoided, and no advice on what sorts of outside interests are "legitimate" or, in the long term, "contrary to the public interest." Indeed, if the ultimate goal is to make the system better as a whole, the Institute's approach can also be criticized for missing the big picture.[67] The entire thrust of the Declaration is to promote sovereign authority—to give nations the power to promote their own parochial objectives. But enhancing the autonomy of each country to design its own patent system fails to consider the value of coordination, of building a patent system that takes into account the needs and capabilities of the entire globe. We next turn to an approach that introduces a concept of proportionality as a substitute for the Declaration's vigorous support for sovereignty. In our view, global regulations aimed at coordinating the international innovation system would be better at drawing out innovation that increases consumer welfare, it would be more equitable, and it would increase economic efficiency.

III. CREATING A BETTER BALANCE

The two Declarations are not the Max Planck Institute's only forays into the debate over regulatory sovereignty under the TRIPS Agreement. In another

65. MAX PLANCK DECLARATION, *supra* note 1, § 10.1 at 17 (emphasis added).

66. Alan O. Sykes, *TRIPS, Pharmaceuticals, Developing Countries, and the Doha "Solution,"* 3 CHI. J. INT'L L. 47, 65–66 (2002).

67. *See* Annette Kur, *Agreement on Trade-Related Aspects of Intellectual Property Rights, in* INTELLECTUAL PROPERTY RIGHTS IN A FAIR WORLD TRADE SYSTEM: PROPOSALS FOR REFORM OF TRIPS 455, 526–27 (Annette Kur & Marianne Levin eds. 2011).

initiative, the Institute participated in a project suggesting modifications to TRIPS that would go beyond the clarification of existing options to expand the Agreement's latitudes.[68] While we are sympathetic to the objectives of all of these efforts, we suggest that it is time to contemplate a more transcendent reform. In its essence, international lawmaking is intended to facilitate coordination among national systems. Rather than fight this goal by identifying loopholes that can be exploited to maximize sovereign authority, it is worth considering steps to deepen the degree of coordination. In this section, we demonstrate how a global perspective on two issues—the obligation to adopt a twenty-year term of protection and international exhaustion[69]—would promote innovation on a worldwide scale and, at the same time, strike the appropriate balance among generations of innovators, between innovators and consumers, and take account of both developing and developed countries' views and aspirations.

A. Term of Protection

The TRIPS Agreement requires all WTO members to adopt a twenty-year patent term for all technologies.[70] This is an easily administered system. However, it leaves countries with only standards on the availability of patents (issues such as the subject matter of protection or the height of the inventive step) and the breadth of protection (exceptions, compulsory licenses, government use rights, and the like) to use as tools for balancing competing interests.[71] These are the techniques the Declaration advocates, but as we saw, their use lowers domestic incentives to innovate, including especially incentives to meet needs that foreigners are unlikely to identify or fulfill. Even the threat that a compulsory license might issue or that a judge will find that an injunction *may* affect a legitimate interest or impinge on an ill-defined concept of social welfare can scare potential investors and prevent them from transferring technology to a developing country or devoting resources to its technology sector. As important, use of these flexibilities gives the impression of shirking: that countries that use them are free riding and not paying their fair share of the costs of development. That perception, in turn, leads developed countries to demand the elimination of the flexibilities—that is, to argue over how TRIPS should be interpreted and to negotiate TRIPS-plus agreements. To developing countries, however, these actions are viewed as attempts to force them to forego use of inventions that would improve social welfare or to require them to pay foreigners

68. *Id.* At 526–27.
69. TRIPS Agreement, *supra* note 3, arts. 6, 33.
70. *Id.*
71. *Id.* art. 27–34.

for advances that would, in all likelihood, have been invented anyway.[72] In the end, both sides see the agreements as unfair.[73]

But economists have long understood that the term of the patent can be used in much the same way as patent breadth to balance competing interests and calibrate the patent reward.[74] Typically, their arguments concern differences in technological fields and lead to recommendations to vary the length of the term to accommodate factors such as the cost of research in each field, the social value of invention within that sector, and characteristics of the demand function.[75] The proposals are then routinely rejected because lawyers consider them impossible to administer. It would be difficult to calculate the optimum term for each technology, to update the calculation as fields mature, or to deter skilled patent prosecutors from drafting around the categories to obtain longer terms for their clients.

However, as Donoso has argued, the length variable could be used on a geographic basis to achieve a much-sought balance.[76] Instead of imposing on all WTO members a minimum term of twenty years, the TRIPS Agreement could require protection for a term that the WTO would calculate on the basis of each country's wealth.[77] This single change could turn everything around. Developing countries would contribute to the overall global effort to innovate according to their individual capacities to pay. They would thus no longer find it imperative to use flexibilities, exceptions, and limitations, which reduce their contributions and diminish investments in innovation, but are perceived as necessary to address the unbalanced nature of the basic regime.[78] If wealth were used to calculate the required patent term, developing countries might, in fact, become pro-protection, as they would then carry the same burden, measured in proportion to their affluence, as would a developed country.

This approach would be easy to administer: the country of registration is immutable and the term would be set according to an objective criterion, such as

---

72. *See, e.g.*, Rochelle Dreyfuss & Susy Frankel, *From Incentive to Commodity to Asset: How International Law is Reconceptualizing Intellectual Property*, 36 MICH. J. INT'L L. 557, 575 (2015) (claiming that FTAs can be seen as requiring countries to bring laws into closer harmony, i.e., granting greater patent protection in more developed countries to their detriment).

73. *See, e.g.*, Richard A. Epstein & F. Scott Kieff, *Questioning the Frequency and Wisdom of Compulsory Licensing for Pharmaceutical Patents*, 78 U. CHI. L. REV. 71 (2011); Susan K. Sell, *TRIPS Was Never Enough: Vertical Forum Shifting, FTAs, ACTA, and TPP*, 18 J. INTELL. PROP. L. 447, 453 (2011).

74. *See, e.g.*, Amir H. Khoury, *Differential Patent Terms and the Commercial Capacity to Innovate*, 18 TEX. INTELL. PROP. L. J. 373, 374–75 (2010); Ted O'Donoghue et al., *Patent Breadth, Patent Life, and the Pace of Technological Progress*, 7 J. ECON. & MGMT. STRATEGY 1, 2 (1998).

75. William D. Nordhaus, INVENTION, GROWTH AND WELFARE: A THEORETICAL TREATMENT OF TECHNOLOGICAL CHANGE (1969). For a literature review, see Khoury, *supra* note 74, at 393–97.

76. DONOSO, GLOBAL SOLUTION, *supra* note 13, at 9; Donoso, *Proportional Rewards*, *supra* note 13, at 115.

77. *See* Donoso, *Proportional Rewards, supra* note 13, at 125–30 (providing an example of what such a formula might look like).

78. *Id.* at 125–26, 131–34.

gross domestic product. Under this system, a country suffering from a bad economy would be allowed to establish a shorter term of protection. But once its economic problems are solved, conditions improve, and it is in a position to contribute more to the technological progress of humanity, it would be required to extend the exclusivity period for future inventions.[79] As with the current TRIPS Agreement, the WTO-calculated term would represent the minimum required; countries could choose to adopt a longer period of protection, either across the board or for special cases, such as for pharmaceutical inventions, in order to ensure that inventors receive adequate remuneration.[80]

Varying the patent term could be coupled with other obligations. For example, a country that is allowed a shorter term could be required to forego other flexibilities, such as compulsory licensing in all but the most dire circumstances.[81] The approach would have many advantages. A term certain, coupled with a reduced threat of losing exclusivity unpredictably, would furnish firmer grounds for investment. With greater certainty, local innovators would enjoy an incentive to engage in the sort of incremental innovation that their countries particularly need and that they are uniquely capable of providing. The system would also better motivate foreign inventors to invest locally and to engage in research on problems that are especially prevalent in developing nations. And the approach would decrease deadweight loss, for consumers who cannot afford to pay supracompetitive prices would have access to inventions sooner.

For nations that are having trouble identifying flexibilities, or implementing them into law (or on the ground) effectively,[82] the option of adopting a shorter term would be an especial boon. The rule would be easy to implement and, if used instead of complicated modifications of patentability standards, would allow these countries to rely more on foreign examinations and permit their patent offices to join efforts, such as the patent prosecution highway, that lower the costs of administering the patent system.[83] Further, it would eliminate much of the need for local post-grant challenges or for second looks by other government agencies.[84]

---

79. *See* DONOSO, GLOBAL SOLUTION, *supra* note 13, at 92 (discussing in detail the frequency and effect of revising the term length and the positive implications that can be derived from applying a variable factor).

80. *See, e.g.*, Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified at 21 U.S.C. § 355 and 35 U.S.C. §§ 156, 271); Council Regulation 1768/92, 1992 O.J. (L 182) (EC) 1 (concerning the creation of a supplementary protection certificate for medicinal products).

81. Australia-United States Free Trade Agreement, Austl.-U.S., art. 17.9(7), May 18, 2004, 43 I.L.M. 1248 (permitting compulsory licensing only to prevent anticompetitive conduct and in the case of national emergency or extreme urgency) [hereinafter AUSFTA].

82. *See, e.g.*, Amy Kapczynski, *Harmonization and Its Discontents: A Case Study of TRIPS Implementation in India's Pharmaceutical Sector*, 97 CALIF. L. REV. 1571, 1574 (2009) (noting that the patent office in India lacks the resources to apply § 3(d) properly).

83. *Patent Prosecution Highway (PPH)—Fast Track Examination of Applications*, USPTO (Feb. 20, 2016), http://www.uspto.gov/patents-getting-started/international-protection/patent-prosecution-highway-pph-fast-track [https://perma.cc/PQ83-XRNA].

84. *See, e.g.*, Lei No. 10.196, de 14 de Fevereiro de 2001, Col. Leis Rep. Fed. Brasil, 62,

This approach would also reduce the need for complex judicial determinations in the remedial stage of enforcement actions or in connection with applications for compulsory licenses.

But the major difference lies in the global impact of this approach. For inventions that are of equal interest to people all over the world, there would no longer be reason to think that developing countries are free riding or that the imposition of supracompetive pricing is unjust. A regime that calibrated the term by reference to a measure of national wealth would, essentially, require countries to contribute to the cost of innovations that they use, in an amount (roughly) proportionate to their economic capacity to pay. The burden of supporting scientific advancement and technological development would, in short, be felt equally in all countries regardless of their state of economic development. Suspicions of free riding (on the one hand) and profiteering (on the other) might then abate. With a tool that equalizes the burden, the members of the WTO might also be willing to revive the negotiations that have been stalled for over a decade.

B. Exhaustion

All of the ideas discussed so far—clarifying the existing agreement, tweaking the current system, or (more dramatically) changing the patent term—suffer from one problem: countries that make money from their inventive capacity will not agree to any of these approaches because there is no coordination on the question of international exhaustion. Under the current TRIPS regime, as long as countries abide by their national treatment and most favoured nation obligations, they can, in the Patent Declaration's words, determine "whether patent rights are to be exhausted nationally, regionally, or internationally."[85] As a result, once the patent holder makes embodiments of its invention available in any one country, other countries are free to "parallel import" them to their own territory, where they can then be sold or used without further authorization (or further payment), even in the face of large global price differentials.

Indeed, the Declaration doubles down and encourages states to use this flexibility.[86] Thus, it points out that:

> Some industries may be more prone to parallel imports than others; and some may depend more on price differentiation than others. States remain free to apply the concept of exhaustion that they expect to be most favourable for the development of the industry in the field of technology concerned.[87]

Fevereiro 2001 (Braz.) (requiring the National Health Surveillance Agency (ANVISA) to review patent awards to ensure that they will not endanger public health).

85. MAX PLANCK DECLARATION, *supra* note 1, § 5.1 at 14; TRIPS Agreement, *supra* note 3, art. 6.

86. MAX PLANCK DECLARATION, *supra* note 1, § 5.2 at 14.

87. *Id.* at 7.

To be sure, the relationship between Article 27's principle of nondiscrimination by field of technology and Article 6's agnosticism regarding exhaustion presents a difficult question. Article 27's ban on discrimination by field of technology forestalls special-pleading lobbying and thus ensures that all inventors receive equivalent opportunities to appropriate returns from their inventive efforts. Because parallel importation can undermine the rewards a right holder can obtain in any particular jurisdiction as surely as can any other flexibility a country might adopt, the ban should, in theory, apply there as well. However, Article 6 specifically states that as far as exhaustion is concerned, only issues related to the national treatment and most favoured nation obligations are subject to dispute resolution.[88] It is therefore likely that WTO members can recognize international exhaustion for some industries and not for others without fear of a TRIPS challenge in the DSB.[89]

The harder question is whether encouraging international exhaustion promotes the values of international intellectual property law (or even the Declaration's goal of increasing regulatory sovereignty). Arguably, it does the opposite. International exhaustion, coupled with cheap transportation costs and dramatic increases in global trade, can make countries hypersensitive to externalities generated by their trading partners.[90] *Kirtsaeng v. John Wiley & Sons, Inc.*[91] furnishes a good example. The case involved a claim that the importation of cheap textbooks from Thailand into the United States infringed the publisher's copyrights. After the Supreme Court recognized a doctrine of international exhaustion in U.S. copyright law, thereby allowing importation of the texts, Wiley announced it would increase the price of the international editions of its books.[92] Access for Thai students will thus decrease, even as the books become cheaper for already-privileged Americans.

To make matters worse, TRIPS's failure to coordinate rules on parallel importation means that countries like Thailand have no control over whether

88. TRIPS Agreement, *supra* note 3, art. 6.

89. Whether such action would be subject to challenge under other provisions of the GATT is a different question and beyond the scope of this article.

90. International intellectual property law recognizes this point in at least two places. The Appendix to the Berne Convention allows developing nations special rights over translations—but only into languages that are unpopular. An Appendix to the Berne Convention for the Protection of Literary and Artistic Works, App. Arts. II, III, Sept. 9, 1886, as last revised July 24, 1971, amended Oct. 2, 1979, S. Treaty Doc. No. 99-27, 828 U.N.T.S. 221. Translation into languages that would attract exportation of cheap copies into major markets are highly disfavoured. *See id.* art. II(2). Similarly, while the Doha Declaration on Public Health recognized the need to modify art. 31(f) of TRIPS to allow countries to issue compulsory licenses to meet certain special needs of foreign markets, implementation introduced conditions intended to prevent leakage of cheap products into markets that can afford to pay patent prices, see WTO, Implementation of Paragraph 11 of the General Council Decision of 30 August 2003 on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, Dec. 6, 2005, IP/C/41, http://www.wto.org/english/news_e/news05_e/trips_decision_e.doc.

91. Kirtsaeng v. John Wiley & Sons, Inc., 133 S. Ct. 1351, 1357 (2013).

92. *Pricing of U.S. Textbooks*, WILEY-VCH (Jul. 10, 2013), http://www.wiley-vch.de/publish/dt/company/news/archive/19545/?sID=5ookr615teu3o57e8dsnee8fc0 [https://web.archive.org/web/20160304192519/http://www.wileyvch.de/publish/dt/company/news/archive/19545/?sID=5ookr615teu3o57e8dsnee8fc0].

countries like the United States recognize international exhaustion and allow importers to roam the world for the best deals on protected works. Nor can one nation control the conditions under which other countries permit parallel imports—for instance, whether they permit them only when right holders voluntarily put goods on the market at prices they set themselves, or also allow it when threats of compulsory licenses, government takeover, or price controls coerce right holders into selling at reduced prices. And while TRIPS can certainly be interpreted to require right holders to affirmatively exercise their right to exclude (presumably, that is why the concept is referred to as "exhaustion"), arguments have been made that anytime goods are lawfully on the market (for example, through the use of compulsory licenses or in the absence of a local patent), parallel importation is permissible.[93]

To put the point more generally, a key reason for international intellectual property law is to prevent each country's intellectual property policies from spilling over outside its borders and affecting the way other nations have balanced the interests of domestic users and producers. Rules permitting parallel importation violate that principle by creating extremely interdependent markets. Accordingly, they encourage countries that see high levels of protection as desirable locally to inflict that view on nations where less protection is more appropriate. For example, because TRIPS takes no position on price controls, countries enjoy substantial leeway to ameliorate the effect of patents on important products, such as pharmaceuticals. But the availability of low-price medication on world markets has led the United States to negotiate new free trade agreements that limit governmental authority over price setting.[94] Similarly, the United States has sought to cabin exclusions from protection[95] and compulsory licensing.[96] Indeed, its strident position on data exclusivity may stem less from the desire to earn high profits in places like Central America and more from the fear that cheap drugs will become available for export.[97]

An international rule on parallel importation would be helpful if it did no more than add a definition of exhaustion to Article 6. For example, the Agreement could make it clear that the patent holder cannot be regarded as having exhausted its

93. *See* Christopher Heath, *Exhaustion and Patent Rights, in* PATENT LAW IN GLOBAL PERSPECTIVE 419, 463 (Ruth L. Okediji & Margo A. Bagley eds., 2014).

94. *See e.g.*, United States-Korea Free Trade Agreement, U.S.-S. Kor., art. 5.3(1)–(2), June 30, 2007, http://www.ustr.gov/trade-agreements/free-trade-agreements/korus-fta/final-text [hereinafter KORUS]. In a Confirmation Letter, Korea also agreed to ensure that the body setting prices be independent of the health authorities. The United States also uses trade preferences to pressure countries over their methods of controlling price. *See* OFFICE OF THE U.S. TRADE REPRESENTATIVE, 2015 SPECIAL 301 REPORT 25, https://ustr.gov/sites/default/files/2015-Special-301-Report-FINAL.pdf [https://perma.cc/53SB-Q2HS] (commenting on New Zealand's Pharmaceutical Management Agency (PhARMAC)).

95. *See, e.g.*, KORUS, *supra* note 94, art. 18.8(2).

96. *See, e.g.*, AUSFTA, *supra* note 81, art. 17.9(7).

97. *See, e.g.*, Dominican Republic-Central America Free Trade Agreement art. 15.10, Aug. 5, 2004, 43 I.L.M. 514.

interests unless it voluntarily allowed its goods to be sold (and then, perhaps, only if the price was not influenced by governmental action or threats of such action). But a complete bar on parallel importation would be most efficient economically, for it would allow the right holder to squeeze out deadweight loss. Or as Sykes put it:

> If trading nations as a whole ban parallel imports, pharmaceutical patent holders should be willing to sell their products at a low price to nations where customers cannot afford to pay much for them as long as that price covers the marginal cost of making the drug and delivering it. They will be willing to do so because each sale yields some profit, and they need not fear that their low-priced sales in one market will be re-exported to undercut their prices elsewhere.[98]

Sykes was speaking of pharmaceutical products, but his conclusion applies to all patented inventions. Because segmenting markets prevents externalization of the costs of each country's policies, there would be less reason to be concerned about how individual nations balance intellectual property rights against other interests. A coordinated international exhaustion system would thus make the Declaration's other recommendations considerably more palatable and it would also allow countries to freely experiment with intellectual property protection in ways the Declaration did not anticipate. Moreover, it might reduce the pressures currently placed on developing countries to enter into new agreements that further reduce access for their consumers and for follow-on inventors.

A rule that bars international exhaustion would also further the goals of the proportionate-return system discussed above. Strictly speaking, a complete bar is not a prerequisite to the proposal for varying the patent term according to national wealth.[99] As long as exhaustion is properly defined, a patentee could avoid losing global profits by withdrawing from markets in countries with shorter terms once its patents in those countries have expired. Admittedly, at that point, third parties could enter the market. However, the patentee could rely on Article 28's exclusive right of importation to require countries where the patent remains in force to prevent those parties from selling goods in their territories. Nevertheless, a bar on parallel imports would work better. Patentees who leave markets forego the possibility of earning a competitive return. With lower prospective profits, the patentee may be unwilling to make the investments necessary to enter in the market in first place (especially, as with pharmaceuticals, where the cost of entry is high). An international rule on exhaustion would thus not only ensure each country shoulders a burden of the cost of development, it would also make it more likely that patentees will be willing to exploit these markets and make their inventions available to those who live in places where the term is less than twenty years.

---

98. Sykes, *supra* note 66, at 64.

99. *See* DONOSO, GLOBAL SOLUTION, *supra* note 13, at 99–100; Donoso, *Proportional Rewards*, *supra* note 13, at 120, 124–25.

CONCLUSION

The Max Planck Declaration is a noble effort to clarify national options under the TRIPS Agreement. In a sense, however, it is too noble an effort. Its aggressive interpretation of certain of the Agreement's provisions undermines the credibility of the enterprise as a whole. Moreover, if adopted *in toto*, the Declaration would extinguish local incentives to invent and undermine the effort to move all nations to the technological frontier, where they can become innovative in their own right. More reasonable positions, explained in greater detail, would be far more useful.

In the final analysis, however, it is not clear whether the problem with TRIPS is, as the Declaration implies, too little sovereign authority, or whether the trouble is insufficient coordination. The TRIPS Agreement eschews use of the patent term to balance competing interests. Were the WTO to focus on that variable and calculate the minimum term based on each nation's ability to pay, the system would more fairly distribute the burden of contributing to the advancement of knowledge. When coupled with a ban on parallel importation, such a regime would also be more efficient economically, for it would lower worldwide examination costs, permit discriminatory pricing, and eliminate deadweight loss. It would also encourage global compliance and reduce pressure for inappropriate levels of top-down harmonization. Both developed and developing countries' interests will be satisfied and, more importantly, a better and balanced system will be created. More innovation would follow.