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## Evaluating Flexibility in International Patent Law

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# Evaluating Flexibility in International Patent Law

SARAH R. WASSERMAN RAJEC\*

*Global patent law has raced toward harmonization over the past decades. Countries with vastly different industries, values, and levels of development now offer robust patent rights with similar contours through membership in the World Trade Organization and consequent adoption of the Agreement on Trade-Related Aspects of Intellectual Property Rights (“TRIPS”). However, patent law is still far from harmonized among countries or static within countries. Jurisdictions tailor their patent laws to accommodate differences between industries, unforeseen inefficiencies, and diverse views of the costs and benefits associated with offering patent rights to stimulate innovation. Prior scholarly work consists of either doctrinal analyses of relevant governing treaties or utilitarian analyses of the measures’ consistency with an “ideal” level of patent protection. The first perspective sidesteps normative questions by assuming the balance between harmonization and flexibility embodied in TRIPS and provides little guidance for cases in which TRIPS compliance is unclear. The second adopts assumptions that either impose foreign preferences or tacitly accept local preferences embodied in the measure. Any conclusion thus over-privileges background preferences and predetermines a normative conclusion.*

*This Article puts forth a framework for evaluation of a tailoring measure based on whether it meets the justifications for allowing flexibility while accounting for the concerns that favor uniformity and harmonization. The proposed framework looks to the implementing institution and the adequacy of the stakeholder representation to determine the desirability, from a global perspective, of a given mechanism. Rather than offering a strict formula, I suggest that honoring diversity among regimes requires acceptance of measures that are open to criticism from consequentialists but does not preclude critical analysis of the means of development or implementation. Such an analysis allows for a productive evaluation of tailoring measures that honors differences among jurisdictions while properly accounting for the justifications underlying harmonization.*

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## INTRODUCTION

Patent law is territorial; each country grants rights that can only be enforced within its borders, and “there is no such thing as a ‘global patent.’”<sup>1</sup> The decision by a government to grant a patent on an invention is a trade-off. A patent is a time-limited right to exclude, meant to provide incentives to invest and engage in innovation and to disclose the fruits of that innovation. This is an incentive that comes at the cost of public use and access to the technology on terms other than the inventor’s. Despite differences among fields of technologies that bear on the costs and potential profits associated with them, modern patent law is largely uniform within countries. Thus, the same rights to exclude—and

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1. MARTIN J. ADELMAN ET AL., GLOBAL ISSUES IN PATENT LAW 3 (2011).

attendant remedies—are available for inventions in all fields of technology, for all applicants, and, excepting antitrust violations or other misuse, without regard to the patent holder’s use of those rights. Countries may choose to deviate from this uniformity and thereby tailor the law to particular circumstances. Since the Paris Convention in the late nineteenth century, the first major international treaty to attempt a degree of harmonization of patent rights, the pendulum has been swinging toward greater harmonization among countries, and thus necessarily toward greater uniformity within countries. Harmonization efforts have reduced the flexibility of countries to enact tailoring measures. The strong prescriptions of the Agreement on Trade-Related Aspects of Intellectual Property Rights (“TRIPS”) and its enforcement mechanism<sup>2</sup> may be indications that the international community is nearing the apex of this swing. Some further efforts at harmonization have moved to the formation of new arrangements, such as regional trade agreements and enforcement treaties. At the same time, developing and “least developed” countries, which have consistently been asked to increase the strength of patent rights and infringement remedies, are providing a counter-force. India has been at the forefront of this resistance—both during negotiations of TRIPS and through its expansive interpretation of flexibilities allowed by the agreement. Thus, India’s passage and interpretation of laws excluding certain types of chemicals from patentability and allowing for compulsory licensing of pharmaceutical products serve as examples of tailoring measures (or flexibilities) that reject a uniformly applicable patent law and thereby undermine global harmonization.

India has come under criticism for its aggressive use of flexibilities but it is by no means alone in its attempts to tailor patent laws to fit its needs. The United States—a stalwart negotiator of global patent law harmonization—employs tailoring measures as well.<sup>3</sup> The Drug Price

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2. Margaret Chon describes the TRIPS agreement as effecting a “tectonic shift in the landscape of intellectual property law.” Margaret Chon, *Intellectual Property and the Development Divide*, 27 *CARDOZO L. REV.* 2821, 2824 (2005).

3. In addition to existing tailoring mechanisms, legal scholars have suggested numerous other means of tailoring patent laws to particular industries or situations. Some of these suggestions relate to judicial interpretation of current law. *See, e.g.*, DAN L. BURK & MARK A. LEMLEY, *THE PATENT CRISIS AND HOW THE COURTS CAN SOLVE IT* (2009) [hereinafter *THE PATENT CRISIS*]; Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 *VA. L. REV.* 1575 (2003); Michael W. Carroll, *One Size Does Not Fit All: A Framework for Tailoring Intellectual Property Rights*, 70 *OHIO ST. L.J.* 1361 (2009) (proposing a framework to evaluate existent and proposed tailoring measures based on the traditional economic case for intellectual property protection); Anna B. Laakmann, *An Explicit Policy Lever for Patent Scope*, 19 *MICH. TELECOMM. & TECH. L. REV.* 43 (2012) (suggesting that the courts use patentable subject matter doctrine as an explicit policy lever for calibrating patent scope); Sarah R. Wasserman Rajec, *Tailoring Remedies to Spur Innovation*, 61 *AM. U. L. REV.* 733, 742–48 (2012) (suggesting that courts analyze the public interest in granting incentives to innovate and maintain access in order to

Competition and Patent Term Restoration Act of 1984 (the “Hatch-Waxman Act”) provides a complex legislative framework that interacts with the patent law to alter the incentive structure for pioneer, patent-holding pharmaceutical companies, and for generic drug companies seeking to market drugs following the expiration of the patent term. The exclusive marketing rights granted by Hatch-Waxman provides “pseudo-patent” protection.<sup>4</sup> In addition, the courts have interpreted and applied the seemingly uniform law in industry-specific ways, affecting both the availability of patents in some fields and the availability of remedies to certain types of entities. This is not unique to the United States. The protections afforded by a patent are only theoretically uniform within a given jurisdiction. Because of the heterogeneous nature of the inventions and technologies covered, perfect uniformity would be as difficult to assess as it would be to achieve. As a result, all patent systems contain laws that apply in non-uniform ways, whether by design or in application.

Nevertheless, developed countries have strongly pursued international harmonization, negotiating international and bilateral agreements that cement high minimum levels of patent rights in member countries of the World Trade Organization (the “WTO”). These agreements permit only minimal exceptions and are backed by the considerable weight of the WTO dispute resolution mechanism. Moreover, the flexibility that is incorporated in the TRIPS agreement is based on currently accepted tailoring mechanisms but does not allow for future variations.<sup>5</sup> The international legal system is on a slow march to harmonize, unify, and entrench patent laws without a methodology for analyzing and evaluating existing and potential future flexibilities. In particular, it is missing a means of coming to a country-neutral method of evaluation that recognizes the purposes and value of a patent system while accepting that tailoring mechanisms will necessarily reflect the

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determine the appropriateness of a permanent injunction for a company that lacks market share). Other suggestions would require legislative action. *See, e.g.*, Gideon Parchomovsky & Michael Mattioli, *Partial Patents*, 111 COLUM. L. REV. 207 (2011) (suggesting two new patent forms in addition to the current system to mitigate social costs of traditional patents and increase access by subsequent inventors).

4. Rebecca S. Eisenberg, *The Role of the FDA in Innovation Policy*, 13 MICH. TELECOMM. & TECH. L. REV. 345, 359–64 (2007) (explaining how FDA regulation provides similar protections to patent law, often for purposes that align more closely with patent law than with the health and safety concerns more typically associated with its mission).

5. Graeme B. Dinwoodie & Rochelle C. Dreyfuss, *TRIPS and the Dynamics of Intellectual Property Lawmaking*, 36 CASE W. RES. J. INT'L L. 95, 98–100 (2004) (discussing how TRIPS does not allow flexibility for future negotiation of similar arrangements, even where all stake-holders are represented in bargaining, and suggesting that because the WTO's dispute settlement body looks at challenged legislation piece-meal, the result is that concessions benefiting the public are more likely to be struck down while measures appealing to patent-holders will be upheld, thus undermining the negotiations).

regimes in which they are conceived and implemented. Doctrinal analysis of a particular measure to determine whether it is allowed by TRIPS takes the balance struck by the agreement as a given. Although clearly practical and necessary, this analysis does not help us choose among options allowed by TRIPS. In addition, it fails to provide normative conclusions, though it may be used to support already-formed opinions about the desirability of a tailoring mechanism. When applied expansively, a utilitarian analysis is similarly conclusory. A utilitarian cost-benefits analysis can theoretically determine normative value, but this type of conclusion has little extrinsic insight. It relies on assessments of the utility of innovation, the costs of reduced access, and the strength of the connection between the incentives granted and the innovation encouraged. But these are the very measures that are likely to vary among countries. Ignoring such differences undermines some purposes of having flexibility; adopting local preferences uncritically undermines the purposes of uniformity and harmonization. Conclusions are thereby determined by the original assumptions. While endorsing the utilitarian view of the patent grant, this Article accepts that such an analysis may yield different results in various countries and suggests how these results may be evaluated on their ability to promote the purposes of harmonization, even while deviating from it.

This Article proposes a framework to analyze and evaluate the use of flexibilities in patent law from an international perspective. Such a framework has descriptive value in comparisons of patent protection among countries with varying levels of development. It also has prescriptive value, allowing for normative claims about when tailoring measures may be desirable departures from international standards and how they may best be implemented.

Harmonization among countries (and uniformity within countries) can be justified by arguments sounding in certainty, fairness, and economy, as well as public choice arguments that point out the possibility of capture in specialized laws. Certainty is of value to those engaged in innovation whose potential to attract investors is based upon the future ability to protect inventions. Harmonized laws protect certainty interests. Proponents of harmonization also argue that it is unfair for all the members of a country with high levels of patent protection to bear the costs of research and development (passed on to consumers through the higher costs associated with patented products), while those in countries with lower levels of protection gain the same benefits from the innovation.<sup>6</sup> In addition, low barriers to trade have resulted in

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6. Nor are lower levels of protection the only method of achieving greater levels of access to innovation. Countries that enable domestic price discrimination (through local rules of exhaustion or

increasingly globalized businesses that seek protection and engage in production in multiple jurisdictions. Thus, harmonization of laws is supported by considerations of economy for companies that seek rights worldwide. Sacrifices in flexibility may therefore be justified by decreasing the costs of bringing innovation to many different countries. Finally, for laws that apply uniformly across industries, pressure in support of or in opposition to the laws will come from multiple viewpoints and be apparent to a variety of stakeholders, whereas laws that target specific industries are subject to one-sided lobbying and a dilution of opposition.

Flexibility can serve important purposes as well, allowing for tailored efficiency and the incorporation of diverse local interests, values, and needs. Flexibility also fosters experimentation and improvement in the law. Measures that tailor patent law to specific industries or problems allow solutions to the inefficiencies inherent in a uniform system. In addition, because different countries have different views on the balance between incentives to innovate and the need for access to inventions, allowing for flexibility honors the diversity of the countries that have nevertheless come together to express the value of patent systems in encouraging innovation. These different views may be based on how innovation and access are respectively valued, but may also reflect the differing development needs of countries. Finally, from a federalist or neo-federalist perspective, variation among laws allows us to humbly recognize that improvement in the law is always possible and often desirable.

These competing justifications are expressions of abstract values. Their prescriptions become concrete when applied to evaluate specific tailoring measures. In particular, looking at how well specific tailoring measures have taken the viewpoints of all relevant stakeholders into account allows an evaluation of whether the measure is useful in attaining tailored efficiency and meeting the needs of the relevant jurisdiction. At the same time, it answers concerns about possible capture and other justifications for a harmonized system. Accounts of the institutional implementation of a tailoring measure similarly permit an assessment of whether it meets the justifications for flexibility while accounting for the concerns raised by uniformity.

This Article begins with an explanation of the patent grant, its purposes, and its generally uniform application to various fields of technology. Next, the Article describes tailoring measures that, despite this uniformity, have been adopted by India and the United States, including their implementation processes and the level of relevant stakeholder representation in their development. The discussion then

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other market mechanisms) encourage broader consumer access without impairment of exclusive rights.

turns to an explanation of the historical move toward harmonization in patent law and counter movements. This account leads into a discussion of the arguments for uniformity and harmonization in patent law, followed by arguments for tailoring and flexibility. These arguments inform a framework for evaluation based on the implementing institution and the stakeholder involvement in development of a tailoring measure. The Article then demonstrates how this framework may apply for analysis of particular provisions of law, and to some general conclusions that can be drawn about institutional choice in implementation of these tailoring measures.

### I. PATENTS: THE MODERN PATENT AND ITS LIMITS

Patents are government-granted rights to inventors meant to encourage scientific progress.<sup>7</sup> As such, the patent is characterized by the right to prevent others from making, selling, or using a patented product or process for a specified number of years.<sup>8</sup> Most national patent laws require patented products or processes to be novel, non-obvious, and useful, although the legal terms for these requirements vary.<sup>9</sup> “Patents are widely considered essential . . . to provide appropriate incentives for innovation.”<sup>10</sup> The exclusive right embodied in a patent is meant to offer protection for information that may otherwise be easily appropriated and, because it is information-based, copied without any tangible (and therefore recoverable) depreciation to the inventor.<sup>11</sup> The protection offered by a patent thus encourages investment in innovation by allowing exclusion of others from the market. Social benefits associated with the patent system include access to innovation that otherwise might not have occurred. This access is typically had at a higher price during the course of the patent, and, due to market competition, lower prices following expiration of the patent. Patents also require that an inventor disclose the nature and functioning of her invention, thereby allowing others to

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7. U.S. CONST. art. I, § 8, cl. 8 (“To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.”).

8. JOHN H. JACKSON ET AL., *LEGAL PROBLEMS OF INTERNATIONAL ECONOMIC RELATIONS: CASES, MATERIALS AND TEXT ON THE NATIONAL AND INTERNATIONAL REGULATION OF TRANSNATIONAL ECONOMIC RELATIONS* 844–45 (3d ed. 1995).

9. *Id.*

10. *Id.* at 845.

11. Accordingly, patents solve a free-rider problem that creates incentives for would-be innovators to be “second-movers” in the market place, waiting for others to invent and profiting from their efforts while appropriating the market for the invented good.

benefit from the knowledge and to engage in further innovation that builds upon it.<sup>12</sup>

The American patent system is representative of many modern national patent systems.<sup>13</sup> To promote scientific progress, American patent law, like that of other countries, offers a time-limited right to exclude others to inventors who disclose their inventions.<sup>14</sup> This formulation of the purposes of patent law is consistent with the utilitarian justification for intellectual property. Also termed the “incentive theory” of patents, this justification suggests that patents are necessary incentives for innovation. According to this theory, inventors might choose to keep their inventions as trade secrets without patent protections, thereby depriving the public and other innovators from knowledge of and access to the inventions.<sup>15</sup> Patents also may reassure investors, without whom the inventions could not be brought to market. This formulation is attractive because it suggests that one might weigh incentives to innovate with other considerations—such as the interest of the public in access to inventions or the needs of downstream innovators or producers to access new technology—thereby determining an ideal balance of interests.<sup>16</sup> In contrast, accounts based on natural law suggest that inventors have inherent rights based on creating

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12. See KEITH E. MASKUS, *INTELLECTUAL PROPERTY RIGHTS IN THE GLOBAL ECONOMY* 29 (2000) (Intellectual property rights “generate monopoly positions that reduce current consumer welfare in return for providing adequate payoffs to innovation, which then raises future consumer welfare.”).

13. See *infra* Part II (discussing the history of global patent law and the move to harmonization, while section III, *infra*, references current differences among these systems). This Part, however, serves merely to demonstrate the philosophical bases and general contours of modern-day patents.

14. Modern American patent law is rooted in the Constitution, which gives Congress the power to “promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.” U.S. CONST. art. I, § 8, cl. 8. See Rebecca S. Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use*, 56 U. CHI. L. REV. 1017, 1022 (1989), reprinted in MARTIN J. ADELMAN ET AL., *CASES AND MATERIALS ON PATENT LAW* 33–34 (1998) (explaining how the courts expect the right of exclusion to provide an incentive for individuals to invest in research and to disclose their new inventions, thereby benefiting the general public); see also David S. Olson, *Taking the Utilitarian Basis for Patent Law Seriously: The Case for Restricting Patentable Subject Matter*, 82 TEMP. L. REV. 181, 195–97 (2009) (analyzing how the patent system offers a solution to the public goods problem by granting inventors exclusive right to control their invention for twenty years).

15. See *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 63 (1998) (“[T]he patent system represents a carefully crafted bargain that encourages both the creation and the public disclosure of new and useful advances in technology, in return for an exclusive monopoly for a limited period of time.”); WILLIAM M. LANDES & RICHARD A. POSNER, *THE ECONOMIC STRUCTURE OF INTELLECTUAL PROPERTY LAW* 12–16 (2003) (utilizing “the tragedy of the commons” to demonstrate the need for individual property rights in order to encourage innovation).

16. Michael Abramowicz and John Duffy suggest direct application of this sort of weighing in *The Inducement Standard of Patentability*, arguing that a patent application should be denied “if the innovation would be created and disclosed even without patent protection,” because “denying a patent on the innovation costs society nothing . . . and saves society from needlessly suffering the well-known negative consequences of patents.” Michael Abramowicz & John F. Duffy, *The Inducement Standard of Patentability*, 120 YALE L.J. 1590, 1594 (2011).

something new.<sup>17</sup> However, the utilitarian vision of the incentive theory is most often relied upon to justify taking innovation out of the public domain for some time period immediately after invention.<sup>18</sup>

The patent grant constitutes the right to exclude others from making, using, selling, or offering for sale a patented invention or performing a patented process.<sup>19</sup> There are, of course, costs associated with granting patents that are ultimately absorbed by consumers of innovation. Because others are excluded from the market, patent holders can charge a premium on a patented product, which explains why patents are sometimes characterized as monopolies.<sup>20</sup> This premium may result in reduced access to certain innovations for the duration of the patent, affecting consumers and other innovators who are interested in building upon prior innovations. Patents also require transaction costs,<sup>21</sup> including costs associated with obtaining<sup>22</sup> and enforcing<sup>23</sup> patents. The U.S. Patent and Trademark Office (the “PTO”) supports itself with the fees it sets;<sup>24</sup> nonetheless, one can expect those fees get passed on to consumers.

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17. Following Locke’s labor theory, the inventor’s rights in her invention are derived from the labor with which it is imbued, resulting in property rights over the resulting invention. *See, e.g.,* HOLGER HESTERMEYER, HUMAN RIGHTS AND THE WTO: THE CASE OF PATENTS AND ACCESS TO MEDICINES 29–30 (2007) [hereinafter HESTERMEYER, HUMAN RIGHTS] (explaining—and dismissing—a natural law rationale for patent law); ROBERT P. MERGES, JUSTIFYING INTELLECTUAL PROPERTY 34–67 (2011) (discussing the application of John Locke’s ideas to theories justifying intellectual property law). Other justifications for the patent system include the contract theory, the reward theory, and the prospect theory. HESTERMEYER, HUMAN RIGHTS, *supra*, at 30–33.

18. HESTERMEYER, HUMAN RIGHTS, *supra* note 17, at 31–32.

19. 35 U.S.C. § 154(a)(1) (2006).

20. *See* Steven Wilf, *The Making of the Post-War Paradigm in American Intellectual Property Law*, 31 COLUM. J.L. & ARTS 139, 191–92 (2008) (explaining the common, hostile view of patents as monopolies during the post-war years). *But see* *United States v. Dubilier Condenser Corp.*, 289 U.S. 178, 186 (1933), *amended by* 289 U.S. 706 (1933) (“Though often so characterized, a patent is not, accurately speaking, a monopoly . . . . In consideration of [an invention’s] disclosure and the consequent benefit to the community, the patent is granted.”).

21. David Fagundes & Jonathan S. Masur, *Costly Intellectual Property*, 65 VAND. L. REV. 677, 696–98 (2012).

22. *See* Fagundes & Masur, *supra* note 21, at 689–90 (estimating that between legal costs and Patent Office fees, “an average patentee will spend approximately \$22,000 to successfully prosecute a patent application.”). Filing fees for patents start in the hundreds of dollars, but rise with additional claims, drawings, and length of application; issuance of the patent comes with its own fees as well. *See* Setting and Adjusting Patent Fees, 78 Fed. Reg. 4212 (Jan. 18, 2013) (to be codified at 31 C.F.R. pts. 1, 41, 42); U.S. PATENT & TRADEMARK OFFICE, CURRENT FEE SCHEDULE (Oct. 4, 2013).

23. *See* David E. Sosnowski, *Resolving Patent Disputes via Mediation: The Federal Circuit and the ITC Find Success*, MD. B.J., Apr. 2012, at 24, 26 (citing findings on patent litigation costs that averaged \$916,000 when less than \$1 million was at risk, \$2.8 million when between \$1 million and \$25 million was at risk, and \$6 million when more was at risk).

24. *See* Omnibus Budget Reconciliation Act of 1990, Pub. L. No. 101-508, § 10101, 104 Stat. 1388, 1388–91 (1990); *see also* Melissa F. Wasserman, *The PTO’s Asymmetric Incentives: Pressure to Expand Substantive Patent Law*, 72 OHIO ST. L.J. 379, 407 (2011) (explaining the costs to the agency of the various stages of examination and grant as compared to the fees charged).

There are also costs to other innovators associated with searching for patents and obtaining licenses from patent holders or designing around others' patents. Because of the territorial nature of the patent right, the costs associated with obtaining and enforcing a patent are duplicated in each jurisdiction in which a patent is sought.

Although there are costs to a patent system, the law constrains the rights granted in multiple ways. Patent law includes constraints on the subject matter eligible for protection.<sup>25</sup> In addition, patent law limits patent grants to inventions that are novel, non-obvious, and useful.<sup>26</sup> The scope of the patent is limited to the invention as set forth in the claims and described in the specification, and the patent applicant must further describe the best mode of the invention in order to receive a patent.<sup>27</sup> Last, the scope of the rights granted by the patent may be constrained. Thus, the right to exclude will not be enforced in cases of misuse.<sup>28</sup> In addition, permanent injunctions do not issue automatically after a patent has been adjudged infringed. Rather, the court balances a set of factors including the harm done to the patent holder by infringement, the adequacy of money damages to compensate her, and the balance of hardships to the parties and the public interest before determining whether an injunction is appropriate.<sup>29</sup> Globally, various countries have enacted compulsory licensing statutes, allowing private companies to circumvent a patent holder's refusal to license (at a "reasonable" rate) when the market is not being served by the patent holder or existing licensees.<sup>30</sup> The duration of the patent term is another limitation. The rights of the patent holder expire when the patent does. The patent term is currently twenty years from the date the application was filed,<sup>31</sup> though it has been changed at various times.<sup>32</sup>

American patent law is generally considered a uniform law, in that it applies uniformly to all fields of technology. In addition, the rights and remedies associated with a patent are not dependent on the identity or business choices of the patent holder. This view is subject to some strong caveats, which I will mention here and elaborate on in Part III. Any discipline must meet the requirements of 35 U.S.C. § 101 to be patent

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25. 35 U.S.C. § 101 (2012).

26. *Id.* §§ 101-03.

27. *Id.* § 112.

28. *Morton Salt Co. v. G.S. Suppiger Co.*, 314 U.S. 488, 493-94 (1942). The doctrine has been limited somewhat by statute. *See* 35 U.S.C. § 271(d) (2012).

29. *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 391 (2006).

30. *See infra* Part III.A.

31. Uruguay Round Agreements Act § 154.

32. *See, e.g.*, Uruguay Round Agreements Act, Pub. L. No. 103-465, 108 Stat. 4809 (1994) (amending 35 U.S.C. § 154) (implementing a TRIPS-compliant patent term of twenty years from filing of the patent rather than the previous seventeen-year term, measured from issuance).

eligible, so some areas are categorically excluded—such as mathematics—whereas some are always eligible—such as engineering.<sup>33</sup> Section 101 is technology-neutral, however, and the subsequent patentability requires only that an invention be new, useful, and non-obvious, and includes provisions for remedies.

The laws governing patents vary among jurisdictions, although less so following the passage of TRIPS as part of the WTO agreement. Under the incentive theory of patents, lawmakers should form limitations to encourage innovation without overly harming the access interests of the public and other innovators. The contours and implementation of a given regime reflect the value it puts on the two sides of this balance, *inter alia*. However, local variations have taken a backseat to the larger project of harmonization, beginning with the Paris Convention and gathering steam with the passage of TRIPS and subsequent regional developments.

## II. INTERNATIONAL PATENT LAW: MOVING TOWARD HARMONIZATION

### A. EARLY HISTORY

The practice of granting patents originated in Venice in the late fifteenth century and eventually spread throughout Europe.<sup>34</sup> Early patents may have been granted by municipalities or “petty German states”<sup>35</sup> but in Great Britain, patents were granted by the sovereign, and have since become “creature[s] of national law”<sup>36</sup> throughout the world.<sup>37</sup> As such, every country legislates and administers its own patent laws. This has allowed for great variation in the protection of patent rights among countries. In their early development, some European countries had weaker patent protection, possibly for the purpose of “borrow[ing] and copy[ing] freely from more advanced nations abroad.”<sup>38</sup> As late as the nineteenth century, for example, Switzerland and the Netherlands

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33. 35 U.S.C. §§ 100–01 (2012).

34. CHRISTINE MACLEOD, *INVENTING THE INDUSTRIAL REVOLUTION: THE ENGLISH PATENT SYSTEM, 1660–1800*, at 40 (1988). MacLeod explains how the fifteenth-century Venetian patent system spurred the development of other modern patent systems: “Emigrant Italian craftsmen, seeking protection against local competition and guild restrictions as a condition of imparting their skills, disseminated knowledge of their patent systems around Europe.” *Id.* at 11. See John F. Duffy, *Inventing Invention: A Case Study of Legal Innovation*, 86 TEX. L. REV. 1, 21–23 (2007) (“[P]olicy set forth in Venetian statute was quite plainly copied throughout Europe.”).

35. MACLEOD, *supra* note 34, at 11.

36. ADELMAN, *supra* note 1, at 1.

37. See ROBERT P. MERGES & JOHN F. DUFFY, *PATENT LAW AND POLICY: CASES AND MATERIALS* 7 (5th ed. 2011) (discussing how state patents were granted in the American colonies and how conflicts among the states led to the creation of a national patent system, rooted in the Constitution).

38. MADHAVI SUNDER, *FROM GOODS TO A GOOD LIFE: INTELLECTUAL PROPERTY AND GLOBAL JUSTICE* 179 (2012).

did not have patent systems for more than fifty years.<sup>39</sup> Countries termed “least developed” countries and “developing” countries<sup>40</sup> have historically had lower levels of patent protection than developed countries. The modern and accelerating trend, however, has been toward the adoption and harmonization of patent laws.

Harmonization has focused on different areas of patent law in order to address a number of problems faced by those interested in doing business globally. Some harmonization measures address procedural difficulties that emerge from filing for and maintaining patents in multiple jurisdictions; others address substantive issues related to the grant of patents and attempts to assert rights—the substance of which may vary—in legal regimes that apply different standards to enforcement.<sup>41</sup> Both types of harmonization have been addressed by successive, multi-lateral treaties. These instruments, beginning with the Paris Convention for Industrial Property (“Paris Convention”), have used different mechanisms to reach harmonization, ranging from easing procedural burdens on applicants to defining the circumstances and degree to which member countries may depart from an absolute right to exclude.<sup>42</sup>

The Paris Convention was ratified by eleven European countries in 1883, joined by the United States in 1887, and now has 175 signatories.<sup>43</sup> The Paris Convention included provisions that eased procedural difficulties with obtaining patents in multiple countries by allowing applicants to claim a priority date to the first application filed in a member state, alleviating the potential need to file simultaneously in multiple jurisdictions.<sup>44</sup> It also contained provisions that affected substantive rights. Article 5 affects the scope of rights granted by a patent by permitting countries to “take legislative measures providing for the grant of compulsory licenses to prevent the abuses which might result from the

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39. MERGES & DUFFY, *supra* note 37, at 9 (citing Fritz Machlup & Edith Penrose, *The Patent Controversy in the Nineteenth Century*, 10 J. ECON. HIST. 1 (1950)).

40. “The WTO recognizes as least-developed countries (LDCs) those countries which have been designated as such by the United Nations.” *Least-developed Countries*, WORLD TRADE ORG. [WTO] (last visited Oct. 31, 2013), [http://www.wto.org/english/thewto\\_e/whatis\\_e/tif\\_e/org7\\_e.htm](http://www.wto.org/english/thewto_e/whatis_e/tif_e/org7_e.htm). Least Developed Countries are nations identified as such by the United Nations Economic and Social Council through its Committee for Development Policy and includes countries with “a low per capita income, a low level of human resource development and a high degree of economic vulnerability.” *Criteria for the Least Developed Countries*, WORLD INTELLECTUAL PROP. ORG. [WIPO], [http://www.wipo.int/lcds/en/criteria\\_ldcs.html](http://www.wipo.int/lcds/en/criteria_ldcs.html) (last visited Oct. 31, 2013).

41. ADELMAN, *supra* note 1, at 3 (discussing procedural and substantive problems that an inventor seeking protection globally will face).

42. *Id.* at 3–4.

43. *Id.* at 4; Paris Convention for the Protection of Industrial Property, Mar. 20, 1883, 21 U.S.T. 1583, 828 U.N.T.S. 305 (as amended July 14, 1967) [hereinafter Paris Convention].

44. *See id.* art. 4 (providing a twelve month grace period for filing). In addition, the Paris Convention provided for “national treatment,” requiring member states to provide equal treatment to foreign nationals and their own citizens. *Id.*

exercise of the exclusive rights conferred by the patent, for example, failure to work.”<sup>45</sup> Thus, countries could (but needed not) require that a patent holder either practice her patented invention locally or lose the right to exclude others from making or selling the patented product.<sup>46</sup> Where a patent holder failed to work a patent locally, a compulsory license could be granted, allowing others to make, use, or sell otherwise infringing goods after paying a reasonable amount, subject to certain limitations.<sup>47</sup> This provision, although allowing for tailoring of patent rights, at the time a strengthened the patent grant because prior to the Paris Convention, failure to work a patent could result in forfeiture.<sup>48</sup>

Although the Paris Convention addresses both procedural and substantive elements of global patent law, the treaty reflects the political reality that it is easier to agree on harmonization of laws that are seen as procedural. Thus, Article 4 *requires* all signatories to give priority (equal status) to foreign filings, whereas Article 5 is permissive, allowing countries to issue compulsory licenses under certain broadly defined circumstances. Specifically, Article 5 does not harmonize the laws with respect to compulsory licensing because it neither requires implementation of compulsory licensing nor prohibits such implementation. It merely proclaims that countries may have such a provision and describes the allowable contours.<sup>49</sup>

Although widely adopted, industrialized countries eventually viewed the Paris Convention as inadequate because it failed to set substantive standards of patent law, such as criteria for patentability or a

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45. *Id.* art. 5A(2).

46. *Id.* art. 5(A) (limiting the conditions under which a compulsory license may be granted to at least four years after the filing of the patent or three years after the grant of the patent, stating that a compulsory license must be refused “if the patentee justifies his inaction by legitimate reasons” and requiring that compulsory licenses be non-exclusive). This requirement actually strengthened the rights of the patent holder. Previously, numerous countries had working requirements that called for a forfeiture of patent rights upon the failure of a patent holder to work the patented invention. J.H. Reichman, *Beyond the Historical Lines of Demarcation: Competition Law, Intellectual Property Rights, and International Trade after the GATT’S Uruguay Round*, 20 *Brook. J. Int’l L.* 75, 100 n.113 (1993). Thus, by allowing only a compulsory license, the Paris Convention allowed the patent holder to maintain ownership of her patent and receive licensing revenue from the recipient of the compulsory license.

47. *Id.* The Paris Convention required that the patent holder be granted at least three years before the patent could be challenged for failure to work, and allowed the patent holder to challenge an application for a compulsory license by demonstrating why it was taking longer to bring the invention to market.

48. Jerome H. Reichman & Catherine Hasenzahl, *Non-voluntary Licensing of Patented Inventions: Historical Perspective, Legal Framework Under TRIPS, and an Overview of the Practice of Canada and the USA*, UNCTAD-ICTSD Project on IPRs and Sustainable Development, Issue Paper No. 5, at 10, (June 2003), [http://ictsd.org/downloads/2008/06/cs\\_reichman\\_hasenzahl.pdf](http://ictsd.org/downloads/2008/06/cs_reichman_hasenzahl.pdf).

49. *See id.*

patent term.<sup>50</sup> Movement in substantive harmonization would still take some time. The next notable treaty to attempt harmonization of patent laws was the Patent Cooperation Treaty (“PCT”), effective 1970.<sup>51</sup> The PCT was focused on procedural harmonization. Building on the Paris Convention, the PCT was meant “to simplify and render more economical the obtaining of protection for inventions where protection is sought in several countries.”<sup>52</sup> Thus, it provided a method of filing patent applications in multiple countries simultaneously, administered by the then newly-created World Intellectual Property Organization (the “WIPO”), which also administers the Paris Convention.<sup>53</sup> This centralized process for filing patents did not impact the standards for patentability of signatories or the substantive rights associated with subsequently granted patents.

#### B. THE TRIPS AGREEMENT

The TRIPS Agreement in 1995 marked another move toward uniformity in patent law.<sup>54</sup> In part because the TRIPS Agreement is an annex to the Uruguay Round Agreement forming the World Trade Organization, the focus on substantive harmonization is not surprising. The role of technology and innovation in goods in international trade had grown significantly since the drafting of the General Agreement on Tariffs and Trade (“GATT”).<sup>55</sup> The lower trade barriers that resulted from the GATT led to more transnational production and a proliferation of international enterprises. The purpose of the negotiations leading to the WTO was to further facilitate trade by constraining, reconciling, and harmonizing differing trading practices among nations.<sup>56</sup> However, the minimum levels of intellectual property protection advocated by the

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50. “By the late 1970s, from the standpoint of industrialized country patent holders, the Paris Convention was most notable for what it does not do. The Paris Convention does not define a patent or what criteria are used for granting it. It does not prescribe subject-matter coverage, it does not set a minimum—or maximum—term of a patent, it does not define the rights of patent holders, and it was perceived as having a weak dispute settlement mechanism.” FREDERICK M. ABBOTT, *Intellectual Property, International Protection*, in MAX PLANCK ENCYCLOPEDIA OF PUBLIC INTERNATIONAL LAW ¶ 21 (2010).

51. Patent Cooperation Treaty, June 19, 1970, 28 U.S.T. 7645, 1160 U.N.T.S. 231.

52. *Id.* pmbl.

53. ADELMAN, *supra* note 1, at 4 (explaining how the PCT allows for centrally filing a patent application and noting the countries in which the applicant would like to apply for patent protection); see also Sisule F. Musungu & Graham Dutfield, *Multilateral Agreements and a TRIPS-Plus World: The World Intellectual Property Organisation (WIPO)*, TRIPS Issues Papers No. 3, at 4, (2003) (discussing the history of WIPO, its creation under the Stockholm Convention, and subsequent status as a specialized agency of the United Nations).

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

55. Frederick M. Abbott, *Protecting First World Assets in the Third World: Intellectual Property Negotiations in the GATT Multilateral Framework*, 22 VAND. J. TRANSNAT’L L. 689, 696 (1989).

56. CHARAN DEVEREAUX ET AL., 1 CASE STUDIES IN US TRADE NEGOTIATION 2 (Inst. for Int’l Econs. ed., 2006).

developed countries were in sharp contrast to the desires of developing countries.<sup>57</sup>

Negotiations leading to TRIPS divided participants into developing and least developed countries. On the one hand, developed countries pushed for harmonization and strong protection, but on the other hand, least developed countries advocated flexibility for countries to implement lower levels of intellectual property protection.<sup>58</sup> The United States was one of the strongest voices in support of uniformity among domestic patent law regimes.<sup>59</sup> Indeed, the United States has been criticized for using coercive negotiating techniques to gain the consensus of developing countries.<sup>60</sup> In particular, the Office of the United States Trade Representative threatened countries with trade retaliations under Special 301 Report<sup>61</sup> if they chose to object to the negotiating positions of the United States on intellectual property rights in the TRIPS agreement.<sup>62</sup> Ultimately, compromises were made and a formal agreement was reached.

The TRIPS Agreement has provided a big step toward patent harmonization.<sup>63</sup> Requirements address patent-eligible subject matter, patentability standards, and the duration and scope of rights. Thus, TRIPS requires that patents be available “without discrimination as to . . .

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57. The introduction of intellectual property to trade discussions in the Uruguay Round negotiations of the GATT were preceded by a clash at WIPO in which developed countries tried to revise the Paris Convention to include stronger protections for intellectual property rights and the developing countries formed a movement in favor of a new international economic order and sought to “relax protection of intellectual property,” *inter alia*. ABBOTT, *supra* note 50, ¶ 26.

58. Hanns Ullrich, *Expansionist Intellectual Property Protection and Reductionist Competition Rules: A TRIPS Perspective*, 7 J. INT'L ECON. L. 401, 404 (2004).

59. See Abbott, *supra* note 55, at 692 (explaining how the United States resolved to protect intellectual property rights, whether unilaterally or multilaterally); see also Devereaux et al., *supra* note 56, at 1; Susan K. Sell, *Post-TRIPS Developments: The Tension Between Commercial and Social Agendas in the Context of Intellectual Property*, 14 FLA. J. INT'L L. 193, 194 (2002) (explaining that the lobbying Intellectual Property Committee, “which consists of chief executive officers from a handful of well-connected and economically powerful American-based multinational corporations” played a significant role in drafting and pushing for adoption of TRIPS).

60. HESTERMEYER, HUMAN RIGHTS, *supra* note 17, at 39–40 (describing how the United States withdrew certain trade benefits and threatened trade sanctions under Section 301 of the Trade Act in retaliation for refusals to grant certain patent rights).

61. See generally DEMETRIOS MARANTIS, OFFICE OF THE U.S. TRADE REPRESENTATIVE, 2013 SPECIAL 301 REPORT.

62. See HESTERMEYER, HUMAN RIGHTS, *supra* note 17, at 39–40; see also Clyde H. Farnsworth, *Washington's Hard Line on Trade*, N.Y. TIMES, June 25, 1989, <http://www.nytimes.com/1989/06/25/business/washington-s-hard-line-on-trade.html> (reporting that during an interview, then-Deputy United States Trade Representative S. Linn Williams defended the U.S. threat to use trade sanctions against Brazil for its lack of sufficient protection of patent rights for pharmaceuticals).

63. See Amy Kapczynski, *Harmonization and Its Discontents: A Case Study of TRIPS Implementation in India's Pharmaceutical Sector*, 97 CALIF. L. REV. 1571, 1574 (2009).

the field of technology” in addressing patentable subject matter.<sup>64</sup> Pharmaceutical patents presented a challenge as there was not a consensus among countries on their patent eligibility. Developing countries did not want to be bound to offer such protection but the agreement ultimately requires that patents be available for pharmaceutical products, allowing a grace period before the requirement entered into force and making provisions for protection in countries that had yet to implement a regime that allowed them.<sup>65</sup> Although the terms used by member countries differ, all recognize that to be patentable, a claimed invention must be new, nonobvious, and useful.<sup>66</sup> In addition, TRIPS requires a minimum patent term of twenty years from the date the patent is filed.<sup>67</sup>

Although the negotiations and resulting agreement evidenced a strong tide toward harmonization and increased intellectual property rights worldwide, there were other undercurrents to the story. For example, developing countries negotiated for trade concessions unrelated to intellectual property rights and were thereby able to open markets in areas of particular economic interest.<sup>68</sup> These negotiations make an objective evaluation of the interests represented by the TRIPS agreement more difficult. We are accustomed to seeing patent protection as a balance between the competing, private interests of patent holders and the access interests of the public.<sup>69</sup> Adding an orthogonal set of interests upsets the logical symmetry; as a result, discussions of the balance struck by TRIPS rarely take these non-intellectual property concessions into account.<sup>70</sup> From the utilitarian point of view, this makes

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64. TRIPS, *supra* note 54, art. 27.1. *But see id.* art. 27.2 (allowing exceptions for inventions “the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality”); *see also id.* art. 27.3 (allowing exclusion from patentability of “diagnostic, therapeutic and surgical methods for the treatment of humans or animals” and “plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes”).

65. *See id.* arts. 65–66; *see also* World Trade Organization, Ministerial Declaration of 14 November 2001, WT/MIN(01)/DEC/2, 41 I.L.M. 746 (2002) [hereinafter Doha Declaration] (extending the transition period for least developed country members with respect to pharmaceutical products); *see also* TRIPS, *supra* note 54, art. 70.8–9 (requiring countries to make certain provisions for pharmaceutical patents to be filed even if those countries did not yet recognize eligibility for pharmaceutical patents).

66. TRIPS, *supra* note 54, art. 27.

67. *Id.* art. 33.

68. GRAEME B. DINWOODIE & ROCHELLE C. DREYFUSS, A NEOFEDERALIST VISION OF TRIPS: THE RESILIENCE OF THE INTERNATIONAL INTELLECTUAL PROPERTY REGIME 32 (2012) [hereinafter NEOFEDERALIST VISION] (casting the TRIPS agreement as an intellectual property “tax” developing countries accepted as the cost of doing business in other sectors).

69. *See supra* Part I.

70. For those who ascribe to a non-utilitarian justification for intellectual property rights, there is less difficulty. For example, if access rights are seen as a moral imperative in some situations, the

sense. An optimal patent system, under such a view, is one which balances private and public interests in a way that best encourages innovation. Yet, where countries stand in as proxies for these interests, the complexities of a normative evaluation of patent law are brought into relief. A need for access to medicine by the people of a developing country may be weighed against the economic gain those people face at the prospect of selling their goods in a new market. More generally, and as this Article discusses below, the commercial needs of any given country will play a role in the level of patent protection that country seeks to implement independent of the binary balance discussed above.

This is demonstrated by another concession made in negotiations. A temporal concession also mitigated the requirement of strong levels of intellectual property protection in TRIPS: developing countries and least developed countries did not have to implement the agreement until 2005.<sup>71</sup> Although the developing countries have now implemented legislation in order to become TRIPS-compliant, least developed countries have continued to request and be granted extensions for TRIPS-compliance. Certainly these delays allowed necessary time for countries to consider and implement a complex legal and regulatory regime. However, for those who have noted that many now-developed countries have strengthened their patent law regimes synchronously with domestic industrial growth, the delay in TRIPS compliance should again show us that no country can fully be a proxy for “the public interest.” Thus, for countries considered developing at the time TRIPS was negotiated, stronger intellectual property rights were predictable as their industry grew. By postponing the implementation of TRIPS until 2005, these countries had more time to lay the industrial infrastructure that would allow domestic industry to blossom under a stronger regime of intellectual property rights.<sup>72</sup> These side stories illustrate the mistake of assuming that developed countries take positions representing “private” interests while developing countries represent the needs of the public.

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bargain struck under TRIPS cannot impose contrary restrictions. *See, e.g., MERGES, supra* note 17, at 270–87.

71. *See* TRIPS, *supra* note 54, at art. 66.1 (providing that least developed member countries have a grace period of ten years for implementing most of the requirements of the agreement, with the possibility of an extension). *But see id.* art. 70.8 (requiring members who do not implement patent protection for pharmaceutical products or agricultural chemical products when the WTO agreement enters into force to make certain provisions by which applications for such patents can be filed, thus preserving their filing dates in anticipation of the availability of such patents).

72. Indeed, companies that have focused on production of generic drugs in India, for example, have begun investing in research and development for innovative drugs. *See, e.g.,* Kiran Somvanshi, *Innovation Will Be Key to Survival, Says Glen Saldanha, Chairman & MD, Glenmark Pharma*, *ECON. TIMES*, Dec. 21, 2011, [http://articles.economictimes.indiatimes.com/2011-12-20/news/30534740\\_1\\_indian-pharma-generics-glenmark-pharma](http://articles.economictimes.indiatimes.com/2011-12-20/news/30534740_1_indian-pharma-generics-glenmark-pharma).

Each has a variety of stakeholders whose needs sometimes follow the same path and sometimes pull in different directions. Understanding the role and input of these stakeholders is important to any attempt to make normative claims about individual patent provisions in any given country.

The common view that the TRIPS agreement imposes rigid obligations on its members has been criticized. There are some who now argue that the actions of developing countries in the years since TRIPS was implemented show that they may have negotiated more carefully than observers initially recognized. They included language, for example, that was open to the possibility of weaker intellectual property rights under some circumstances.<sup>73</sup> It is not clear that the language reflects carefully-concocted nuance as opposed to the customary indeterminacy of language subject to legal interpretation, but the developed countries' interpretations of particular terms is certainly being challenged.<sup>74</sup> In addition, the TRIPS Agreement does not, for the most part, address the procedure of harmonization. Thus, the Agreement requires only that countries follow "reasonable procedures and formalities" in implementing the agreement, without specifying the means by which the agreement must be implemented.<sup>75</sup> This has left countries flexibility in their methods of becoming TRIPS-compliant.

A word about enforcement is also necessary, as it distinguishes agreements that form part of the WTO agreement from other areas of public international law. The inclusion of TRIPS in the WTO gave the Agreement teeth previously lacking in international intellectual property agreements, allowing member countries to challenge each others' practices before the dispute settlement body of the WTO.<sup>76</sup> That body does not award the traditional remedies that domestic courts award private parties to a dispute, such as compensatory and other damages and injunctive relief. Rather, where a violation is found, the offending country is given time to bring its law into compliance; if the violation continues, the members bringing the case are permitted to retaliate by

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73. NEOFEDERALIST VISION, *supra* note 68, at 14.

74. *See infra* Part III.A.

75. TRIPS, *supra* note 54, arts. 62.1, 62.2.

76. In comparison to much of the rest of international public law, the compulsory dispute settlement system and the inability of countries to "pick and choose" among WTO obligations may be seen as "elevat[ing] the importance of public international law generally." James Cameron & Kevin R. Gray, *Principles of International Law in the WTO Dispute Settlement Body*, 50 INT'L & COMP. L.Q. 248, 249 (2001). However, these characteristics also remove WTO obligations from the reach of flexibility analysis theorized in that field. *See, e.g.*, LAURENCE R. HELFER, *Flexibility in International Agreements*, in INTERNATIONAL LAW AND INTERNATIONAL RELATIONS: TAKING STOCK 175–96 (Jeffrey Dunoff & Mark A. Pollack eds., 2012) (analyzing non-substantive methods of exercising flexibilities in international law in formal manners—such as the use of reservations, escape clauses, and withdrawal provisions—and informal practices—such as "auto-interpretation," nonparticipation, and noncompliance).

withholding preferential treatment in an amount proportional to the injury suffered. In an asymmetric twist, the benefits withheld need have no connection to the area of the violation. Thus, a member may withhold preferential treatment on an industry that does not benefit from the non-compliant intellectual property laws. There is another theoretical justification for this: the intellectual property regime (or any other WTO violative measure) will benefit a country as a whole, so it does not matter how the punishment is allocated. As a practical matter, an industry that does not benefit from deviations from the TRIPS standards but is punished for it is more likely to lobby for their change. Just as the developing countries negotiated for access to unrelated markets in exchange for concessions in the TRIPS negotiations, WTO remedies tie intellectual property to trade in a way that clouds attempts to analyze patent measures solely in terms of incentives to innovate and access. The link between patent flexibilities that violate TRIPS and potential retribution in unrelated trade matters may be a fair reflection of the increasingly global nature of patent law. All amendments to patent law have effects beyond their jurisdiction.

#### C. BEYOND TRIPS: MULTILATERAL AGREEMENTS AND TRIPS PLUS

Trade negotiations, including those related to intellectual property, have most recently been conducted outside the bounds of the WTO. There are multiple explanations for the movement back to bilateral and regional trade agreements, ranging from the structural (the WTO has so many participants it is difficult to garner support for changes), to the practical (some issues are specific to a regional group or other smaller groups of frequent traders), to the cynical (larger countries can better manipulate smaller countries in more intimate settings).<sup>77</sup> All of these have some truth to them. Regardless of the reason, regional trade agreements (“RTAs”) have proliferated in the years since the WTO was established.<sup>78</sup>

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77. Another tactical reason to conclude that regional trade agreements harmonize intellectual property protection is that in subsequent, large-scale harmonization negotiations, it will be easier for countries with whose practices are widespread to argue that others should harmonize “to them.” See NEOFEDERALIST VISION, *supra* note 68, at 166 (suggesting that the hard law common to multiple free trade agreements should be taken into account by the WTO dispute settlement body when “clarifying undefined terms and considering normative issues,” while noting the difficulty of taking interpretations that may have been negotiated-for concessions between two parties and applying them to other situations).

78. See Raymundo Valdés & Runyowa Tavengwa, *Intellectual Property Provisions in Regional Trade Agreements* 7 (WTO, Working Paper No. ERSO-2012-21, 2012).

Member countries to the WTO are required to report their regional trade agreements to the WTO Secretariat.<sup>79</sup> More than three hundred regional or bilateral trade agreements were in force in 2012.<sup>80</sup> These agreements govern many different aspects of trade, and not all of them mention intellectual property; of those that do, some do not do more than note its importance or requiring stronger protection than is already required by TRIPS.<sup>81</sup> Nevertheless, there are RTAs that represent a negotiation of stronger patent rights in exchange for other trade concessions such as greater access to desirable markets. Such strengthened provisions—generally called “TRIPS-plus” initiatives—may include rules on aspects of patent law left to the states under the TRIPS agreement. The free trade agreement between the United States and Morocco, for example, requires the parties not to recognize the principle of international exhaustion.<sup>82</sup> The United States-Oman RTA requires that judicial authorities be able to award up to treble damages for patent infringement.<sup>83</sup> Most common are provisions relating to border measures to protect from imports that infringe on patent and other intellectual property rights.<sup>84</sup>

Another move toward regional harmonization comes from efforts to create a European patent and a Unified Patent Court in Europe. The

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79. Requirements are contained in GATT 1994. See General Council Decision, *Transparency Mechanism for Regional Trade Agreements*, WT/L/671 (Dec. 18, 2006).

80. See Valdés & Tavengwa, *supra* note 78, at 7 (finding 351 regional and bilateral trade agreements in force in 2012 when goods and services notifications were counted separately; examining agreements reported before 2010 in detail); see also WTO, *Regional Trade Agreements*, [http://www.wto.org/english/tratop\\_e/region\\_e/region\\_e.htm](http://www.wto.org/english/tratop_e/region_e/region_e.htm) (last visited Oct. 31, 2013) (suggesting a lower number of 319 regional and bilateral agreements in force).

81. Valdés & Tavengwa, *supra* note 78, at 6–7 (finding that 165 of the 194 agreements examined had some sort of intellectual property provision, 139 of which were entered into since the establishment of the WTO in 1995; further finding that 76 of those contained references to specific types of intellectual property and 54 contained pharmaceutical provisions).

82. United States-Morocco Free Trade Agreement, U.S.-Morocco, art. 15.9(4), June 15, 2004; NEOFEDERALIST VISION, *supra* note 68, at 149 (discussing TRIPS plus measures). The Court of Appeals for the Federal Circuit has considered exhaustion of patent rights to occur “when a patented device has been lawfully sold in the United States.” See *Jazz Photo Corp. v. Int’l Trade Comm’n*, 264 F.3d 1094, 1105 (Fed. Cir. 2001). Under this rule, an article patented in the United States but sold elsewhere under a license would be considered infringing when imported. This interpretation was reiterated in *Ninestar Technology Co. v. International Trade Commission*, 667 F.3d 1373 (Fed. Cir. 2012), *cert. denied*, 133 S. Ct. 1656 (2013). The Supreme Court recently ruled that there is international exhaustion in the copyright context. *Kirtsaeng v. John Wiley & Sons, Inc.*, 133 S. Ct. 1351, 1371 (2013). That case need not affect the common law rule in patent law because it involved statutory interpretation instead of the Copyright Act. See *id.* at 1363–64.

83. United States-Oman Free Trade Agreement, U.S.-Oman, Jan. 1, 2009 art. 15.10.29.

84. Valdés & Tavengwa, *supra* note 78, at 18–19 (explaining that more than ninety percent of the studied RTAs involving the United States include reference to enforcement procedures and that RTAs involving the United States “have the most extensive provisions relating to border measures,” often requiring parties to provide for action by customs authorities in the absence of a formal complaint by a rights-holder, something allowed, but not required, by TRIPS).

unified system was intended to replace the piecemeal process of obtaining and enforcing patents that currently exists. Today, an inventor can file applications centrally at the European Patent Office but must select the European countries where she seeks protection and subsequently enforce rights in the national courts.<sup>85</sup> In some states, litigation is further fragmented due to the separation of litigation for infringement and claims of invalidity.<sup>86</sup> The European Parliament approved the unitary patent rules.<sup>87</sup> The plan for a unitary patent and court system is moving forward despite the disagreements that have led some countries to drop out<sup>88</sup> and the need to make “unitary patent protection . . . optional and co-exist[ent] with national and European patents.”<sup>89</sup> As a result, the so-called unitary system will likely lead to a more complex system, at least in the near future, but it may yet serve as a stepping-stone toward cohesive and comprehensive unification of patent grants and increased enforcement in Europe.

The movement toward harmonization is undeniable. However, a countercurrent has arisen in many developing countries resisting international harmonization. The greatest resistance to harmonization in developing countries comes in technology areas that impact access to medicine. There are also implicitly anti-harmonization views in developed countries, in particular where scholars and interest groups suggest tailored patent rights as a means to solve the inefficiencies that arise from applying a uniform patent law consistently to very different situations. These countercurrents manifest in laws directed at specific technology areas and in technology-specific interpretations of otherwise uniform laws.

### III. DE FACTO FLEXIBILITY

Despite significant strides toward harmonization in the years following the conclusion of the TRIPS Agreement, unification is not in sight. Opportunities for more harmonization have been accompanied by countercurrents of diversity and flexibility that slow attempts to treat all

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85. 2 HERBERT HOVENKAMP ET AL., *IP AND ANTITRUST: AN ANALYSIS OF ANTITRUST PRINCIPLES APPLIED TO INTELLECTUAL PROPERTY LAW* § 45.2 (2009).

86. In Germany, for example, infringement claims are brought and litigated in court as private law issues, while challenges to patent validity are considered public law questions and are initially decided by the German Federal Patent Court. See M.A. Smith et al., *Arbitration of Patent Infringement and Validity Issues Worldwide*, 19 HARV. J.L. & TECH. 299, 334 (2006).

87. Press Release, European Parliament, Parliament Approves EU Unitary Patent Rules (Dec. 11, 2012).

88. Spain and Italy are opting out because the approved languages—German, French, and English—don’t include their official languages.

89. *Proposal for a Regulation of the European Parliament and of the Council Implementing Enhanced Cooperation in the Area of the Creation of Unitary Patent Protection, Explanatory Memorandum*, COM (2011) 215 final (Apr. 13, 2011).

subject matter equally, from patent grant to enforcement. In addition to legislative tailoring measures—flexibility by design—there are variations in how patent law is applied to different technologies and entities that cannot be eliminated.<sup>90</sup> These differences are easiest to explain for common law countries, where in theory the law is painted with broad brush strokes and the courts fill in the details. This allows for (often slow) legal evolution to meet unforeseen situations through derivations from old principles to new rules. In reality, courts in countries with civil law perform the same function to varying degrees.<sup>91</sup> As a result, identical laws may evolve divergently as they are applied to new factual situations. In addition, when a single law is meant to apply identically in different forums, courts can always come to different conclusions on questions of fact or of mixed fact and law.<sup>92</sup>

Regardless of a given regime's position on harmonization, patent laws include tailoring mechanisms in both developing and industrialized countries. Flexibility exists in global patent law, and it is used both in design and application. Examples from the United States and India—countries of differing development but similar engagement in intellectual property law—are described in the Subparts that follow, with particular emphasis on the purposes of the flexibility, the method of implementation, and the breadth of stakeholder participation.

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90. Carroll, *supra* note 3, at 1401–06 (explaining that U.S. patent law is not unitary in fact, looking first to tailored legislative measures, but also judicial interpretations and administrative treatment by the PTO to show how different industries may be granted rights that differ in substance if not in form).

91. Though continental Europe is primarily governed by civil law, the difficulty of writing a legal code that anticipates all situations is apparent. One example is the treatment that national courts have given to requests for permanent injunctions on patents that are essential to a standard (such as those dictating technical specifications for DVD players) and to a defense based on competition law, which is implemented across the European Union. In these cases, defendants who are found to infringe essential patents argue that there can be no permanent injunction under the theory that a plaintiff may not request that which he would have to return upon its grant. Because holders of standards-essential patents must agree to license them on fair, reasonable, and non-discriminatory terms (“FRAND”), infringers have argued that a permanent injunction should not issue; the patent holder would have to immediately start licensing the patent and thus the injunction would be moot. German courts accepted this argument in the “Orange Book” decision, denying an injunction for this reason. Bundesgerichtshof [BGH] [Federal Court of Justice] May 6, 2009, KZR 39/06 (Ger.). Dutch courts disagreed with the German interpretation of the interplay of laws, deciding that until a patent was actually licensed, there was no ground for allowing the defendant use of the patented technology. Rb. Den Haag 17 Maart 2010, 316533 / HA ZA 08-2522 en 316535 / HA ZA 08-2524 (Koninklijke Philips Electronics N.V./ SK Kassetten GmbH & Co. KG) (Neth.).

92. Such divergence occurs within countries, too. In the United States, for example, there is the possibility of different validity decisions from the U.S. PTO and district courts or different decisions from district courts and the U.S. International Trade Commission (the “ITC”). Although federal court decisions are binding on the ITC, the converse is not true. See Sapna Kumar, *The Other Patent Agency: Congressional Regulation of the ITC*, 61 FLA. L. REV. 529, 538–39 (2009).

### A. FLEXIBILITY BY DESIGN

History reveals a number of movements that have tailored patent law to different technologies. Before the TRIPS Agreement imposed the requirement that patents be available in all areas of technology without discrimination, these movements sometimes resulted in specific legislative or administrative measures that did just that. The TRIPS Agreement nevertheless permits some flexibility, encompassing explicit exceptions to the uniform grant and treatment of patent rights as well as interpretations of the agreement that allow for variations. Before the WTO came into existence, the United States implemented the Patent Term Restoration Act (the “Hatch-Waxman Act”) in 1984. As a result, countries generally presumed that its terms were consistent with TRIPS.<sup>93</sup> Nevertheless, it represents a legislative tailoring of exclusive rights that are relatively rare in the United States, where tailoring is generally accomplished through the judiciary.<sup>94</sup> Passage of the TRIPS Agreement required India to strengthen the rights granted by its patent law in dramatic ways. In implementing new laws, however, developing countries such as India have sought to exploit the flexibilities that they perceive in the agreement through its criteria for patent eligibility and in its awards of compulsory licenses.

In the United States, as in other countries, there are various legislative measures that tailor patent rights to specific technologies.<sup>95</sup> These *sui generis* types of protection have most often arisen for technologies that might not fit patent eligibility criteria but are judged to warrant protection. They also predate the TRIPS Agreement, but have since been incorporated into it because they are common to many countries. The most notable example of a legislative tailoring measure covers pharmaceutical inventions. Although it is a field that fits squarely into patent eligible technology, the law adds to the patent term with what Rebecca Eisenberg has called “pseudo-patent” protection.<sup>96</sup> This was the bargain struck between legislators of the Hatch-Waxman Act, which, through grants of market exclusivity following patent expiration essentially alters the duration of the patent term on pharmaceutical

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93. See HESTERMEYER, *HUMAN RIGHTS*, *supra* note 17, at 62–64; *see also* Panel Report, *Canada—Patent Protection of Pharmaceutical Products*, WT/DS114/R (Mar. 17, 2000). The WTO found Canada’s similar provision consistent with TRIPS, but held that a further provision allowing generic companies to produce “stockpiles” of drugs in anticipation of the patent expiration was inconsistent. *Id.*

94. *See infra* Part III.B.

95. In addition to the Hatch-Waxman Act, discussed *infra*, some laws grant patent-like protection to plants. Plant Variety Protection Act of 1970, 7 U.S.C. §§ 2321–2583 (2006). Congress has also legislated *sui generis* protection for semiconductors. Semiconductor Chip Protection Act of 1984, 17 U.S.C. §§ 901–14 (2000).

96. *See* Eisenberg, *supra* note 4, at 359.

products.<sup>97</sup> This legislation transformed the Food and Drug Administration's ("FDA") main role from ensuring the safety and efficacy of pharmaceutical products before they enter the market to a "market gatekeeper in ways that might be better understood in terms of innovation policy, calibrating the balance of costs and incentives for both innovating firms and generic competitors."<sup>98</sup> Furthermore, the Hatch-Waxman Act balances the varied interests of patent-holding drug manufacturers, companies that manufacture generic drugs, and the patient population through a complex regulatory scheme that includes the grant of additional market exclusivity to patent holders, as well as a short term of semi-exclusivity to second-movers, encouraging challenges to weak patents and early entry by generic companies following the expiration of valid patents.<sup>99</sup>

Innovation in the pharmaceutical industry differs from other areas both in characteristics inherent to the field of technology and in the complex regulatory framework in which it operates. Pharmaceutical products are typically easy to reverse engineer, making this a field where innovation is easily appropriated absent legal protection.<sup>100</sup> Drug development is a long process, but patents are typically filed and issued early in the development process, which reduces the eventual period of exclusive use.<sup>101</sup> In addition, before they are allowed to enter the market, firms must satisfy FDA requirements by showing that new chemical entities are safe and effective.<sup>102</sup> These requirements are time and money-intensive; in the early 1980s, they applied to all firms that wanted to market a drug, not just the patent-holding "pioneer" drug developers.<sup>103</sup>

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97. In addition to extending the term of exclusivities granted to patent holders, the protections offered by the Hatch-Waxman Act also provide pseudo-patent protection on drugs that otherwise do not meet the patentability criteria, because unpatented drugs may sometimes receive market exclusivity. Gregory Dolin, *Exclusivity Without Patents: the New Frontier of FDA Regulation for Genetic Materials*, 98 Iowa L. Rev. 1399, 1450–51 (2013) (explaining that drugs receiving FDA approval as "new chemical entities" block FDA review of Abbreviated New Drug Applications attempting to piggyback on the pioneer drug's data the subsequent five years, even if the pioneer drug is unpatented or off-patent).

98. See Eisenberg, *supra* note 4, at 348.

99. *Id.*

100. See, e.g., Burk & Lemley, *supra* note 3, at 1581–82 (discussing characteristics of pharmaceutical discoveries that make patent protection important to the industry). The biotech industry serves as a counter-example. Methods of producing biopharmaceutical products are less amenable to reverse engineering and may therefore be kept as trade secrets.

101. See Eisenberg, *supra* note 4, at 348–49.

102. Ellen J. Flannery & Peter Barton Hutt, *Balancing Competition and Patent Protection in the Drug Industry: The Drug Price Competition and Patent Term Restoration Act of 1984*, 40 FOOD DRUG COSM. L.J. 269, 273 (1985) (detailing the 1962 FDA requirements for approval of all new drugs based on a showing of safety and efficacy).

103. Data submitted to the FDA by the pioneer drug company was kept confidential and not available for use by subsequent applicants. *Id.* at 275–76.

Thus, prior to the Hatch-Waxman Act, generic medicines were too often not developed or brought to market because of the prohibitive cost. Unlike patent holders, generic drug companies could not count on future monopoly profits to offset these costs. Additionally, the necessary tests were considered to infringe, so even when there was sufficient incentive to bring a generic drug to market, the process was delayed, which effectively allowed a patented drug to continue in its monopoly position beyond the patent term.<sup>104</sup> Partly as a result of FDA requirements, patent-holding pharmaceutical companies complained of shortened periods of market exclusivity, while generic pharmaceutical manufacturers complained of the high costs of regulatory review and difficulty of entering the market soon after patent expiration. In addition, consumers suffered from limited access to generic products (with their attendant lower prices) and FDA resources were wasted because reviews of generic drugs that were duplicative of the tests required for the patented drugs.<sup>105</sup>

The resulting law allowed for an extension (or “restoration”) of the patent term to make up for time spent seeking regulatory approval for pioneer drugs.<sup>106</sup> At the same time, the Hatch-Waxman Act established abbreviated review and approval processes for generic drugs based on their demonstrated equivalency to already-approved drugs.<sup>107</sup> To further facilitate entry of generic drugs following patent expiration, the law provided that manufacture and use of patented drugs would not be considered infringement when undertaken for the purposes of regulatory approval for sale following expiration of the patent.<sup>108</sup> The overlapping laws and regulations governing patent rights, market exclusivity, and the approval process for pioneer and generic drugs are myriad. However, it is clear that many interests were at stake and represented in the outcome. The structural and participatory elements of the process are also evident, both in the outcome and in the legislative process.

Drafting negotiations reflected the various interests at stake, including innovative and imitative pharmaceutical companies and patient

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104. H.R. REP. 98-857, pt. 2, at 4 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2686. *See* Brief for Knowledge Ecology Int'l as Amicus Curiae Supporting Petitioner, at 2–3, *FTC v. Watson Pharms., Inc.*, 133 S. Ct. 787 (2013) (No. 12-416), *sub nom* *FTC v. Actavis, Inc.*, 133 S. Ct. 2223 (2013) (discussing the purposes of the Hatch-Waxman Act).

105. H.R. REP. 98-857, pt. 1, at 14 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2686.

106. Section 201 of the Hatch-Waxman Act governs patent term restoration. 35 U.S.C. § 156 (2011) (allowing for restoration of patent term for patented products or methods that have been subject to regulatory review).

107. *See* Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(j) (2006); *see also* *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 676 (1990) (explaining the abbreviated approval process and interpreting the act to exclude from infringement medical devices made and used for the purposes of obtaining FDA approval).

108. 35 U.S.C. § 271(e)(2) (2006).

advocates. The congressional record shows that the primary participants in negotiations were the Generic Pharmaceutical Industry Association and the Pharmaceutical Manufacturers Association (“Pharma”).<sup>109</sup> The bill was supported by various unions and the American Association of Retired Persons, who favored the possible savings from cheaper generic drugs.<sup>110</sup> The parties disagreed about many aspects of the proposal,<sup>111</sup> as might be expected with significant stakeholder involvement. The Hatch-Waxman Act has been criticized for its substance and complex provisions that have allowed for opportunistic behavior.<sup>112</sup> It also provided a separate forum for lobbying so that the drug industry could look for increasing market exclusivity measures through FDA-implemented legislation without fighting the inertia of the patent system or having its needs weighed against that of other industries. The “pseudo patent protection” offered by the Hatch-Waxman Act and the attendant overlapping legislation represents one of the largest legislative departures from uniform protection for all types of technologies in recent history. It has been widely adopted by other countries and, perhaps in part because it predated the TRIPS Agreement, it has been found not to violate the Article 27 prohibition against discrimination based on field of invention.<sup>113</sup>

Other countries have also engaged in recent and significant efforts to tailor patent law. In the years since the TRIPS Agreement was negotiated and implemented, India has sought to exploit perceived flexibilities to pursue its policy goals rather than adopt patent laws that mirror those of developed countries.<sup>114</sup> India was one of the strongest voices on the side of developing countries during the negotiations of the TRIPS Agreement because of the growing needs of its patient population, its economic difficulty filling those needs, and its strong

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109. H.R. REP. 98-857, pt. I, at 4.

110. *Id.*

111. *Id.* (noting objections from Gerald Mossinghoff, Commissioner of Patents and Trademarks, to aspects of the bill and objections from some innovator drug companies that the bill would “hamper innovation and research, create unnecessary litigation and unconstitutionally take property from patent owners”).

112. *See, e.g.*, Elizabeth Powell-Bullock, *Gaming the Hatch-Waxman System: How Pioneer Drug Makers Exploit the Law to Maintain Monopoly Power in the Prescription Drug Market*, 29 J. LEGIS. 21 (2002) (arguing that legal and marketing strategies by pioneer pharmaceutical companies have thwarted the goals of the legislation); Natalie M. Derzko, *The Impact of Recent Reforms of the Hatch-Waxman Scheme on Orange Book Strategic Behavior and Pharmaceutical Innovation*, 45 IDEA 165, 185, 195 (2005) (describing how pharmaceutical companies strategically listed numerous patents for each approved drug to garner longer terms of market exclusivity and how generic companies accepted anti-competitive settlement agreements to stay off the market, and discussing the extent to which reforms solved these problems).

113. *See, e.g.*, HESTERMAYER, HUMAN RIGHTS, *supra* note 17.

114. Kapczynski, *supra* note 63, at 1573–74 (explaining that while many developing countries have adopted strict intellectual property laws, India “has instead mapped out an extraordinary array of TRIPS flexibilities, some of which are unknown elsewhere in the world”).

generic drug industry.<sup>115</sup> Implementation of flexibilities has focused on standards of patentability and the scope of protection granted because of the TRIPS Agreement's prohibition on discrimination with respect to field of invention.<sup>116</sup> Thus, the Indian patent law now allows patenting of pharmaceutical products but excludes from the definition of invention "the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance."<sup>117</sup> The statutory definition of invention in India's section 3(d) stands in contrast to the common law rule in the United States that new uses of a known substance may indeed be patented.<sup>118</sup> It also stands in

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115. According to the World Health Organization's Country Cooperation Strategy brief on India, India accounts for twenty-one percent of the world's global burden of disease. WORLD HEALTH ORG., COUNTRY COOPERATION STRATEGY AT A GLANCE: INDIA (2012). The total expenditure on health per capita in India in 2010 constituted four percent of GDP that year, the majority of which was out of pocket. *Id.*

116. CYNTHIA M. HO, ACCESS TO MEDICINE IN THE GLOBAL ECONOMY: INTERNATIONAL AGREEMENTS ON PATENTS AND RELATED RIGHTS 91 (2011). Although India's patent laws under British rule allowed for pharmaceutical patents, India subsequently prohibited patents on pharmaceutical compounds, from 1970 until it was required to under TRIPS in 2005. See V.K. Unni, Symposium, *Indian Patent Law and TRIPS: Redrawing the Flexibility Framework in the Context of Public Policy and Health*, 25 PAC. McGEORGE GLOBAL BUS. & DEV. L.J. 323, 327–28, 333 (2012) (explaining that under the 1970 law, India allowed short patent terms for processes of making pharmaceutical products; processes which are trivial to design around). Although India was not required by TRIPS to grant patents on pharmaceutical products until 2005, it was required to accept applications earlier for later processing and granting of exclusive marketing rights under some circumstances, followed by a grant of the remaining patent term. This transitional provision of TRIPS is known as "the Mailbox Rule," and its precise requirements spurred WTO litigation by the United TRIPS, *supra* note 54, art. 70.8(a); see also Appellate Body Report, *India—Patent Protection for Pharmaceutical and Agricultural Chemical Products*, WT/DS50/AB/R (Dec. 19, 1997) (holding that the required means of filing applications must include allocation of filing and priority dates in addition to preserving novelty and priority as of those dates).

117. The Patents Act, 1970, No. 39, Acts of Parliament, 1970 (India) (*as amended by* The Patents (Amendment) Act, 2005, No. 15, section 3(d), Acts of Parliament, 2005 (India)). The section is followed by an explanation that "salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regards to efficacy." *Id.*

118. See 35 U.S.C. § 100(b) (2011) ("'[P]rocess' means . . . a new use of a known . . . composition of matter, or material."). However, the Indian law may be providing a model for other developing countries, as Thailand and Argentina are considering similar provisions. See Shan Kohli, *Section 3(d) Equivalent in the Offing for Thailand . . .*, SPICY IP BLOG (Nov. 02, 2011, 4:21 AM), <http://spicyipindia.blogspot.in/2011/11/section-3d-equivalent-in-offing-for.html> (noting that Thailand is considering a similar provision); Shouvik Kumar Guha, *Argentina goes the 3(d) Way: Creases of Worry for the Pharmaceutical Patent Applicants?*, SPICY IP BLOG (May 23, 2012, 10:25 PM), <http://spicyipindia.blogspot.com/2012/05/argentina-goes-3d-way-creases-of-worry.html> (stating that Argentina is considering a similar provision). It appears that developed countries are fighting back by including provisions requiring that new forms of known substances be considered patentable regardless of efficacy in regional trade agreements, such as the Trans-Pacific partnership. See, e.g., DOCTORS WITHOUT BORDERS, HOW THE TRANS-PACIFIC PARTNERSHIP AGREEMENT THREATENS ACCESS TO MEDICINES: TPP ISSUE BRIEF 3 (Sept. 2011).

contrast with United States patent law by specifically denoting obviousness requirements for new forms of known substances, rather than allowing the patent office and courts to apply the same standards to all applications.<sup>119</sup> The Indian law thus pins the patentability of new “forms”<sup>120</sup> of chemicals on their efficacy. However, there is no further definition of efficacy in the statute. Instead, the Indian Patent Office interpreted it first<sup>121</sup> when it denied Novartis’s patent to the cancer-fighting drug Glivec. In the most high profile case to date, the Indian Patent Office found that Glivec did not have a significantly different efficacy from other known substances, despite the improvement it provided in absorption.<sup>122</sup> The Supreme Court of India recently upheld the decision.<sup>123</sup> In its holding, the Court stated that it had “no doubt that the ‘therapeutic efficacy’ of a medicine must be judged strictly and narrowly” and suggested two interpretations that would significantly narrow the exception.<sup>124</sup> First, the Court interpreted the statute so that it would never allow “salts, esters, ethers,” and other listed substances to demonstrate increased efficacy.<sup>125</sup> Next, the Court narrowly defined therapeutic efficacy to exclude bioavailability, thermodynamic stability, and other characteristics that one might commonly associate with an improved drug.<sup>126</sup> The decision indicates a willingness by the patent office and the courts to apply the exclusion vigorously and limit the exception

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119. See, e.g., *Schering Corp. v. Geneva Pharms., Inc.* 339 F.3d 1373 (Fed. Cir. 2003) (invalidating a patent under the theory of inherent anticipation).

120. The statute explains that different forms of known substances will include “salts, esters, ethers, polymorphs, metabolites, particles, i.e., isomers, mixtures of isomers, complexes, combinations, and other derivatives of known substance.” The Patents Act, No. 39, section 3(d) (India).

121. See *Ho*, *supra* note 116, at 93–94 (discussing the *Novartis* case and criticizing the law for requiring the patent office to make efficacy determinations when the data to prove it will likely not yet exist and because patent examiners do not have the type of resources or expertise that agencies, such as food and drug agencies, that typically make such determinations have). The lack of evidence may not have been an issue in the *Novartis* case because that application was filed in 1997 and held by the patent office under the mailbox rule; it was rejected during a pre-grant opposition during the examination which only started in 2005. See generally *Novartis AG v. Union of India*, (2007) 4 M.L.J. 1153 (India).

122. *Id.* The appellate court upheld the decision, holding that section 3(d) was not unconstitutional for being vague, arbitrary, and conferring uncontrolled discretion on the Patent Controller. See *Novartis AG v. Union of India*, 2013 \_\_S.C.R.\_\_ at para 5(c) (No. 2706-2716) (Apr. 1, 2013) (India), available at <http://judis.nic.in/supremecourt/imgs1.aspx?filename=40212>.

123. *Id.* at 57 (explaining that section 3(d) “clearly sets up a second tier of qualifying standards for chemical substances/pharmaceutical products in order to leave the door open for true and genuine inventions but, at the same time, to check any attempt at repetitive patenting or extension of the patent term on spurious grounds[.]” thereby suggesting that 3(d) sets a higher threshold for the definition of an invention).

124. *Id.* at 91.

125. *Id.* at 90–91.

126. *Id.*

for significant increases in efficacy.<sup>127</sup> It does not provide clear guidance as to how the provisions will operate in future cases; for example, the Court advances contrasting interpretations of the statute but does not choose among them, suggesting instead that either would yield the same results; while true in this case, it is unhelpful to those seeking guidance for future cases.<sup>128</sup>

India has implemented another tailoring measure through its provisions for compulsory licensing. Compulsory licensing occurs when a government uses or grants authorization for another to use the subject matter of a patent absent consent from the patent holder. Such compulsory licensing is allowed under Article 31 of TRIPS.<sup>129</sup> But one could argue that compulsory licensing is not a true tailoring measure as it was in the India Patent Act of 1970.<sup>130</sup>

In addition, compulsory licensing was allowed by the Paris Convention under certain conditions.<sup>131</sup> In this sense, the right to implement compulsory licensing is only a flexibility inasmuch as it represents a deviation from an absolute right of exclusion, not as a deliberate attempt to counter harmonization. Nonetheless, although compulsory licenses may be important in acting as safety valves and assuring a patent-wary population that rights are not absolute, until recently the global use of compulsory licenses has been remarkably infrequent. India's uses of the provision may reflect changes in policy. In March 2012, India issued a compulsory license, pursuant to section 84 of the India Patent Act, for the cancer-fighting drug Nexavar (generically,

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127. See Ho, *supra* note 116, at 94 (noting that determinations of efficacy in other jurisdictions are typically made by agencies like the U.S. Food and Drug Administration in the context of the effectiveness—and safety—of a drug for market approval purposes).

128. See, e.g., *Novartis AG*, 4 M.L.J. at 94 (indicating that “whatever way therapeutic efficacy may be interpreted,” the beta crystalline form of Imatinib Mesylate did not meet the standard); *id.* at 95 (“Thus, in whichever way section 3(d) may be viewed, whether as setting up the standards of ‘patentability’ or as an extension of the definition of ‘invention’, it must be held . . . [the drug] fails the test of section 3(d), too, of the Act”).

129. TRIPS, *supra* note 54, art. 70.8(a) (setting parameters for compulsory licensing, such as requirements that the proposed user has attempted to obtain a license—except in cases of national emergency, that authorizations should be done on an individual basis and be limited in scope, that the decision must be reviewable in court, and that adequate remuneration be paid, *inter alia*).

130. In fact, India previously had a system of “licenses of right” for patents on foods and medicines, under which those who sought licenses from patent holders but could not come to mutually agreeable terms could apply to the Controller of patents who would hold a hearing and decide license terms, which, by statute, were not to exceed “four percent of the ex-factory sale price in bulk of the patented article.” The Patents Act, 1970, No. 39, sections 86–88, Acts of Parliament, 1970 (India). These provisions have not applied following the 2005 amendments. Licenses of right would violate the requirement in Article 31 of TRIPS that any compulsory license be individually evaluated, among other requirements. See TRIPS, *supra* note 54.

131. Paris Convention, *supra* note 43, art. 5.

sorafenib), manufactured by Bayer.<sup>132</sup> The head of the Indian Patent and Trademark Office—the Controller of Patents—issued the compulsory license to Natco Pharma Ltd., an Indian generic drug manufacturer, after finding that only two percent of the patient population was served by Bayer, the price of the drug was not “reasonably affordable,” and Bayer did not sufficiently “work” the patent in India.<sup>133</sup> The Intellectual Property Appellate Board upheld the decision on those same grounds, and it was appealed to the high court.<sup>134</sup> The price difference is striking: Bayer’s brand name drug sold for approximately \$5,181 per month, whereas Natco Pharma, the Indian generic pharmaceutical company that sought the license, will sell it for approximately \$160 per month.<sup>135</sup>

In the spring of 2013, India took steps toward issuance of compulsory licenses for three more cancer drugs.<sup>136</sup> India’s compulsory licensing, like its exclusion of certain types of chemicals from patentability, is a legislative patent law flexibility applied through administrative procedures. The process behind the laws reflects the full-throated support for Indian industry and consumers that was evident in the India Patent Law of 1970.<sup>137</sup> The approach also reflects the more

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132. The Patents Act, 1970, No. 39, section 84. The Office of the United States Trade Representative responded to the move in Special 301 Report. See AMBASSADOR RONALD KIRK, OFFICE OF THE U.S. TRADE REPRESENTATIVE, 2012 SPECIAL 301 REPORT (2012).

133. Vikas Bajaj & Andrew Pollack, *India Orders Bayer to License a Patented Drug*, N.Y. TIMES, Mar. 13, 2012, at B; Shannad Basheer, *Breaking News: India’s First Compulsory License Granted!*, SPICY IP BLOG (Mar. 12, 2012, 1:27 PM), <http://spicyipindia.blogspot.in/2012/03/breaking-news-indias-first-compulsory.html>. Note that any of these three conditions would be sufficient to support a compulsory licensing decision.

134. Rumman Ahmed, *India Appeals Body Rejects Bayer’s Plea on Nexavar*, WALL ST. J. ONLINE (Mar. 4, 2013) <http://online.wsj.com/article/SB10001424127887324178904578340013954624212.html>. In its decision, the Appellate Board quoted the Iyengar Committee Report to emphasize that patent rights are in the interest of the national economy as opposed to the inventor and are therefore subject to the public interest. See Sai Vinod, *Guest Post: Eye Witness Account of India’s First Compulsory License Appeal Before the IPAB [Part I]*, SPICY IP BLOG (Mar. 8, 2013, 4:15 PM), <http://spicyipindia.blogspot.com/2013/03/guest-post-eye-witness-account-of.html>.

135. Ahmed, *supra* note 134.

136. See G. Pramod Kumar, *India’s Cancer Burden: Why the Govt’s CL Ruling Is so Important*, FIRSTPOST.INDIA, Jan. 15, 2013, <http://www.firstpost.com/india/indias-cancer-burden-why-the-govts-cl-ruling-is-so-important-589051.html> (lauding government plans to issue compulsory licenses for trastuzumab—the patent for which is due to expire in 2014—dasatinib, and ixabepilone); Kevin Grogan, *India to Issue Compulsory Licenses on Roche, B-MS Drugs*, PHARMATIMES, Jan. 15, 2013, [http://www.pharmatimes.com/Article/13-01-15/India\\_to\\_issue\\_compulsory\\_licences\\_on\\_Roche\\_B-MS\\_drugs.aspx](http://www.pharmatimes.com/Article/13-01-15/India_to_issue_compulsory_licences_on_Roche_B-MS_drugs.aspx); Divya Rajagopal, *Compulsory Licence Likely for Three Cancer Drugs*, ECON. TIMES, Jan. 14, 2013, [http://articles.economictimes.indiatimes.com/2013-01-14/news/36331897\\_1\\_compulsory-licence-indian-patent-act-patent-controller](http://articles.economictimes.indiatimes.com/2013-01-14/news/36331897_1_compulsory-licence-indian-patent-act-patent-controller).

137. See V.K. Unni, *supra* note 116, at 327–28 (noting that the Ayyangar Report that informed much of the 1970 patent law suggested designing the law “with special reference to the economic conditions of the country,” and arguing that through enactment of the law, “the Indian government made a conscious decision to kick-start the lagging Indian economy by supporting domestic drug manufacturing”).

measured approach that sought to comply with the new requirements of TRIPS while not relinquishing more than was necessary in the 2005 amendments.<sup>138</sup> In both instances, the Indian Patent Office determined how to implement the flexibility in ways that showed a willingness to stride boldly into matters of policy.

#### B. FLEXIBILITY IN APPLICATION

While legislative tailoring accounts for some variations in the treatment of different technologies or situations, the factual circumstances associated with different technologies sometimes beg different results, even through the application of uniform law. Moreover, the iterative and evolving nature of the common law in particular allows for changes in treatment of different technologies over time.<sup>139</sup> In the United States, flexibility in application has been the primary means when tailoring patent law.<sup>140</sup>

In a series of articles and a book, Dan Burk and Mark Lemley describe ways courts in the United States apply varied standards to the patent cases before them in different industries. They also argue that this tailoring can—and should—be undertaken in furtherance of patent policy objectives and suggest other means of implementing such tailoring to solve inefficiencies associated with uniformity.<sup>141</sup> Burk and Lemley propose that the uniformity costs associated with technology-neutral protection may be significantly minimized through judicial tailoring or “deliberate modulation” of patent laws to different industries.<sup>142</sup> Some tailoring evolves due to the repeated application of a seemingly uniform standard to different fields. Thus, the standard “person having ordinary skill in the art,” invoked to determine whether a claimed invention is

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138. See Prashant Reddy, *The Political Economy of the Current Round of Compulsory Licensing in India*, SPICY IP BLOG (Jan. 16, 2013, 1:19 AM), <http://spicyipindia.blogspot.com/2013/01/the-political-economy-of-current-round.html> (“The present round of compulsory licencing . . . is widely seen as the fruits of a sustained lobbying effort by the generic pharmaceutical lobby.”).

139. See *supra* note 91 and accompanying text.

140. Craig Allen Nard, *Legal Forms and the Common Law of Patents*, 90 B.U. L. REV. 51, 53 (2010) (“[T]he common law has been the dominant legal force in the development of U.S. patent law for over two hundred years.”); see also Arti K. Rai, *Patent Validity Across the Executive Branch: Ex Ante Foundations for Policy Development*, 61 DUKE L.J. 1237, 1265 (2012).

141. See e.g., Dan L. Burk & Mark A. Lemley, *Is Patent Law Technology-Specific?*, 17 BERKELEY TECH L.J. 1155 (2003) (arguing that courts apply a lower standard of nonobviousness to biotechnology patents while imposing stricter enablement and written description requirements, while, in contrast, loosening enablement and best mode requirements for software patents); Burk & Lemley, *supra* note 3 (arguing that technology-specific tailoring through the courts is desirable); THE PATENT CRISIS, *supra* note 3.

142. THE PATENT CRISIS, *supra* note 3, at 102.

invalid because it is obvious,<sup>143</sup> whether a granted patent disclosed the best mode of practicing the invention, and whether the invention was enabled through the patent disclosure has evolved differently in different fields.<sup>144</sup> In this instance, the divergent application of uniform law affects how easy it is to receive a patent (or defend a granted patent's validity) and how broad the scope of a patent will be.<sup>145</sup> The decisions affecting patent eligibility reflect societal values and moral judgments about the limits of control and possession of natural phenomena and beings. In addition, they reflect the value that society places on future innovation and concerns it has about the possible adverse effects the approval of broad patents would have on natural phenomena and innovation. The most recent Court decision affecting patent remedies was aimed at tailoring the scope of patent rights to increase efficiency; however, the purpose of this decision includes underlying policy preferences about balancing access against innovation.<sup>146</sup>

While rules affecting remedies may greatly affect the value of patents, a rule excluding a technology field from patent eligibility removes it from the exclusive-rights-for-innovation scheme entirely. Thus, the U.S. Supreme Court's 1980 decision in *Diamond v. Chakrabarty*—holding that a genetically engineered bacterium was patentable—is viewed as largely responsible for the growth and dominance of the U.S. biotechnology industry.<sup>147</sup> *Chakrabarty* expressed the general understanding that patents are meant to be available for “anything under the sun that is made by man.”<sup>148</sup> Indeed, the United States Patent Act states that a patent shall be granted to “[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof” subject to other limitations.<sup>149</sup> Nevertheless, there are limits to what is patent eligible. There is controversy around the patent eligibility of living organisms, mathematical algorithms, business methods, and the meaning

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143. The Supreme Court moved to an obviousness standard based on the skills and knowledge of a person having ordinary skill in the art in 2007. *KSR Int'l Corp. v. Teleflex Corp.*, 550 U.S. 398, 419 (2007).

144. Burk & Lemley, *supra* note 141, at 1165–84 (discussing the high level of skill expected from a person of ordinary skill in software and the low level of skill expected from a person of ordinary skill in biotechnology-related fields).

145. *Id.* at 1184–87.

146. *See infra* notes 163–175 and accompanying text.

147. *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980) (upholding Chakrabarty's patent on a bacterium genetically modified to break down the components of crude oil); *see* John M. Golden, *Biotechnology, Technology Policy, and Patentability: Natural Products and Invention in the American System*, 50 EMORY L.J. 101, 106–07 (2001).

148. *See Chakrabarty*, 447 U.S. at 309; *see also* S. REP. NO. 82-1979, at 2395 (1952); H.R. REP. NO. 82-1923 (1952).

149. 35 U.S.C. § 101 (2006).

and scope of the areas excluded from patent eligibility: laws of nature, physical phenomena, and abstract ideas.<sup>150</sup> The Supreme Court's decisions in *Mayo v. Prometheus* and *Association for Molecular Pathology v. Myriad Genetics* raise the potential harm to future innovations of granting patents on broad scientific principles.<sup>151</sup> In addition, both cases address technological areas that impact public health.<sup>152</sup>

In *Mayo*, the Court held that a claimed method of optimizing the use of thiopurine drugs to treat autoimmune diseases while minimizing unwanted side-effects was ineligible for patent protection.<sup>153</sup> The claimed process was based on correlations between metabolite levels produced by the drugs in individual patients and the toxicity and efficacy of the drugs.<sup>154</sup> The patents at issue claimed a process for administering the drug to a patient, determining the resulting metabolite levels in the patient's blood, and using those levels to determine future dose adjustments.<sup>155</sup> The Court reiterated the purpose of excluding "[p]henomena of nature, . . . mental processes, and abstract intellectual concepts" from patent eligibility—because they are scientific tools, and extending protection would impede, rather than promote, innovation<sup>156</sup>—before finding that

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150. *Chakrabarty*, 447 U.S. at 309 (citing *Parker v. Flook*, 437 U.S. 584 (1978); *Gottschalk v. Benson*, 409 U.S. 63, 67 (1972); *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948); *O'Reilly v. Morse*, 56 U.S. 62 (1854); *Le Roy v. Tatham*, 55 U.S. 156 (1853)). The Court went on to give examples of unpatentable subject matter, such as "a new mineral discovered in the earth or a new plant found in the wild," the formula  $E = MC^2$ , or the law of gravity, understanding these as "'manifestations of . . . nature, free to all men and reserved exclusively to none.'" *Id.* (quoting *Funk Bros.*, 333 U.S. at 441). The Supreme Court has shown a recent interest in cases relating to patent-eligibility in these areas. In *Bilski v. Kappos*, the Court affirmed that business methods are eligible for patents, but suggested that they may still be suspect for vagueness. 130 S. Ct. 3218, 3228–29 (2010). In *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 132 S. Ct. 1289 (2012), the Court invalidated a claim under the "law of nature" exclusion. The Court recently addressed the exclusion of living organisms in *Association for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107 (2013). In addition to these cases, the Court of Appeals for the Federal Circuit recently issued an en banc decision discussing the appropriate test to determine whether "a computer-implemented invention is a patent ineligible 'abstract idea.'" *CLS Bank Int'l v. Alice Corp. Pty. Ltd.*, 768 F. Supp. 2d 221 (D.D.C. 2011), *rev'd*, 685 F.3d 1341 (Fed. Cir. 2012), *reh'g granted, opinion vacated*, 484 Fed. App'x 559 (Fed. Cir. 2012) (en banc). In a plurality opinion, the court invalidated the claims before it and drew from Supreme Court precedent to suggest "guideposts" for a framework that "turns primarily on the practical likelihood of a claim preempting a fundamental concept" and might apply to technologies beyond the "computer-implemented inventions presented in this case." *CLS Bank Int'l v. Alice Corp. Pty. Ltd.*, 717 F.3d 1269, 1277 (Fed. Cir. 2013).

151. See *Mayo Collaborative Servs.*, 132 S. Ct. at 1292; *Myriad*, 133 S. Ct. at 2116.

152. See generally *Mayo Collaborative Servs.*, 132 S. Ct. at 1292; *Myriad*, 133 S. Ct. at 2116.

153. *Mayo Collaborative Servs.*, 132 S. Ct. at 1289.

154. *Id.* at 1295.

155. *Id.* at 1290–91.

156. *Id.* at 1292 (quoting *Gottschalk*, 409 U.S. at 67). The Court continues, explaining that "there is a danger that the grant of patents that tie up their use will inhibit future innovation premised upon them, a danger that becomes acute when a patented process amounts to no more than an instruction to 'apply the natural law.'" *Id.* at 1301–02 (citing Mark A. Lemley et al., *Life After Bilski*, 63 STAN. L. REV. 1315 (2011)).

the claimed processes were not patent-eligible applications of natural laws.<sup>157</sup> To make its decision, the Court considered the views of the government,<sup>158</sup> members of the medical diagnostic community,<sup>159</sup> and members of the medical practice community.<sup>160</sup> It responded to the submissions from industry by noting that “we must hesitate before departing from established general legal rules lest a new protective rule that seems to suit the needs of one field produce unforeseen results in another.”<sup>161</sup> *Mayo* concerned the biotechnology industry, which thought that the decision might result in significant exclusions from patent protection. However, the PTO issued guidelines to its examiners that also provided guidance to the industry as to what examiners considered to be patent eligible. Although the Court has the final say, the agency’s interpretation provides some level of certainty to the industry, at least in the short term.<sup>162</sup>

*Myriad* similarly raises the issues of line-drawing between describing natural phenomena and scientific discovery,<sup>163</sup> in addition to questions about how best to grant incentives for innovation in medical diagnosis

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157. *Id.* at 1294.

158. *See generally* Brief for the United States as Amicus Curiae Supporting Neither Party, *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289 (2012) (No. 10-1150) (arguing that the subject matter was sufficiently applied to be patent-eligible, but that the patents were likely invalid under the novelty and nonobviousness requirements of the patent act and further arguing that the claims would not preempt other practical applications of the correlation described).

159. *See, e.g.*, Brief for the Pharm. Research & Mfrs. of Am. as Amicus Curiae Supporting Respondent, *Mayo Collaborative Servs.*, 132 S. Ct. 1289 (2012) (No. 10-1150) (arguing that patent protection for medical processes involving pharmaceuticals has spurred innovation and that a ruling of patent ineligibility will undercut incentives for innovation); *see also* Brief for the Biotech. Indus. Org. as Amicus Curiae Supporting Respondent at 1–2, *Mayo Collaborative Servs.*, 132 S. Ct. 1289 (2012) (No. 10-1150) (arguing that the biotechnology industry is “uniquely dependent on predictable and effective patent protection for the development of new technologies” and promoting patent eligibility for inventions in the biotechnology sector).

160. Brief for the AARP & Pub. Patent Found. as Amicus Curiae Supporting Petitioners, *Mayo Collaborative Servs.*, 132 S. Ct. 1289 (2012) (No. 10-1150) (arguing that patents claiming medical correlations inhibit doctors’ ability to diagnose and treat patients and result in higher costs and lower access to health services).

161. *Mayo Collaborative Servs.*, 132 S. Ct. at 1305 (further noting the role of Congress “in crafting more finely tailored rules where necessary” and refusing to decide the policy question of whether “increased protection for discoveries of diagnostic laws of nature is desirable”).

162. Memorandum from Andrew H. Hirshfeld, Deputy Comm’r for Patent Examination Policy, to Patent Examining Corps, 2012 Interim Procedure for Subject Matter Eligibility Analysis of Process Claims Involving Laws of Nature 3 (July 3, 2012) *available at* [http://www.uspto.gov/patents/law/exam/2012\\_interim\\_guidance.pdf](http://www.uspto.gov/patents/law/exam/2012_interim_guidance.pdf) (laying out a test of process claims involving natural principles to see whether “additional elements or steps [are included that] relate to the natural principle in a significant way to impose a meaningful limit on the claim scope. The analysis turns on whether the claim has added enough to show a practical application.”).

163. *Ass’n for Molecular Pathology v. Myriad Genetics Inc.*, 133 S. Ct. 2107, 2116–17 (2013).

and treatment without deterring downstream innovation.<sup>164</sup> The Court held that merely isolating naturally occurring DNA sequences does not make them patent eligible; however, claims to “cDNA” are patent eligible because that protein is not naturally occurring.<sup>165</sup> The opinion offers a bright line rule in the limited context of the type of genetic research at issue.<sup>166</sup> Its application to future types of medical research is unclear.<sup>167</sup> The patents at issue covered genes that Myriad isolated, and then discovered that mutations on those genes correlate with increased risks of breast and ovarian cancer.<sup>168</sup> Because the subject of the claims is human DNA, the case also raises moral issues about the limits of legal entitlement to material that exists naturally in human beings.<sup>169</sup> The petitioners that challenged the validity of the patents include professional associations of pathologists and women’s health organizations.<sup>170</sup> The views of the government, reflecting advice from relevant agencies, were before the Court in the form of an amicus curiae brief.<sup>171</sup> Other organizations wrote briefs as amicus curiae as well, raising additional questions of access to public health,<sup>172</sup> arguing that exclusion from patent eligibility better serves the purposes of spurring innovation,<sup>173</sup> representing a religious interpretation of patent eligibility,<sup>174</sup> or supporting patent eligibility while suggesting other patent doctrines as sufficient bars to patents likely to impede innovation.<sup>175</sup>

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164. *Id.* at 2116; Petition for Writ of Certiorari at 25, *Myriad*, 133 S. Ct. 2107 (No. 12-398) (“The broad preemptive effect of these patents is further evidence that they claim laws and products of nature. The patents cover all isolated forms of the naturally-occurring genes, whether previously identified or not. The patents grant Myriad the authority to prevent all research and clinical testing of the genes, raising the same concerns about patenting a ‘building-block’ that has troubled the Court.”)

165. *Myriad*, 133 S. Ct. at 2111.

166. See Jacob S. Sherkow & Henry T. Greely, *The Future of Gene Patents and the Implications for Medicine*, 173 JAMA INTERNAL MEDICINE 1569, 1570 (2013) (suggesting that in the short run, the *Myriad* decision means “more competitive markets for diagnostic genetic testing,” for the genes at issue in that case, but that “in the long term, probably [it doesn’t mean] very much”).

167. *Id.*

168. Petition for Writ of Certiorari at 2, *Myriad*, 133 S. Ct. 2107 (No. 12-398).

169. For those who believe that isolated DNA is sufficiently different from naturally occurring molecules, there is no moral question, of course.

170. Petition for Writ of Certiorari at 2, *Myriad*, 133 S. Ct. 2107 (No. 12-398).

171. Brief for the United States as Amicus Curiae Supporting Neither Party at 9, *Myriad*, 133 S. Ct. 2107 (No. 12-398) (arguing that isolated DNA should not be patent eligible because it would unduly compromise the public’s ability to study and use native DNA, inter alia).

172. Brief for the AARP as Amicus Curiae Supporting Petitioners, *Myriad*, 133 S. Ct. 2107 (No. 12-398) (arguing that gene patents impede the ability of patients to obtain medical care—particularly patients covered by Medicare and Medicaid).

173. Brief for the Am. Med. Ass’n. et al. as Amici Curiae Supporting Petitioners, *Myriad*, 133 S. Ct. 2107 (No. 12-398).

174. Brief for the Ethics & Religious Liberty Comm’n of the S. Baptist Convention & Prof. D. Brian Scarnecchia as Amici Curiae Supporting Petitioners, *Myriad*, 133 S. Ct. 2107 (No. 12-398)

Courts have also adapted legal standards to address newly emergent problems that may arise more in technology fields with particular characteristics. For example, the Supreme Court's decision in *eBay v. MercExchange* and subsequent district court decisions denying permanent injunctions following findings of patent infringement were a reaction to the emergence of new business models that took advantage of increasingly complex technologies and created a drag on innovation.<sup>176</sup> Permanent injunctions were nearly presumed following a finding of infringement before the Supreme Court granted certiorari in *eBay*.<sup>177</sup> However, there was an increase in patents that presented holdup opportunities, either because of their broad scope (such as for software patents), or because the ever more complex products that characterize the information technology sector were covered by numerous overlapping patents.<sup>178</sup> The concurrent rise in patent suits filed by entities that acquired patent portfolios solely for the purpose of seeking licensing fees through the threat of lawsuits created pressure to modify the strong presumption of an injunction because of the inefficiencies introduced into the system through the characteristics of these new industries and business models.<sup>179</sup>

The Supreme Court in *eBay* held that there was no "general rule that courts will issue permanent injunctions against patent infringement absent exceptional circumstances," and instead emphasized the importance of weighing each injunction request individually.<sup>180</sup> Although Chief Justice Roberts authored a concurrence emphasizing that

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(arguing that ownership of DNA would upset the fundamental relationships between G-d and humanity, and between human beings as understood through various branches of Christian theology).

175. Brief for the Am. Intellectual Prop. Law Ass'n as Amicus Curiae Supporting Affirmance but Supporting Neither Party, *Myriad*, 133 S. Ct. 2107 (No. 12-398) (arguing that the claims were drawn to isolated DNA that is not found in humans, that patent eligibility should be a low bar with other doctrines of patentability providing stricter limits, and that the Court should respect the moral and ethical considerations reflected by Congress' recognition of patent eligibility for isolated DNA).

176. See Mark A. Lemley & Carl Shapiro, *Patent Holdup and Royalty Stacking*, 85 TEX. L. REV. 1991, 2015 (2007) (explaining that holdup risk is high for complex inventions, particularly when there is no reciprocal risk of litigation and that NPEs bring a significant portion of infringement suits in industries subject to royalty stacking); see also *id.* at 2164 (emphasizing that "holdup is recognized as a form of market failure that leads to inefficiency, primarily by discouraging what would otherwise be socially desirable investments"); Carol M. Nielsen & Michael R. Samardzija, *Compulsory Patent Licensing: Is It a Viable Solution in the United States?*, 13 MICH. TELECOMM. & TECH. L. REV. 509, 510-11 (2007) (describing new technologies as particularly susceptible to holdup due to "patent thicket," where hundreds of patents are needed for a single product, yet they all overlap and block one another).

177. *MercExchange, L.L.C. v. eBay Inc.*, 401 F.3d 1323, 1338-39 (Fed. Cir. 2005), *vacated*, 547 U.S. 388 (2006).

178. See *supra* note 176 and accompanying text.

179. Rajec, *supra* note 3, at 742-48 (detailing the path to *eBay*).

180. *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 391, 395-97 (2006) (noting that issuance of overbroad patents may affect how courts approach the four-factor test).

“[d]iscretion is not whim,” and “that like cases should be decided alike,”<sup>181</sup> four members of the Court were more willing to entertain the idea that patent laws might be tailored for different situations.<sup>182</sup> Indeed, the district court denied an injunction in that case on remand.<sup>183</sup> The Court had before it briefs from industry<sup>184</sup> and academics<sup>185</sup> who were concerned about holdup from non-practicing entities, as well as from professional organizations arguing in favor of a general rule in favor of the grant of permanent injunctions.<sup>186</sup> Moreover, district courts have interpreted *eBay* such that non-practicing entities are less likely to be awarded an injunction than patent holders who practice their patents.<sup>187</sup>

The preceding examples show how patent law may be tailored to meet particular societal needs, better align with local values, or better serve its purpose of incentivizing innovation. Indeed, most of the examples satisfy multiple purposes. Although the arguments that support these measures may be apparent from their descriptions, legitimate concerns underlie the global move toward harmonization, even with its imperative of further uniformity in domestic patent laws. These tensions are explored and a framework for weighing them is proposed in the Parts that follow.

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181. *Id.* at 395 (Roberts, C.J., concurring) (quoting *Martin v. Franklin Capital Corp.*, 546 U.S. 132, 139 (2005)).

182. *Id.* at 396–97 (Kennedy, J., concurring).

183. Although the reasoning was not based on a rule that patent holders who do not practice their inventions should not be entitled to injunctions, the “market share rule” emerging in the district courts following the *eBay* decision accomplishes much the same as such a rule would, albeit with some logical contortions. See *MercExchange, L.L.C. v. eBay Inc.*, 500 F. Supp. 2d 556, 591–92 (E.D. Va. 2007), remanded by 547 U.S. 388 (2006).

184. See e.g., Brief of Am. Innovators’ Alliance as Amicus Curiae Supporting Petitioner at 25–30, *eBay*, 547 U.S. 388 (No. 05-130); Brief of Amicus Curiae Yahoo! Inc. Supporting Petitioner at 5–14, *eBay*, 547 U.S. 388 (No. 05-130); Brief of Int’l Bus. Machs. Corp. as Amicus Curiae Supporting Neither Party at 16–18, *eBay*, 547 U.S. 388 (No. 05-130).

185. Brief of 52 Intellectual Prop. Professors as Amici Curiae Supporting Petitioner at 7, *eBay*, 547 U.S. 388 (No. 05-130).

186. Brief of Am. Intellectual Prop. Law Ass’n & Fed. Circuit Bar Ass’n as Amici Curiae Supporting Neither Party, *eBay*, 547 U.S. 388 (No. 05-130).

187. See, e.g., Rajec, *supra* note 3, at 751–58 (suggesting that following *eBay*, courts are using a “market share rule” to determine whether a permanent injunction is warranted); see also Andrew Beckerman-Rodau, *The Aftermath of eBay v. MercExchange*, 126 S. Ct. 1837 (2006): *A Review of Subsequent Judicial Decisions*, 89 J. PAT. & TRADEMARK OFF. SOC’Y 631, 654 (2007) (“[D]irect competition . . . appears to be the most significant predictor of whether a permanent injunction will be granted.”); Bernard H. Chao, *After eBay, Inc. v. MercExchange: The Changing Landscape for Patent Remedies*, 9 MINN. J.L. SCI. & TECH. 543, 549–55 (2008) (suggesting courts use direct competition as a means for determining the appropriateness of an injunction); Benjamin Petersen, *Injunctive Relief in the Post-eBay World*, 23 BERKELEY TECH. L.J. 193, 196–98 (2008) (suggesting that courts “place a heavy emphasis” on whether the parties are in “direct competition”).

#### IV. THE FRAMEWORK

In order to develop a framework that carries descriptive and prescriptive weight, a tailoring measure should be evaluated by the degree to which it satisfies the purposes of maintaining flexibility and the ways in which it minimizes harm to harmonization interests. Moreover, the implementing institutions and degree of stakeholder involvement in bargaining provide insight into the likelihood that a given tailoring measure will indeed account for these competing values.

##### A. ARGUMENTS FOR HARMONIZATION AND ARGUMENTS FOR UNIFORMITY

Proponents of harmonization and uniformity put forth arguments that sound in the values of certainty, fairness, and economy. The arguments for uniform rules within a patent regime often apply equally in the international sphere.<sup>188</sup> Such arguments rely on the uncertain nature of scientific advancement and the need of investors for certainty about the applicable legal regime when investing in uncertain technologies. Patents are primarily conceived as property rights, allowing a reliance on the ability of private parties to determine the value of an invention without regulatory or legislative intervention.<sup>189</sup> From this view, investments based on the reasonable expectation of patent availability should be protected. In addition to arguments in favor of uniform patent laws in domestic settings, there are arguments unique to harmonizing patent laws among different countries, such as solving free-rider problems and encouraging free trade.

###### *I. Certainty*

Certainty in the law governing innovation is important because the nature of innovation is inherently uncertain. Patent law is meant to accommodate advances in known fields of scientific endeavor as well as those fields that have yet to come into being. If the Patent Office had to wait for the legislature to determine whether “the Next Big Thing” was

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<sup>188</sup> It is worth noting that minimum requirements will not necessarily result in uniformity of laws. In practice, however, countries have not extended protection beyond the levels required by TRIPS, except for the regional trade agreements that include “TRIPS plus” measures. *See, e.g.*, PEDRO ROFFE, QUAKER INT’L AFFAIRS PROGRAMME, *BILATERAL AGREEMENTS AND A TRIPS-PLUS WORLD: THE CHILE-USA FREE TRADE AGREEMENT 2004*. These measures are generally attempts to harmonize, not attempts to implement longer patent terms.

<sup>189</sup> The discussion of property versus liability rules in patent law shows that the difficulty in valuation of patent rights argues in favor of property rules. *See, e.g.*, Michael A. Carrier, *Cabining Intellectual Property Through a Property Paradigm*, 54 DUKE L.J. 1, 1, 52–54 (2004) (noting increasing propertization of intellectual property law but hailing the limits that the property framework can impose); *see also* THE PATENT CRISIS, *supra* note 3, at 140; Carroll, *supra* note 3, at 1396 (summarizing but not endorsing the argument that property rules provide lower administrative costs while still allowing for private contracting).

patent eligible (or form its own policy following administrative procedures or wait for a judicial decision), the delays would render the grant of lower value to wholly new fields of technology. This would result in incentives to engage in incremental innovation, not to pioneer new areas. In the United States, therefore, the patent system is meant to cover “anything under the sun that is made by man.”<sup>190</sup> Although there will always be questions at the margins about patent eligibility,<sup>191</sup> the default rule is patent eligibility for all fields of technology.

For an innovator considering developing and patenting an invention, the value associated with the patent is an important characteristic for deciding whether it is worthwhile to make the investment.<sup>192</sup> If uncertainty exists as to the eligibility of an invention for a patent, the worth of investing in development of such an invention should be discounted<sup>193</sup>—indeed, *Mayo* led to some concern as to appropriate arenas for investment.<sup>194</sup> Fields of scientific research with uncertain patent eligibility would receive less initial funding. In this way, uncertainty about the availability or extent of patent protection will lead to less investment in innovation, particularly in the areas of greatest innovation. Conversely, a uniform patent law that applies to all fields of technology, now and in the future, can be expected to encourage more investment in innovation.

Internationally, the increased harmonization required by TRIPS allows greater certainty that patent protection is available. It also reduces the cost of obtaining knowledge about the parameters of that protection because of the minimum levels of protection it requires. Frederick Abbott suggests that TRIPS benefits existing innovation-based enterprises because it entrenches “existing dominance of these enterprises in technology-dependent fields,” but also because companies benefit “from the enhancement of their legal security in a wider portion of the world

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190. S. REP. NO. 82-1979, at 5 (1952); H.R. REP. NO. 82-1923 (1952); *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980).

191. See, e.g., *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289 (2012); Ass’n for Molecular Pathology v. Myriad Genetics, Inc., 689 F.3d 1303 (2012). Originally, the court of appeals for *Myriad* held that the claimed method was eligible for patent protection, using the “machine-or-transformation” test. *Id.* at 1334. Certiorari was sought and the Court granted, vacated, and remanded the case with instructions to reconsider the case in light of its holding in *Mayo*. Ass’n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107, 2114 (2013). The Federal Circuit issued another opinion upholding the patent. *Id.*

192. But see Mark A. Lemley & Carl Shapiro, *Probabilistic Patents*, 19 J. ECON. PERSPS. 75 (2005) (describing that even after a patent grant, uncertainty remains about the validity and scope of the patent until it has been litigated).

193. Christopher A. Cotropia, *The Folly of Early Filing in Patent Law*, 61 HASTINGS L.J. 65, 70 (2009).

194. See, e.g., Comments of anonymous business leader at GW Law School Round Table on implications of *Mayo v. Prometheus* (May 16, 2012) (suggesting that if a company were considering investing in that field of technology following the Supreme Court decision, it would likely reconsider).

market.”<sup>195</sup> While a structure that reinforces existing dominance of particular companies does not fit all the goals of the patent system,<sup>196</sup> the second suggestion that companies benefit from enhanced legal security would apply universally to entrenched and emerging businesses. Certainty and security are benefits for companies engaging in innovation on a global scale.

For developing countries, in addition to the reduced incentives to innovate associated with a lack of certainty, patentable subject matter exceptions and other lowered levels of intellectual property rights could lead to reduced trade and foreign direct investment.<sup>197</sup> Thus, some industrialized countries have suggested that the legal infrastructure of TRIPS makes enterprises in developed countries more willing to transfer technology to developing countries and also increases direct investment.<sup>198</sup> In addition, industrialized countries suggested that stronger intellectual property rights will allow domestic industry in developing countries the protections needed to grow.<sup>199</sup> This claim appears dubious as it applies to the least developed countries. However, it is more likely to be true for countries that already have industrial and educational infrastructure. Historically, patent laws have developed in parallel with industry, rather than leading it. For the least developed countries, where the administrative cost of a patent system is itself a burden and infrastructure is weak, the suggestion that complex innovation is likely to spring up with the passage of strong patent laws falls flat.<sup>200</sup> Nonetheless, for countries that may be close to transitioning from imitative industries to innovative industries, the certainty offered by robust patent laws can make investment more attractive.

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195. Frederick M. Abbott, *The Enduring Enigma of TRIPS: A Challenge for the World Economic System*, 1 J. INT'L ECON. L. 497, 499 (1998).

196. See *supra* Part I.

197. See, e.g., MASKUS, *supra* note 12, at 186–94.

198. See Abbott, *supra* note 195, at 499, 506–07 (describing the argument); see also TRIPS, *supra* note 54, art. 66.2 (“Developed country Members shall provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to least-developed country Members in order to enable them to create a sound and viable technological base.”).

199. See Abbott, *supra* note 195, at 499. Abbott goes on to suggest that “[m]easuring the effects of [intellectual property rights] in the economic development process” would require disaggregating those rights “from other determinants of economic development,” and suggests that the difficulty of that task has “so far precluded meaningful measurement of the role of [intellectual property rights] in the economic development process.” *Id.* at 503–04.

200. JAGDISH BHAGWATI, IN DEFENSE OF GLOBALIZATION 183 (2004) (suggesting that the idea that poor countries will benefit from “having to pay for patents they had been accessing freely” was “as implausible as the Mafia telling its victims that the protection money would keep them safe from arson”).

## 2. *Fairness*

The fairness argument casts countries with lower levels of intellectual property protection as free-riders on members of countries with higher levels of protection.<sup>201</sup> As John Duffy put it, “externalities provide a particularly powerful justification for transnational patent harmonization because one nation’s patent law can create a global externality.”<sup>202</sup> According to this argument, industries in countries with strong patent rights bear the costs of research and development. If their own country is the only one with strong intellectual property protection, those companies must increase prices to recoup their research and development costs from domestic consumers. In contrast, manufacturers in countries with low levels of patent protection will engage in copying with significantly lower development costs.<sup>203</sup> As a result, such manufacturers will market equivalent products at lower prices. Innovator companies will either be priced out of those markets or lower their prices significantly to compete. Thus, industry and consumers in low-protection countries will benefit from the innovative efforts undertaken by industry in high-protection countries, denying them a market to recoup their costs and pushing the full cost of innovation onto enterprises and consumers in the high-protection countries.<sup>204</sup> Diverse levels of patent protection thereby set the stage for free-riding behavior and appropriation of work.

This argument has limited currency under the incentive theory of patent protection; its primary appeal comes from natural law and contract theory.<sup>205</sup> If the incentive to innovate and bring innovation to market is the main goal of patent protection, then an analysis of the need for harmonization would have to consider whether innovators were undercompensated as a result of not reaping the monopoly premium in

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201. Abbott, *supra* note 55, at 697 (writing prior to the TRIPS agreement and explaining that the “intellectual property problem therefore concerns devising a mechanism for protecting industrialized country intangible wealth” from appropriation without compensation).

202. John F. Duffy, *Harmony and Diversity in Global Patent Law*, 17 *BERKELEY TECH. L.J.* 685, 695 (2002).

203. Of course, this varies among industries. The possibility of reverse-engineering is often brought up as particularly easy in the field of pharmaceutical development, which is also characterized by cheap production costs relative to research and development of new chemical entities. Clarisa Long, *Our Uniform Patent System*, 55 *Fed. Law.* 44, 45 (2008) (“Pharmaceutical research is a high-cost, highly uncertain process, with a final product that is cheap to reverse engineer, copy, and mass produce.”).

204. In addition to patented innovation, un-patentable basic research undertaken in high-protection countries is also subject to free-riding. These arguably incidental advances are a net benefit to the worldwide scientific community, although costs are borne by companies and governments that fund the research and passed on to consumers as well. Long, *supra* note 203 at 45.

205. The free-rider argument appeals most strongly to those who ascribe to the idea that an inventor has an inherent right to her invention, so that any appropriation of that invention must constitute a type of stealing. *See supra* note 17 and accompanying text.

countries with lower levels of patent protection. Failure to reap such a reward could be the consequence of choosing not to market a product there or of selling it for the lower price associated with a competitive market. Additionally, one might query whether consumers in countries with strong patent rights had the ability to pay sufficient prices to induce optimal levels of innovation without contribution from consumers elsewhere. Certainly, one concern could be that the higher prices companies need to charge in a non-harmonized world make innovation inaccessible to large numbers of consumers in high-protection countries. In that case, lower-income consumers in high-protection countries would miss out on access to innovation to the benefit of all consumers in low-protection countries. However, there are other benefits—such as jobs and other capital generation—that may accrue to citizens of high-protection countries by virtue of innovative industries. Thus, although the fairness argument is often used in favor of harmonization, it relies on other justifications for intellectual property that presume a right to exclude before concluding that it is unfair to deprive an inventor of that right. Its applicability is therefore limited.

The fairness argument lends further support to the argument about the importance of certainty in the face of the unpredictable nature of science. If the patent right is meant to provide *ex ante* incentives to innovators, then in situations involving the greatest potential gain to society—those large jumps in innovation that Schumpeter described as the most important to stimulate<sup>206</sup>—it would be unfair to remove the incentive *ex post* based on characteristics of the field that were not known or understood at the time of invention. This argument is premised on it being a reasonable assumption that an invention will be eligible for patent protection. As a result, it applies to systems that offer broad patent protection but attempt to use flexibility to tailor those laws *ex post*. It would not apply to a system that did not offer uniform or strong patent protection to begin with.

### 3. *Economy*

The process of obtaining patents is cumbersome and expensive in any jurisdiction, as it consists of drafting and filing an application, responding to office actions (usually a type of conditional rejection) from the examiner by making amendments, and paying fees all along the way to issuance.<sup>207</sup> If a patent application is rejected in the United States, for

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206. JOSEPH A. SCHUMPETER, CAPITALISM, SOCIALISM, AND DEMOCRACY 84 (1950) (touting the importance of “competition from the . . . new technology . . . which strikes not at the margins of the profits and the outputs of the existing firms but at their foundations and their very lives”).

207. Following issuance, maintenance fees are also required. U.S. PATENT & TRADEMARK OFFICE, *supra* note 22.

example, the applicant may choose to challenge the decision at the PTO and further appeal any adverse decision to the Court of Appeals for the Federal Circuit and the Supreme Court.<sup>208</sup> Even if a patent is issued, it may be challenged in post-grant review.<sup>209</sup> In addition, the validity of patents is routinely challenged during post-grant infringement litigation.<sup>210</sup> These costs accrue to both patent applicants and to the administrative and judicial systems of jurisdictions supporting patent systems. Even in the United States, the ability to litigate in various jurisdictions has come under fire for its wastefulness.<sup>211</sup> If there are no meaningful differences between the laws that are applied, replicating the process in multiple jurisdictions—each with its own procedures—would certainly be wasteful.<sup>212</sup> The “meaningful differences” caveat is no small condition, of course. However, where it is met, harmonization lowers patent costs by reducing “unnecessary redundancy [that] drives up the costs of obtaining and enforcing worldwide patent protection to a level that can only be afforded by the largest multinational corporations. . . . [and] also adversely impacts the governments themselves.”<sup>213</sup>

Justifications for harmonization thus include the procedural efficiency gained when understanding, filing for, and managing patent portfolios in numerous jurisdictions. When costs are high, legal variations may be seen as barriers to efficient trade and investment. In addition, substantive harmonization or unification may be seen as necessary to allow innovators to fully reap the rewards of their contributions. As globalization increases, information is unconstrained by borders. The cost of accessing a patent obtained in the United States or Europe is as low as the cost of finding Internet access.<sup>214</sup> Because those contemplating patent protection may also

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208. 28 U.S.C. § 1295(a)(4)(A) (2006) (granting the Court of Appeals for the Federal Circuit jurisdiction over appeals from rejections of patent applications).

209. Post-grant review has been expanded with passage of the America Invents Act. 35 U.S.C. §§ 321–29 (2011).

210. 28 U.S.C. § 1295(a)(1) (2006) (granting the Court of Appeals for the Federal Circuit jurisdiction over appeals in patent cases).

211. See *supra* note 92 and accompanying text (arguing that nothing less than the repeal of section 337 will fix the problem of allowing multiple jurisdictions for patent litigation).

212. It could be argued that the cost of filing for and obtaining a patent serves a certain gate-keeping role. See, e.g., Michael W. Carroll, *One For All: The Problem of Uniformity Cost in Intellectual Property Law*, 55 AM. U. L. REV. 845, 880–81 (2006) (suggesting that patent law deploys call options by noting that the “potential patentee must assess the option value or strike price of patent protection and compare that to the costs of exercising the option through patent prosecution” and noting that the potential patentee will weigh this against keeping trade secret protection or defensively publishing). However, it is hard to support a costly process simply for its sorting value, particularly where the same result could be obtained by charging higher fees for a streamlined, multi-jurisdictional process.

213. Gerald J. Mossinghoff & Vivian S. Ku, *World Patent System Circa 20XX, A.D.*, 38 IDEA 529, 530 (1998).

214. Both the PTO and the European Patent Office maintain free, user-friendly, online search engines. See U.S. PATENT & TRADEMARK OFFICE, DEP’T OF COMMERCE, <http://www.uspto.gov/patents/>

opt to keep their innovations as trade secrets, the universal availability of information contained in patents could, when combined with low levels of protection in other countries, weigh in favor of non-disclosure. In the aggregate, such decisions have the ability to retard future innovation.

One other argument for harmonization is that it may be a means to target types of innovation that have small or underfunded markets in individual countries. Collaborations facilitated by WIPO, for example, create initiatives to address malaria prevention through concerted efforts among innovators and establishment of intellectual property hubs.<sup>215</sup> These coordinated efforts are easier to implement with harmonized intellectual property laws. The counterargument is that a patent system is not the only, or necessarily the most efficient, way of producing innovation.<sup>216</sup> Other methods of encouraging innovation have been proposed and analyzed. Some of these have been implemented. The most discussed alternative consists of offering prizes for finding the solutions to difficult problems.<sup>217</sup> And there are industries that have never traditionally been eligible for patents that have thrived and produced innovation.<sup>218</sup> Nevertheless, the efficiency of harmonizing aspects of the patent system is clear given that many countries have patent systems, companies have relied on them to fund their innovation, and trade barriers have been lowered and trade increased by leaps and bounds in the past few decades. Of course, efficiency alone may not be enough to counterbalance arguments in favor of flexibility. Thus, efficiency weighs heavier in arguments about harmonizing procedural aspects of patent law than substantive aspects.

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process/search (last visited Oct. 31, 2013); EUROPEAN PATENT OFFICE, <http://www.epo.org/searching.html> (last visited Oct. 31, 2013). Google also has a patent search tool that creates a search bar specifically for patents. GOOGLE, <http://www.google.com/?tbs=pts> (last visited Oct. 31, 2013).

215. Matt Rainey, Director: Innovation Division, World Intellectual Prop. Org., Address at the World Intellectual Property Organization's 6th Advanced Research Forum on Intellectual Property Rights: Networked Innovation: Solutions for Local and Regional Needs (July 12, 2012) (describing how the creation of research and development networks and intellectual property hubs in Colombia, various Western African countries, and the middle east can focus on problems like neglected diseases or development of an innovation industry—goals that would be near impossible for any one of the governments to accomplish on their own). Non-governmental organizations, such as the Pan-American Health Organization, also create some of these pharmaceutical collaborations. See PAN AM. HEALTH ORG., <http://new.paho.org/hq/index.php?lang=en> (last visited Oct. 31, 2013) (search for "Pharmaceutical Collaborations").

216. HESTERMEYER, HUMAN RIGHTS, *supra* note 17, at 158–66.

217. See generally Michael Abramowicz, *Perfecting Patent Prizes*, 56 VAND. L. REV. 115 (2003) (discussing prizes as incentives); James Love & Tim Hubbard, *The Big Idea: Prizes to Stimulate R&D for New Medicines*, 82 CHI.-KENT L. REV. 1519 (2007).

218. KAL RAUSTIALA & CHRISTOPHER SPRIGMAN, *THE KNOCKOFF ECONOMY: HOW IMITATION SPARKS INNOVATION* (2012) (examining innovative industries that thrive without formal intellectual property protection).

One might expect that the gains to patent applicants from harmonization could be counterbalanced by access-enhancing measures, but that has not been the case. For example, if a patent applicant can access more markets because of the ready availability of patent protection in multiple jurisdictions, perhaps a shorter patent term would suffice to recompense her the cost of research and development. But by and large, no one has suggested that harmonization should be accompanied by concessions from patent holders. Thus, negotiations that move toward harmonization are favorable to patent applicants and holders by reducing the cost of securing patent protection in multiple jurisdictions. They are favorable to patent offices, which may be able to rely in part on work from other patent offices in making their determinations. The benefits in terms of access, however, are indirect, and rely on a mercantilist assumption that consumers in countries without patent protection will not have access to new technologies because no one in those countries will manufacture there. If instead countries without patent protection would have cheaper access to the technology (from manufacturers who need not go to the expense of negotiating licenses), then these consumers do not benefit from harmonization in any direct sense.

#### 4. *Capture and the Public Choice Argument*

There is another reason that uniform rules for all technologies might be preferable to a balkanized patent regime. Diverse stakeholders make their voices heard in the legislative and administrative processes that govern patent law; however, applying technology-specific rules may make it easier for associated industries to capture the process by dividing groups that are likely to oppose them. Once a different set of rules is held to apply to one area, those with vested interests in that area can focus their lobbying efforts on it, while natural opponents will only sometimes be as focused in their resistance.<sup>219</sup>

In the international setting, this same argument applies *a fortiori*. Prior to the TRIPS Agreement's entry into force, many countries granted lower levels of patent protection for pharmaceutical inventions. Notably, this was true in Brazil and India, both of which have robust

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219. THE PATENT CRISIS, *supra* note 3, at 99–100 (2009) (explaining that industry-specific legislation is more vulnerable than general legislation to lobbying); see Robert Patrick Merges & Glenn Harlan Reynolds, *The Proper Scope of the Copyright and Patent Power*, 37 HARV. J. ON LEGIS. 45, 50–56 (2000) (discussing how rent-seeking, backward-looking behavior can undermine the forward-looking purposes of the patent system).

domestic industries in generic drug production.<sup>220</sup> Of course, TRIPS now requires that there be no discrimination in patent laws as to fields of technology.<sup>221</sup> Before the TRIPS requirements went into force, stakeholders in the pharmaceutical industry in these countries had interests that aligned with the public health and access industries of the populations. Manufacturers in these countries made generic versions of drugs that were patented in other countries, and thus had no incentive to seek patent protection for pharmaceutical products. In terms of public health, there was no incentive to increase patent protection because it would lead to higher prices and less availability of medicines. None of the stakeholders in the legislative process would be likely to voice the benefits of having a patent system that covered pharmaceutical products. If there were no requirement of patent availability without discrimination as to field of technology, the dominant industry in each country would be able to capture the legislature and press for laws that were only beneficial to that industry. If those laws were objectively good, then they might be beneficial in other industries as well. If instead those laws struck a poor balance between innovation and access, the opposition would more likely be fragmented as laws would only apply to one technology area.

This Part has explained the justifications for harmonization among countries and uniformity within them. These arguments sound in certainty, fairness, economy, and public choice. Compelling though they may be, there are sound arguments that favor tailoring measures. These include the efficiencies associated with tailoring, the ability to respond to diverse local needs—including specific needs like access to medicine—and the benefits of experimentation and improvement in the law. These arguments all underlie the instances of tailoring discussed in this Article.

## B. THE OTHER SIDE: THE VALUE OF FLEXIBILITY

### 1. Tailored Efficiency

Many scholars have explained how the uniform duration of patent rights will lead to overcompensation in some situations and under compensation in others.<sup>222</sup> Some patent holders will receive protection for

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220. Jeffery Atik & Hans Henrik Lidgard, *Embracing Price Discrimination: TRIPS and the Suppression of Parallel Trade in Pharmaceuticals*, 27 U. PA. J. INT'L ECON. L. 1043, 1047 (2006) (describing India and Brazil as having “vibrant generic drugs sectors”).

221. TRIPS, *supra* note 54, art. 27.1 (“[P]atents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.”).

222. See, e.g., JAMES BESSEN & MICHAEL J. MEURER, PATENT FAILURE: HOW JUDGES, BUREAUCRATS, AND LAWYERS PUT INNOVATORS AT RISK 132 (2008); see also FRANK EMMERT, *Trade and Intellectual Property*, in INTERNATIONAL TRADE LAW 4 (Henry Wang ed., 2012); Brian J. Love, *An Empirical Study of Patent Litigation Timing: Could a Patent Term Reduction Decimate Trolls Without Harming*

much longer than would have been necessary to induce them to innovate. In other situations, the patent term will not be sufficient for an inventor to recoup costs and be rewarded for her contribution to “science and the useful arts.” This too-short term will either result in under compensation or, more troubling from a utilitarian, innovation-optimizing viewpoint, lower levels of innovation based on ex ante predictions of potential future profitability. In a series of articles, Michael Carroll addressed the inefficiencies that arise from having uniform intellectual property laws and proposed a framework for tailoring rights to avoid such costs.<sup>223</sup> Assuming that the current patent regime encourages the optimal level of innovation at least sometimes, the dual risks of under-stimulation of innovation and over-protection of intellectual property will manifest in inventions that differ in technology areas or business structures. Thus, the optimization of patent protection will depend on the varied attributes of different technology areas, including the research and development life cycle, the ease of reverse engineering a product (a process of recreating the innovation from the end product), and the complexity and number of parts included in the final product. These concerns are manifest in attempts to curb the patenting of software and to increase patent protection for pharmaceutical products. Software has a shorter research and development life cycle than pharmaceuticals, which have the additional hurdle of regulatory approval. In addition to being difficult to develop, pharmaceutical products are easy to reverse engineer, making patent rights necessary to market control. Calls for reform in these areas have focused on these attributes while arguing for the importance—or irrelevance—of patent protection to support innovation.

In addition, although the uncertain nature of technological progress may weigh in favor of certainty in the law,<sup>224</sup> it can also justify flexibility. In particular, because science and technology are always advancing in ways that are impossible to predict, a flexible regime allows policy makers to “modify their intellectual property rules to readjust the

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*Innovators?*, 161 U. PENN. L. REV. (forthcoming 2013) (finding that the length of the patent term is exploited by non-practicing entities who primarily sue for infringement during the last years of the patent term, primarily in high tech industries).

223. Carroll, *supra* note 212 (identifying and exploring the nature of uniformity costs associated with different types of intellectual property and suggesting solutions, such as expanding the use of patent renewal fees, to tailor the duration of rights); Michael W. Carroll, *Patent Injunctions and the Problem of Uniformity Cost*, 13 MICH. TELECOMM. TECH. L. REV. 421, 429 (2007) (applying a uniformity cost analysis to the grant of permanent injunctions and suggesting that application of the equitable four factor test will result in industry-specific rules that alleviate some of that cost); Carroll, *supra* note 3 (providing a framework for determining when proposed tailoring is desirable based on the innovation-producing goals of intellectual property and the political economy justifications for otherwise issuing one-size-fits-all rights).

224. See *supra* Part IV.A.

balance between public and private rights.”<sup>225</sup> This also applies to changes in the structure of funding innovation. Markets for patents and the emergence of non-practicing entities is the most recent example of the emergence of a business structure that may upset the innovation-access balance.<sup>226</sup> Thus, in contrast to the certainty and fairness justifications for uniform application of the law discussed in this Article, flexibility can be defended in technology areas that already exist, where rights-holders may be able to negotiate with each other, deriving a more efficient system based on the specific attributes of a particular technology.

## 2. Diverse Local Interests

Patent systems do not exist in a vacuum, and their benefits are measured according to the values and needs of the populations in which they are implemented. It should be no surprise, then, that countries with vastly different industrial strengths and public needs would strive to implement systems that best suit those values and needs. Thus, in contrast to situations in which tailoring patent laws remedies some objective inefficiency in the incentive-access balance, countries may pursue tailoring measures that reflect their varied assessments of the relative benefits of innovation and the costs of reduced access.

One widely used example is the unique treatment countries give to patents on inventions related to healthcare. Tailoring measures in this area include those discussed in Part III, such as the Hatch-Waxman Act, India’s decision to implement legislation excluding from patent eligibility new chemical forms of known substances, and others, like the European exclusion of surgical, diagnostic, and therapeutic methods from patent eligibility.<sup>227</sup> In the Indian and European examples, the cost of granting exclusive rights has been determined as too high, regardless of the benefits. There is an overwhelming interest in access in these situations; in particular, it has been the main concern for developing countries in the years surrounding the TRIPS Agreement’s negotiation and entry into force. In developing countries, the public may not be able to afford to pay the premium associated with a patent monopoly. If, instead of seeing innovation as holding importance on its own, one sees it as a means to other social goods,<sup>228</sup> then developing countries rightly privilege those

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225. Dinwoodie & Dreyfuss, *supra* note 5, at 95.

226. See *supra* Part III (discussing the permanent injunctions following *eBay v. MercExchange*).

227. Article 53 of the European Patent Convention excludes surgical, therapeutic, and diagnostic methods for humans or animals from patent eligibility. European Patent Convention art. 53, Oct. 5, 1973, 1065 U.N.T.S. 199 (revised version entered into force Dec. 13, 2007).

228. See, e.g., Stuart Minor Benjamin & Arti K. Rai, *Fixing Innovation Policy: A Structural Perspective*, 77 GEO. WASH. L. REV. 1, 8 (2008) (suggesting that technological innovation can suit the

social goods over a system that will act as a barrier to their realization. A strong patent regime is associated with a lack of access to new technologies for the public—an effect that is particularly troubling when applied to global health.<sup>229</sup> Thus, many of the disagreements surrounding harmonization have focused on the availability and strength of patents for pharmaceutical products or processes.

Also of particular concern to developing countries is the relationship between patents and industrial development. While strong patent systems are associated with countries that are considered innovative, the characteristics have tended to evolve together. The industrial interests of a country are likely to be dynamic, a characteristic acknowledged by WTO member countries in their definition of a large swath of countries as “developing,” a term that denotes growth and movement from one type of economy to another.<sup>230</sup> In evaluating potential flexibilities in their patent laws, countries will likely evaluate their industrial needs, and they will likely differ from those of other countries depending on the level of development and the relative strength of different sectors of industry. This is apparent from observations of the effects of strong intellectual property law on economies with different levels of development.

It is not a given that high levels of intellectual property will spur innovation in a country that does not already have an infrastructure to support it. The argument in favor of harmonization is that higher levels of protection will strengthen developing countries economically, if not through directly spurring innovation, then by encouraging foreign investment. Without endorsing the argument, Frederick Abbott explained that new intellectual property rights infrastructures “would encourage local innovation as developing country inventors were enabled to exploit the fruits of their own labor. Foreign enterprises would be more willing to transfer technology as it became protected under local law. Foreign direct investment would increase as local conditions became more technology protection-friendly.”<sup>231</sup> Many developed countries used this argument during TRIPS negotiations: that local investors would profit and access would be increased as foreign companies felt encouraged to invest in regimes with hitherto weak patent

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goal of increasing welfare “[b]y mitigating disease and hunger [and] . . . foster[ing] educational, political, and social development”).

229. See generally HESTERMEYER, HUMAN RIGHTS, *supra* note 17.

230. *Understanding the WTO: Developing Countries*, WTO, [www.wto.org/english/thewto\\_e/tif\\_e/dev1\\_e.htm](http://www.wto.org/english/thewto_e/tif_e/dev1_e.htm) (last visited Oct. 31, 2013) (listing various provisions of special treatment for developing countries).

231. See Abbott, *supra* note 195, at 499 (“[T]he achievement of certain social, political and legal preconditions may be needed before markets can be left to take care of themselves.”).

protection. However, many argue that the gains of TRIPS accrue to wealthy countries—where the majority of innovative activity is centered—while the costs accrue to poor countries.<sup>232</sup> This view is supported by the concessions granted to developing countries during the negotiation of TRIPS that did not relate to intellectual property, but instead centered on the opening of new markets to textiles and other goods.<sup>233</sup>

For the least developed countries, there is little evidence to support a claim that the sudden imposition of strong intellectual property laws will encourage development. Patent systems are attractive to countries with innovative industries, as shown by the historical development of patent law in modern industrialized nations. The establishment of the publishing industry in the United States through rampant copying of foreign works is one example of industrial development fostered by initially low levels of intellectual property rights.<sup>234</sup> Subsequently, of course, the industry became stronger and therefore motivated to push for stronger protection.<sup>235</sup> Anupam Chander looks at much more recent history and suggests that comparative flexibility in intellectual property-related laws is in part responsible for Silicon Valley's location in the United States.<sup>236</sup> Some developing countries have strong domestic industries that are imitative rather than innovative, and for whom patent laws would be destructive.<sup>237</sup> The generic drug industry in India is one example.<sup>238</sup> As a result, the access concerns of the public and of public

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232. See, e.g., T.N. Srinivasan, *The TRIPS Agreement: A Comment Inspired by Frederick Abbott's Presentation* 3 (Nov. 29, 2000) (unpublished comment), available at <http://www.econ.yale.edu/~srinivas/TRIPS.pdf>.

233. NEOFEDERALIST VISION, *supra* note 68, at 32.

234. B. Zorina Khan, *Does Copyright Piracy Pay? The Effects of U.S. International Copyright Laws on the Market for Books, 1790–1920* (Nat'l Bureau of Econ. Research, Working Paper No. 10271, 2004). This relationship between industrial development and lax legal protections was also famously made in the context of tort law. MORTON J. HORWITZ, *THE TRANSFORMATION OF AMERICAN LAW 1780–1860* (1977). *But see* Gary T. Schwartz, *Tort Law and the Economy in Nineteenth-Century America: A Reinterpretation*, 90 *YALE L.J.* 1717, 1735 (1981) (challenging Horwitz's interpretation of early American tort law).

235. The United States has very strong copyright protection, made stronger through industry lobbying for longer copyright terms. What used to be a comparable term of rights to patent rights, copyright terms now extend for seventy years after the death of the author of a work. 17 U.S.C. § 302(a) (2012).

236. Anupam Chander, *How Law Made Silicon Valley*, EMORY L.J. (forthcoming 2013), available at [http://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=2340197](http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2340197) (arguing that comparatively less rigid privacy laws and a robust right to free speech in the United States made it far more attractive to Internet-related innovation than other countries).

237. See JAYASHREE WATAL, *INTELLECTUAL PROPERTY RIGHTS IN THE WTO AND DEVELOPING COUNTRIES* 12 (2001) (noting that in India, there is a strong industry that produces “credible equivalents of products protected by IP elsewhere”).

238. *Id.*

health advocates in such countries is bolstered by the interests of local industry and those it supports.<sup>239</sup>

Other country-specific factors may influence the desire to deviate from the new intellectual property norms.<sup>240</sup> Furthermore, efficiency concerns, differing public interests,<sup>241</sup> and diverse industrial policies and preferences will align in some cases and be at odds in others. All are likely to inform an analysis of a given measure. In addition to these, however, there is an argument for flexibility for its own sake, which this Article will now address.

### 3. *Federalist Arguments for Flexibility*

Flexibility among patent law regimes may also be desirable precisely because it results in a diversity of laws. John Duffy has suggested that diversity among patent laws allows for legal experimentation, innovation, and ultimately improvement.<sup>242</sup> While recognizing that some level of harmonization may be desirable, Duffy suggests that in addition to allowing countries to be responsive to local needs and preferences, diversity allows for precisely the type of innovation in patent law that patent law is meant to spur in the sciences.<sup>243</sup> This argument, championing flexibility *qua* flexibility, imagines a dynamic global patent regime under constant improvement. It also underscores the dynamic

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239. *Id.*

240. A separate line of argument relating to both the level of industrial development in developing countries and the access concerns of the public suggests that the traditional patent regime, rewarding an individual inventor with rights impinging on public access, does not fit with the model of discovery and innovation in certain developing countries. Thus, for countries rich in “traditional knowledge,” valuable subject matter and knowledge is possessed collectively and benefited from by all. At the same time, for various reasons, such knowledge would not be patentable. These reasons include that the subject matter may be considered unpatentable laws of nature or that the knowledge is old enough not to be considered novel. Nonetheless, companies from developed countries may exploit the knowledge for free while protecting the results with patents. Imagine, for example, a plant that is known by indigenous peoples to have curative powers. While the plant and its use in medicinal applications is likely unpatentable, an isolated chemical derived from the plant might result in high profits to the company that learns of its use and appropriates that knowledge without paying a premium. This possibility has led to calls for protection of indigenous rights in traditional knowledge. For example, WIPO established the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore in September 2000, and in 2009 tasked it with drafting a recommendation or treaty on this topic. For an overview of their progress, see *Intergovernmental Committee*, WIPO, <http://www.wipo.int/tk/en/igc/index.html> (last visited Oct. 31, 2013).

241. MASKUS, *supra* note 12 (“There is no clear answer to whether an IPRs system should favor invention (exclusion) or diffusion (access) without knowing a broad range of related national (or regional) characteristics, including society’s objective function. Such answers would vary between closed and open economies and between developed and developing economies, with rapidly industrializing economies somewhere between.”)

242. See Duffy, *supra* note 202, at 707–09; see also Dinwoodie & Dreyfuss, *supra* note 5.

243. See Duffy, *supra* note 202, at 692.

nature of both industrial development and legal protection that has characterized development around the world.

The Federalist conception of global patent law can accommodate the substantive justifications for flexibility discussed in the previous Subparts. Developing countries have less-developed industry in addition to less wealthy populaces. Both of these conditions have led to a general consensus that for developing countries, strong levels of intellectual property rights are also less desirable.<sup>244</sup> Critics of harmonization dismiss the idea that strong intellectual property rights will necessarily lead to higher levels of development.<sup>245</sup> Others take a social justice viewpoint, focusing on the impact prices that include a patent premium can have on health in poor societies.<sup>246</sup> Both the development concerns for developing countries and the access concerns for their populations inform arguments suggesting that local preferences may dictate variations from a unified patent law under a federalist view of global law. Moreover, this argument provides a response to the efficiency argument supporting harmonization, suggesting instead that a varied global system will ultimately support adoption of more efficient law. Any current costs borne from the inefficiency of maintaining multiple systems may be counteracted by future gains accrued as a result of as-yet unforeseen improvements. Ultimately, the Federalist argument may be a way to make peace with flexibility that is inherent in the system, either because it is impossible to reach agreement or because legal rules develop to incorporate considerations of beneficial tailoring in a fact (and therefore industry) specific way. Regardless of the reason, much flexibility remains. These arguments in favor of and against harmonization provide the means for assessing these deliberate and inherent flexibilities.

### C. INSTITUTIONS AND INTERESTS

An assessment of the flexibilities implemented by a country that is separate from the legal question of TRIPS-compliance and also recognizes and honors the different ways that countries weigh the costs

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244. See, e.g., Jerome H. Reichman & Rochelle Cooper Dreyfuss, *Harmonization Without Consensus: Critical Reflections on Drafting a Substantive Patent Law Treaty*, 57 DUKE L.J. 85, 94–99, 103–08 (2007).

245. Srinivasen, *supra* note 232 (suggesting that the “theoretical justification for, and even more importantly, the empirical evidence” in support of arguments that TRIPS-level protection is necessary to encourage innovation and that foreign enterprises strongly weigh the strength of IPR before investing “is not at all strong”); see Marci A. Hamilton, *The TRIPS Agreement: Imperialistic, Outdated, and Overprotective*, 29 VAND. J. TRANSNAT’L L. 613, 614 (1996) (stating that the successful implementation of TRIPS will be “one of the most successful vehicles of Western imperialism in this story”).

246. HESTERMEYER, HUMAN RIGHTS, *supra* note 17, at 207 (examining whether access to medicine is a human right under the WTO).

and benefits of innovation and access must draw from the arguments for and against harmonization. These arguments—for certainty, fairness, economy, and public choice on the harmonization side, for tailored efficiency, diverse local interests, and legal innovation on the other—lead to insights about the desirability of a flexibility based on the implementing institution and the interests and stakeholders represented. Looking to the process by which a given flexibility is introduced and applied gives insight into how well it meets the justifications for departure from uniformity. Although each measure requires individual evaluation, some generalizations can be drawn from analysis of the institution that implements the measure and how broadly the various patent law stakeholders are represented.

Legislative tailoring measures can satisfy many of the values that proponents of flexibility champion. Given that lawmakers are accountable to the public through elections and therefore may be best positioned to realize the particular interests in their jurisdiction, they can react to inefficiencies in specific industries and adjust the grant and scope of patents accordingly. In addition, legislative procedures generally allow for input from affected industries and other stakeholders, including foreign stakeholders. One might challenge the ability to weigh the interests of stakeholders who are not constituents, but outside stakeholders are not without their means of influence, and it is typically greater at a national, policymaking level than with administrative bodies or the judiciary. Legislative measures also satisfy federalist arguments for diversity of laws by making explicit the conditions under which the “experiment” of a tailored measure will operate, potentially allowing for a more thoughtful evolution of patent law.

Legislative tailoring is not without its drawbacks, however, particularly in terms of accounting for the arguments in favor of harmonized patent law. The certainty justification cuts both ways. On the one hand, a legislative tailoring measure can have carefully drawn contours so that patent holders and the public are on notice as to the target and scope of the measure. However, this requires line-drawing between industries, which can be difficult for existing technologies, never mind the development and synthesis of new fields of study.<sup>247</sup> Uncertainty in developing fields is thus a likelihood with legislative measures, particularly given the generally slow pace of legislative reaction. In addition, the attempt to provide certainty can lead to complex laws that

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247. THE PATENT CRISIS, *supra* note 3, at 97–98. Burk and Lemley also point to the difficulty of crafting laws that will remain relevant as technology advances. *Id.* at 98–99 (suggesting that the obsolescence of the Semiconductor Chip Protection Act is likely “nature of the semiconductor business changed to make the manufacturing process much more difficult and hence harder to imitate at low cost”).

attempt to address many possible scenarios. This is costly given that certainty is impossible to achieve and it frustrates the economy concerns behind harmonization by creating complex legal carve-outs. Most importantly, legislative tailoring, when ambitious enough, may result in public choice problems, particularly in later rounds of lawmaking. When a particular field of technology is separated from others, subsequent lobbying efforts for reform raise stronger concerns about public choice.

Some of the problems associated with legislative tailoring measures can be alleviated through broadly worded laws that delegate interpretation to administrative agencies. Agencies are able to adapt to changes in industry more quickly than legislatures due to their focus on particular subject matters and their non-democratic structures. Furthermore, peopled with experts, they may get it right more often. Agency implementation satisfies many of the same flexibility goals as legislative tailoring measures while maintaining the transparency and detailed rules that allow for greater certainty. For example, a patent office with the authority can issue rules governing its patent eligibility criteria for relatively newly-developed industries far more quickly than a legislature, providing some level of *ex ante* certainty for nascent industries. Nonetheless, such a scheme suffers from the same problems in hindering global efficiency and in public choice. From a global viewpoint, administrative implementation of flexibilities raise concerns because however broadly an agency sees its constituency, foreign stakeholder interests are likely to come in a far third to the interests of the domestic public and domestic industry. Industry capture (at the expense of the public interest) is also a concern in administrative setting.<sup>248</sup>

Judicial tailoring can also satisfy the purposes of flexibility. Burk and Lemley suggest that judicial tailoring is more desirable than legislative tailoring for reasons that sound in efficiency justifications.<sup>249</sup> According to their account, the fact-specific way that economic theory applies to patents makes it particularly difficult and costly to detail in laws.<sup>250</sup> If courts were willing to make industry-specific rulings with policy in mind, then they would better satisfy the efficiency purposes of flexibility. In addition, courts are likely less vulnerable to capture, but this does not always mean that all stakeholder interests are represented

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248. In particular, agency personnel are often not politically accountable to the extent that elected officials are. At the same time, they are more likely to have ties to the industry that they regulate and may see that industry as their funding source, either for the institution or for future employment. *See, e.g.,* DANIEL A. FARBER & PHILIP P. FRICKEY, *LAW AND PUBLIC CHOICE: A CRITICAL INTRODUCTION* 1–37 (1991); Merges & Reynolds, *supra* note 219.

249. *THE PATENT CRISIS*, *supra* note 3, at 97–99.

250. *Id.*

in that forum, either.<sup>251</sup> While judicial hearings involve parties on two sides of an issue, patent law does not only have two sides.<sup>252</sup> And while appellate courts often invite and accept amicus briefs from non-parties expressing interests not otherwise represented in the litigation, such representation is less likely in subsequent district court cases that adapt and apply the law to new situations. Possibly most important in the context of international assessment of flexibility is the comparative advantage that courts have in their “institutional competence and doctrinal flexibility to adapt to” assessments of ever-changing industries that are necessarily “preliminary and subject to revision.”<sup>253</sup> Nevertheless, this very same “doctrinal flexibility” has a considerable influence on certainty. In addition, because court decisions are backwards-looking, certainty concerns are amplified by having courts make policy decisions. And if domestic scholars cannot agree—or speculate as to—the intended meaning and scope of a Supreme Court opinion, surely this tailoring method will not inspire certainty abroad, nor is it likely to lead to similar rules in other jurisdictions. As is evident, all of these institutions have benefits and drawbacks as implementers of patent tailoring regimes. However, this Article proposes a framework for viewing specific tailoring measures from a “country-neutral” perspective.

#### V. IMPLICATIONS

That the framework discussed in the previous Parts gives no black and white answers should be no surprise to scholars of international law or intellectual property law. Nonetheless, the framework provides a productive means of evaluation of past tailoring measures as well as future contemplated measures, by focusing evaluation of tailoring measures on their means of implementation and the extent to which they accommodate harmonization values. Thus, the Hatch-Waxman Act can be categorized as a complex legislative scheme, negotiated with all the relevant stakeholders, and administered by the Food and Drug Administration. The complexity allows for careful tailoring but, as one might expect, problems emerge alongside new technologies that might benefit from similar treatment, but that do not fall under the scope of the

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251. *Id.* at 104–05.

252. For example, while one might expect biotechnology companies to bring claims of patent infringement and invalidity against each other, they are highly unlikely to argue that biotech should not be patent eligible subject matter. This can lead to situations where companies in an industry have no incentive to challenge the patent eligibility of that technology while the public has no standing to do so. Thus in *Myriad*, for example, the ACLU’s standing to challenge so-called “gene patents” is hotly contested.

253. THE PATENT CRISIS, *supra* note 3, at 165.

law.<sup>254</sup> In addition, while the Act balanced innovation incentives, access interests, and the interests of both the generic and pioneer drug industries, the capture concerns outlined above appear to have manifested in some of the strategic behavior exhibited by pioneer and generic drug companies.<sup>255</sup> These criticisms do not mean that the Hatch-Waxman Act should not have been passed, but rather focus critical evaluation of the measure and can help to inform future reforms.

The Indian tailoring measures discussed above were enacted through less complex legislation with more discretion left to the Indian Patent Office and courts. The law barring new forms and uses of known chemicals was meant to counteract criticism that pharmaceutical companies elsewhere have been able to gain protection for longer than their initial discoveries warrant through creative claiming of new forms and uses of chemicals. Thus, it can be seen as an efficiency-enhancing law, solving a discrete problem in line with the purposes of flexibility. It also meets the local needs, which, in the case of India, include both a large patient need for lower-cost medicines and the needs of the local generic drug industry.

However, there may yet be cause for concern. Because the involved stakeholders' interests align and are implemented through an institution that is less sensitive to foreign concerns, the measures raise fairness concerns. Certainty is also a concern, as the standards for determining an "efficacious" new use or form of a substance are unclear. Indeed, the Court failed to shine any light on the matter, issuing a results-oriented opinion that raised and failed to distinguish between numerous interpretations. In the end, it may be that no follow-on pharmaceutical patent will be found valid—a result the Court insists is not its aim, but seems likely given its detour into discussions of patient need and suggested statutory interpretations.<sup>256</sup> In addition, the measures are technology specific, again raising public choice concerns. The compulsory licensing provision similarly satisfies the justifications for flexibility while

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254. The treatment of FDA approval for generic forms of biologics provides one example. Biologic treatments are derived from living materials. Although these treatments are similar in innovative process and market role to drug development, they were not covered by the provisions of the Hatch-Waxman Act. Legislative action was necessary to include biologics in that framework. Patient Protection and Affordable Care Act, Pub. L. No. 111-148, tit. VII.A, 124 Stat. 119, 804–21 (2010). While the Hatch-Waxman Act may have balanced the needs of multiple stakeholders, that does not mean that those actors will unquestioningly accept the same scheme for biologic treatments. Thus, Abbott Laboratories filed a petition with the FDA requesting that applications submitted before enactment of the Biologics Price Competition and Innovation Act of 2009 be exempt, suggesting that allowing generic firms to rely on data it had submitted would constitute a taking under the Fifth Amendment. Citizen Petition from Abbott Laboratories to the FDA, No. FDA-2012-P-0317-0001/CP (Apr. 2, 2012).

255. See, e.g., Derzko, *supra* note 112.

256. See *supra* Part III.A.

raising fairness, capture, and certainty concerns. Stakeholders who might oppose the measure do not know the frequency with which such measures will be implemented or the circumstances.

The judicial tailoring measures discussed above can also be evaluated according to this framework. In all the cases, relevant stakeholders were represented through the submission of amicus briefs, reducing public choice concerns.<sup>257</sup> However, faced only with the facts of the cases before it, the Court does not have the same leeway to tailor measures as does the legislature and thus we might be concerned about the quality of any resulting rule. In terms of certainty, the trends and rules adopted by the district courts following *eBay* became predictable relatively quickly, even if their methodology is subject to criticism.<sup>258</sup> Thus, although there may have been some initial certainty concerns, sophisticated non-practicing entities will likely factor in the likelihood of obtaining an injunction to valuations of patent portfolios. It remains to be seen whether these tailoring measures result in greater access for consumers while maintaining sufficient incentives to innovate, but on balance, it appears to be a tailoring mechanism that meets the purposes of allowing flexibility while minimizing the concerns underlying our generally uniform system. It is possible that certainty will emerge for patent eligibility over the years following *Mayo* and *Myriad*. However, the Court's reluctance to draw easily-administered—or easily extrapolated—lines between patent-eligible subject matter and ineligible subject matter has necessarily resulted in reduced certainty for domestic and foreign industry and fails to provide coherent rules that could provide a model for other jurisdictions if it is in fact successful.

#### CONCLUSION

All jurisdictions engage in some measure of tailoring, whether in the design or the application of their laws. These can be evaluated in different ways. One measure of possible analysis is whether a measure is legal under the international agreements governing patent law that strive for uniformity. The doctrinal evaluation is an important endeavor, but one that accepts the negotiated agreements as fully accounting for all needed flexibility. This perspective will always give credence to national

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257. See, e.g., Brief for the Pharm. Research & Mfrs. of Am. as Amicus Curiae Supporting Respondent, *Mayo Collaborative Servs.*, 132 S. Ct. 1289 (2012) (No. 10-1150); Brief for the AARP & Pub. Patent Found. as Amicus Curiae Supporting Petitioners, *Mayo Collaborative Servs.*, 132 S. Ct. 1289 (2012) (No. 10-1150).

258. See Rajec, *supra* note 3 (suggesting that courts are denying injunctions to non-practicing entities, but that their methodology for doing so based on market share is both under and over inclusive, properly applied, and arguing for such determinations to be made under the public interest prong of the *eBay* test, allowing for an explicit accounting of the public interest in access).

attempts at tailoring, but cannot be extended to draw normative conclusions about those measures. Another approach is for flexibilities to be analyzed by how well they match the local values vis à vis innovation, recognizing that patents are a balance between incentives to innovate and access. Such an analysis looks at how well a measure solves a particular inefficiency or meets the specific and varied needs of diverse jurisdictions. The prescriptive analysis has its purposes, too, of aiding those who wish to endorse, criticize, or amend specific tailoring measures within a jurisdiction. Such an analysis must assign weight to the values underlying a patent system, necessarily privileging efficiency, access, innovation incentives, and short- and long-term industrial goals relative to each other. As such, and similar to the doctrinal approach, the consequentialist approach is an analytical method useful within a given jurisdiction and the parameters of its values, but it can be done absent any consideration of the content of international agreements. Thus, one approach fails to question the international framework while the other fails to account for it. Neither wrestles with the harmonization justifications in global patent law, because each is undertaken from a domestic perspective. The framework set forth here acknowledges and honors the development of an increasingly harmonized, global patent law while recognizing the value of maintaining flexibility. This recognition encompasses both the realization that flexibility is inevitable and that, from an international perspective, our inquiry should not be whether they allowed to do that or if that is what is best for them. Instead, this Article suggests we ask whether the tailoring mechanism was undertaken in a way that minimizes harm to concerns of certainty, fairness, economy, and public choice, while pursuing efficiency and the legitimate needs of the local population, thereby also allowing for necessary room for improvement in the law.

This framework allows for a normative analysis of an ever-changing legal landscape, consisting of a broad range of tailoring measures that are implemented in countries of varying levels of development and with varied local interests. It respects the global movement toward patent law harmonization by valuing the participation of multiple stakeholders in addition to transparency and the certainty it affords. At the same time, by focusing on the institutions and processes through which tailoring measures are implemented, the suggested framework accepts that even a utilitarian justification for intellectual property may incorporate different and evolving conceptions of an efficient patent system.

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