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**A War Not Easily Won: Curbing Infectious Diseases in Developing Countries**

Chapter 3: Intellectual Property  
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As the previous chapter showed, patent law, data-exclusivity rules, and other forms of intellectual property are crucial components of the set of institutions that currently channel the production and distribution of pharmaceutical products. It thus seems plausible that adjustment of the intellectual-property system could help foster the production and distribution of the vaccines and medicines that we need to curb infectious diseases in the developing world. This chapter pursues that hypothesis. The first section reviews some potential reforms of the intellectual property systems in developing countries. The second proposes a different set of reforms of the systems in the United States and other developed countries.

We emphasize at the outset, that even adoption of the entire slate of recommendations we make in this chapter would not suffice to suppress infectious diseases altogether. It is essential that modification of intellectual-property law be combined with other initiatives, which are discussed in Chapters 4 through 7. But, as we will try to show, adjustments of patent law and its cousins could contribute significantly to a composite solution.

### A. Developing Countries

For the time being, reforms of intellectual property in developing countries are unlikely to have much impact on the creation of *new* drugs aimed at infectious diseases. As the previous chapter showed, when deciding which research projects merit funding, pharmaceutical firms currently focus heavily on those pertaining to diseases that primarily afflict developed countries or that afflict all countries (such as AIDS and COVID-19) and neglect those whose impact is concentrated in the developing world. The reason for this bias is straightforward:

potential revenues from sales of medicines and vaccines in rich countries are vastly higher than potential revenues from sales in poor countries. Neither an increase nor a decrease in the availability of patents on new drugs in poor countries would change that dynamic significantly. That prediction is buttressed by the fact that, in the subset of poor countries where patents on new drugs could be obtained reasonably readily, pharmaceutical firms frequently don't bother to apply for them.

To be sure, the aggressiveness with which (as we saw in the previous chapter) the firms have pursued patent protection for their products in Thailand indicates that, as developing countries become more prosperous, potential revenues from sales of drugs in those markets cease to be trivial. At that point, augmenting patent protection in developing countries to assure innovative pharmaceutical firms that they will be able to exploit fully the markets for their creations can indeed stimulate innovative activity that would otherwise not occur. However, deploying patent law in this fashion will long remain a less efficient lever for fostering research and development than either adjustments of patent protection in *developed* countries or other institutional mechanisms for stimulating discoveries. For the time being, readers are asked to take that assertion on faith, trusting us to substantiate it in the second half of this chapter and in subsequent chapters.

The foregoing generalizations simplify considerably the task at hand. If modifications of developing countries' intellectual-property systems are unlikely to have a significant impact (positive or negative) on what we have been describing as the "incentive" problem, we can focus, when reforming those systems, on devising solutions to the "access" problem – i.e., ensuring that existing drugs are made available to the residents of developing countries at affordable prices. That, in turn, suggests that we should do whatever we can to limit the availability or duration of patents in those jurisdictions. More specifically, we should curtail patent protection for pharmaceutical products as much as the relevant international agreements permit.

Before discussing how this might be done, it must be acknowledged that the benefits secured from limitation of IP protection in developing countries will not be enormous in the short term. The reason is that most drugs aimed at the infectious diseases that afflict poor countries have existed for long enough that they are no longer eligible for protection by patents or data-exclusivity constraints. An imperfect but nevertheless revealing indicator is that over 90% of the drugs on the WHO's Model Essential Medicines List (and a similar percentage of the subset of those drugs aimed at infectious diseases) are currently off-patent in all countries.<sup>1</sup> Because the law no longer limits who can make such drugs, most are now produced by generic manufacturers in India, China, or Brazil, which then sell the drugs, typically at modest prices, to public and private customers throughout the world. (All five of the developing countries

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<sup>1</sup> Because the composition of the Model Essential Medicines List (MEML) changes periodically and patents of course lapse, these percentages vary a bit over time. But all studies have concluded that the percentages are over 90%. See, for example, Reed F Beall, "Patents and the Who Model List of Essential Medicines (18th Edition): Clarifying the Debate on Ip and Access," *World Intellectual Property Organization* (2016), [https://www.wipo.int/edocs/mdocs/mdocs/en/wipo\\_gc\\_ip\\_ge\\_16/wipo\\_gc\\_ip\\_ge\\_16\\_brief.pdf](https://www.wipo.int/edocs/mdocs/mdocs/en/wipo_gc_ip_ge_16/wipo_gc_ip_ge_16_brief.pdf); A. Attaran, "How Do Patents and Economic Policies Affect Access to Essential Medicines in Developing Countries?," *Health Affairs* 23, no. 3 (2004); Cavicchi JR and SP Kowalski, "Report of Patent Literature, Search Methodology and Patent Status of Medicines on the Who Mlem," (2009).

examined in Chapter 2, with the partial exception of Thailand, currently rely almost entirely on imports of this sort for their supplies of medicines.) For obvious reasons, modification of intellectual-property laws will have no impact on the availability or price of drugs whose patents have expired.

However, a crucial subset of the drugs with which we are concerned are still covered by patents. They include many of the third-tier ARVs; some important hepatitis drugs; and some recently developed vaccines (most notably, those aimed at COVID-19).<sup>2</sup> Additional drugs capable of preventing or suppressing infectious diseases are likely to come on the market soon. The rate at which such new drugs are generated would increase if the proposals we make in subsequent chapters are accepted. Most of these new drugs will be subject to patent protection for roughly 12 years after their approval for commercial use. With respect to this growing group, the scope of patent laws in developing countries plainly does matter. This section considers how developing countries could and should adjust those laws to maximize the countries' ability to use such drugs when combatting infectious diseases.

### *1. Constraints*

The principal impediment to curtailment of patent protection for pharmaceutical products in developing countries is the Agreement on Trade-Related Aspects of Intellectual Property Rights, commonly known as the TRIPS Agreement, which binds all members of the World Trade Organization. We encountered TRIPS briefly in the preceding chapter, when discussing the current laws in five developing countries. It's now time to examine it more closely.

The central provision of the Agreement is Article 27, which provides:

1. Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.<sup>3</sup> Subject to paragraph 4 of Article 65,<sup>4</sup> paragraph 8 of Article 70<sup>5</sup> and paragraph 3 of this Article, patents shall be available and patent

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<sup>2</sup> See Beall, "Patents and the Who Model List of Essential Medicines (18th Edition): Clarifying the Debate on Ip and Access".

<sup>3</sup> A footnote to this sentence provides: "For the purposes of this Article, the terms 'inventive step' and 'capable of industrial application' may be deemed by a Member to be synonymous with the terms 'non-obvious' and 'useful' respectively." As we saw in Chapter 2, the latter are the terms used in the patent law of the United States.

<sup>4</sup> Paragraph 4 of article 65 provides: "To the extent that a developing country Member is obliged by this Agreement to extend product patent protection to areas of technology not so protectable in its territory on the general date of application of this Agreement for that Member, as defined in paragraph 2, it may delay the application of the provisions on product patents of Section 5 of Part II to such areas of technology for an additional period of five years." This provision is one of the roots of the current rule delaying until 2033 the duty of LDCs to extend patent protection to pharmaceutical products.

<sup>5</sup> Paragraph 8 of article 70 provides:

Where a Member does not make available as of the date of entry into force of the WTO Agreement patent protection for pharmaceutical and agricultural chemical products commensurate with its obligations under Article 27, that Member shall:

rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.

2. Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.

3. Members may also exclude from patentability:

(a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;

(b) 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. However, Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement.

Although, as can be seen, Article 27 does not refer expressly to pharmaceutical products, the reference in the first sentence to “all fields of technology” is commonly and correctly seen as a requirement that drugs must be eligible for product patent protection. A developing country can lawfully limit drug patent protection only if it can find some way to circumvent this barrier.

For a significant subset of developing countries, this is easy. Currently, 37 countries are not members of the World Trade Organization and are not parties to any other agreements requiring them to extend patent protection to drugs.<sup>6</sup> The principal countries in this group

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(a) notwithstanding the provisions of Part VI, provide as from the date of entry into force of the WTO Agreement a means by which applications for patents for such inventions can be filed;

(b) apply to these applications, as of the date of application of this Agreement, the criteria for patentability as laid down in this Agreement as if those criteria were being applied on the date of filing in that Member or, where priority is available and claimed, the priority date of the application; and

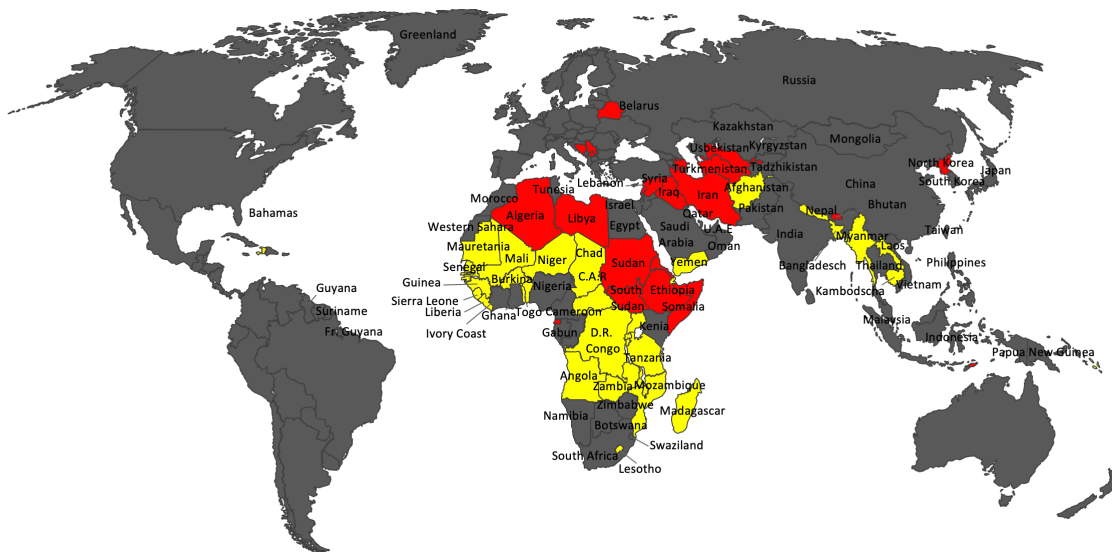
(c) provide patent protection in accordance with this Agreement as from the grant of the patent and for the remainder of the patent term, counted from the filing date in accordance with Article 33 of this Agreement, for those of these applications that meet the criteria for protection referred to in subparagraph (b).

This is the so-called “mailbox” rule. It was critical to the introduction of patent protection for pharmaceutical products in India, but has little relevance to our topic.

<sup>6</sup> The nonmember countries can be subdivided into two loosely separated groups: the “observers,” which are obliged (at least in theory) to begin negotiations for WTO membership within 5 years of becoming observers; and the non-observers, most of which have not yet expressed interest in membership. The observers are: Algeria,

are shown in red in Figure 1. For the time being, these nations are free to deny patent protection for pharmaceutical products, regardless of their state of development. Unfortunately (for present purposes), this situation will likely not last. Several of these countries are already negotiating for entry into the World Trade Organization, a process that requires bringing their laws into compliance with all WTO Agreements. But for the time being, they are unbound.

Figure 1: Countries Not Subject to TRIPS



For another subset of developing countries, Article 27 is not yet problematic for a different reason. The countries shown in yellow in Figure 1 are already members of the WTO, but are classified as “least developed countries” (LDCs). The membership of this group is determined, not by the WTO, but by the Committee for Development Policy of the United Nations, on the basis of countries’ Gross National Income per capita, Human Assets Index, and Economic Vulnerability Index.<sup>7</sup> Among the members are Malawi and Cambodia, discussed in the preceding chapter. As was noted there, LDCs, though bound by most provisions of the TRIPS Agreement, are exempt until 2033 from the obligations to extend patent protection to pharmaceutical products and to recognize intellectual-property rights in clinical data.<sup>8</sup> For the time being, therefore, these countries, like the WTO non-members, could adopt without further ado our recommendation that they deny patents to medicines and drugs pertaining to infectious diseases – or any other diseases, for that matter.

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Andorra, Azerbaijan, Bahamas, Belarus, Bhutan, Bosnia and Herzegovina, Comoros, Curacao, Equatorial Guinea, Ethiopia, the Holy See, Iran, Iraq, Lebanon, Libya, Sao Tome and Principe, Serbia, Somalia, South Sudan, Sudan, Syria, Timor-Leste, and Uzbekistan. The non-observers are Eritrea, Kiribati, Kosovo, Marshall Islands, Micronesia, Monaco, Nauru, North Korea, Palau, Palestine, San Marino, Turkmenistan, and Tuvalu.

<sup>7</sup> Additional information concerning these indices and how they are combined is available at <https://www.un.org/development/desa/dpad/least-developed-country-category/ldc-criteria.html>.

<sup>8</sup> See “WTO Drugs Patent Waiver for LDCs Extended until 2033,” <https://www.un.org/ldcportal/wto-drugs-patent-waiver-for-ldcs-extended-until-2033/>.

Developing countries that do not fall within these two categories no longer have the freedom to deny patent protection altogether to pharmaceutical products. In addition, several other provisions of TRIPS, as we will soon see, constrain to varying degrees countries' discretion to adjust the degree of protection they afford such products. Countries ignore these constraints at their peril. If they violate them, they may be subject to significant trade sanctions.

Another source of limits are the so-called Free Trade Agreements (FTAs). With one exception (discussed below), TRIPS has not been amended significantly since its adoption. Instead, the United States (and to a lesser extent the European Union), when seeking to increase the levels of protection that other countries accord to pharmaceutical products, have relied upon bilateral and regional agreements. These differ substantially in their terms, but some contain provisions that augment the constraints embodied in TRIPS.

The impact of the FTAs upon the options available to the countries with which we are concerned is as yet modest. The number of nations subject to them is still small and, as Figure 2 reveals, most fall into the high-income or upper-middle-income categories. However, the United States and the European Union may well seek similar agreements with poorer countries (or set of countries) in the future. Thus, when cataloguing the ways in which developing countries might tune their intellectual-property systems, we need to keep in mind the hazards that FTAs may impose.

Figure 2: Countries Subject to Free Trade Agreements with the United States



With this background in mind, we can begin our survey of the available options.

## 2. Flexibilities

The zones of discretion left open by the constraints summarized above are now commonly known as “TRIPS flexibilities.” Although the existence of these flexibilities is undisputed, their precise scope is a matter of considerable controversy. In the remainder of this section, we do our best to resolve the disagreements – and thus indicate how far these countries could go in limiting the availability of patents.

These sources of flexibility fall into four groups: (a) opportunities to limit the *exclusive rights* ordinarily enjoyed by patentees; (b) opportunities to regulate the *kinds of innovations* that may be patented; (c) opportunities to limit the *duration* of patent protection; and (d) opportunities to limit the *remedies* available to patentees whose rights are infringed. Type-(a) flexibilities have thus far received the most attention. Partly as a result, the scope of the options in that group is now clearest. However, as we will try to show, the other three groups may be more important in maximizing the availability of medicines.

### a. Limiting Rights

The principal members of the first group are the discretion to permit so-called “parallel importation” and the discretion to impose compulsory licenses on patents in the interest of public health. The provision of TRIPS most relevant to parallel importation is Article 6, which provides:

For the purposes of dispute settlement under this Agreement, subject to the provisions of Articles 3 and 4 nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights.

With respect to compulsory licenses, there are two relevant provisions in the original version of TRIPS. Article 30 provides broadly:

Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.

Article 31 is more narrowly tailored:

Where the law of a Member allows for other use of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected:

- (a) authorization of such use shall be considered on its individual merits;
- (b) such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been

successful within a reasonable period of time. This requirement may be waived by a Member in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. In situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable. In the case of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly;

(c) the scope and duration of such use shall be limited to the purpose for which it was authorized, and in the case of semi-conductor technology shall only be for public non-commercial use or to remedy a practice determined after judicial or administrative process to be anti-competitive;

(d) such use shall be non-exclusive;

(e) such use shall be non-assignable, except with that part of the enterprise or goodwill which enjoys such use;

(f) any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use;

(g) authorization for such use shall be liable, subject to adequate protection of the legitimate interests of the persons so authorized, to be terminated if and when the circumstances which led to it cease to exist and are unlikely to recur. The competent authority shall have the authority to review, upon motivated request, the continued existence of these circumstances;

(h) the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization;

(i) the legal validity of any decision relating to the authorization of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;

(j) any decision relating to the remuneration provided in respect of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;

(k) Members are not obliged to apply the conditions set forth in subparagraphs (b) and (f) where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive. The need to correct anti-competitive practices may be taken into account in determining the amount of remuneration in such cases. Competent authorities shall have the authority to refuse termination of authorization if and when the conditions which led to such authorization are likely to recur;

(l) where such use is authorized to permit the exploitation of a patent ("the second patent") which cannot be exploited without infringing another patent ("the first patent"), the following additional conditions shall apply:

- (i) the invention claimed in the second patent shall involve an important technical advance of considerable economic significance in relation to the invention claimed in the first patent;
- (ii) the owner of the first patent shall be entitled to a cross-licence on reasonable terms to use the invention claimed in the second patent; and
- (iii) the use authorized in respect of the first patent shall be non-assignable except with the assignment of the second patent.

All of these provisions contain important ambiguities – some of them unintentional, others deliberate. For example, instead of explicitly authorizing member countries to set their own rules concerning when patent rights are exhausted, thus enabling products embodying those patents to be imported without the permission of the patentees, Article 6 does so indirectly and incompletely, by limiting the relevance of such rules to “dispute resolution.” Article 30 is perhaps the most ambiguous of all. It contains the so-called “three-step test,” which sets a general limit on countries’ freedom to recognize “exceptions and limitations” to patent rights. (Other versions of this test can be found in several other multilateral intellectual-property agreements.) The crucial terms it employs -- “unreasonably”; “normal”; and “legitimate” – are notoriously vague. Article 31 at first appears more precise than Article 30, but turns out to be leavened with similarly undefined terms: “national emergency”; “extreme urgency”; “adequate remuneration”; “anti-competitive”; and so forth.

These ambiguities help explain why the initial invocations of these flexibilities were so fraught. The first major step was taken by Brazil.<sup>9</sup> In 1996, facing the early waves of the AIDS epidemic, the legislature amended Brazil’s patent statute to impose compulsory licenses on patents if they were not “worked” in the country – specifically, if the patentees did not manufacture products governed by their patents in the territory of Brazil within three years of the patent grants.<sup>10</sup> Pharmaceutical firms denounced the initiative and spurred the U.S. government to initiate a WTO dispute settlement proceeding against Brazil, contending that the amendment violated Articles 27 and 28.<sup>11</sup> Brazil responded aggressively, contending that the compulsory licensing options in Article 31 qualified the non-discrimination provision in Article 27 – and moreover, that if Brazil’s law violated TRIPS, then so did some provisions of the U.S. patent statute, which required that products embodying specific inventions be “manufactured substantially in the United States.” The attractiveness of the U.S. position was further corroded by the obvious effectiveness of Brazil’s campaign to fight AIDS – a campaign sustained in part by low prices on patented ARVs.<sup>12</sup> Those prices, in turn, were linked to the statutory amendment, because the manufacturers, fearing its invocation, had cut prices on the drugs drastically. In 2001, increasingly worried about both the feasibility and the wisdom of

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<sup>9</sup> For a detailed study of Brazil’s initiative, see Jennryn Wezler, Mihir Mankad, and Adam Burrowbridge, “Program on Information Justice and Intellectual Property: Timeline for Us-Thailand Compulsory License Dispute,” (2009), <http://infojustice.org/wp-content/uploads/2012/11/pijip-thailand-timeline.pdf>.

<sup>10</sup> See Article 68 of Law No. 9,279 of May 14, 1996, effective May 1997.

<sup>11</sup> See U.S. Request for Consultations, WT/DS199/1 (June 8, 2000).

<sup>12</sup> See, e.g., Tina Rosenberg, Look at Brazil, N.Y. Times Mag. (Jan. 28, 2001), <http://www.nytimes.com/2001/01/28/magazine/look-at-brazil.html>

pressing the issue, the U.S. retreated, withdrawing its complaint. A Mutually Agreed Settlement submitted by the two countries to the WTO permitted the U.S. to save face, but the practical result was that ARVs remained affordable and widely available in Brazil and the curve of the AIDS epidemic there was flattened.<sup>13</sup>

Meanwhile, a second, even more prominent controversy was brewing.<sup>14</sup> In 1997, the government of South Africa, facing an even more serious threat from AIDS, began considering a bill that asserted the government's right to import patented drugs from countries where they were being sold more cheaply. The bill was denounced by major drug manufacturers as an "abrogation" or "expropriation" of their patent rights. At the manufacturers' behest, the government of the United States threatened South Africa with various trade sanctions. The flames were fanned by indications that South Africa was considering, not just permitting the importation of drugs lawfully sold elsewhere, but also invoking Article 31 to compel the patentees to license generic manufacturers to produce the drugs at issue in return for modest license fees. In hopes of blocking all of these initiatives, the manufacturers brought suit in the High Court of South Africa, contending that they ran afoul of the South African Constitution. The South African government argued, in response, that the initiatives were fully compatible both with TRIPS and with the national constitution.

Three related developments eventually prompted the firms and the U.S. government to back down. First, AIDS activists, both in South Africa and in the United States, vocally supported the South African government's initiatives and accused the pharmaceutical firms and the United States of killing poor patients. Second, Al Gore, who, in his capacity as co-chair of the U.S./South Africa Binational Commission, had lent support to the drug manufacturers, became a candidate for President of the United States and became concerned that the activists' sharp criticisms of his stance threatened his candidacy. Third, the controversy attracted growing attention from the media throughout the world. In combination, these developments prompted Gore and President Clinton to signal a willingness to reconsider the position of the US government and prompted the firms to look for ways of escaping what they had come to see as a public-relations nightmare. By early 2001, the threat of trade sanctions had been withdrawn and the lawsuit had been abandoned. As part of this informal settlement, South Africa pledged to abide by its obligations under the TRIPS Agreement, but all parties understood that the interpretations of those obligations that had been advanced by the firms and the United States Trade Representative were no longer tenable.

Refinement and formalization of the outcomes of these high-profile battles occurred in three stages. First, the scope of the power retained by developing countries to temper

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<sup>13</sup> See Paul Champ and Amir Attaran, "Patent Rights and Local Working under the Wto Trips Agreement: An Analysis of the U.S.-Brazil Patent Dispute," *Yale Journal of International Law* 27 (2002); Amy S. Nunn et al., "Evolution of Antiretroviral Drug Costs in Brazil in the Context of Free and Universal Access to Aids Treatment," *PLOS Medicine* (2007).

<sup>14</sup> The description in the text of the series of events provoked by South Africa's initiative is distilled from William Fisher and Cyrill P. Rigamonti, "The South Africa Aids Controversy: A Case Study in Patent Law and Policy," *Harvard Law School Case Study* (2005), <https://cyber.harvard.edu/people/tfisher/South%20Africa.pdf>. All of the sources on which the account is based are indicated in the footnotes of that document.

intellectual-property rights to respond to health emergencies was one of the main topics of the Fourth Ministerial Conference of the WTO, held in Doha, Qatar in November of 2001. The discussions gave rise to the so-called “Doha Declaration,” which adopted most of the positions advocated by a united group of developing countries.<sup>15</sup> Second, in the wake of the Doha meeting, a prolonged and multi-cornered negotiation concerning the use of compulsory licenses to enable developing countries that lacked domestic drug-manufacturing capacity to import drugs made by generic firms in other countries eventually led to the WTO Decision of August 30, 2003, which ostensibly endorsed this option but burdened it with an extensive set of procedural requirements.<sup>16</sup> Finally, in 2017, the 2003 Decision was embraced by two thirds of the WTO member countries and thus was cemented into a new provision of the TRIPS Agreement itself.<sup>17</sup>

This prolonged and unconventional process by which the meaning of TRIPS was clarified has not eliminated all disagreement concerning the scope of Articles 6, 30, and 31. But at least two important points are now reasonably settled. First, all countries are free to set their own policies pertaining to “exhaustion” of patent rights – and thus may, if they wish, permit importation into their own jurisdictions of drugs sold at low prices in other countries with the authority of the patentees. Second, developing countries have considerable latitude under Article 31 to decide what constitutes a “health emergency” and to compel patentees to give generic firms and/or procurement authorities permission to manufacture, distribute, and import drugs that would alleviate those emergencies, provided that the licensees pay modest license fees.

A good indication of consensus of these points is the way in which pharmaceutical firms and the government of the United States responded in 2016 to the final report of the United Nations High-Level Panel on Access to Medicine. Among the recommendations of that report was that developing countries should use their powers (a) to authorize parallel imports and (b) to impose compulsory licenses to increase the availability of medicines within their jurisdictions. Although the firms and the U.S. government denounced the report, they did not question the existence of these two powers; they argued instead that use of these powers would be unwise or that other ways of increasing access to drugs would be more effective.<sup>18</sup> As we will see, commentators aligned with the firms did contend that other recommendations made in the Report would violate the TRIPS Agreement – but not these.

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<sup>15</sup> Declaration on the TRIPS Agreement and Public Health (14 November 2001), Doc. WT/MIN(O1)/DEC/2 (20 November 2001).

<sup>16</sup> WTO General Council, Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, WT/L/540, Sept. 2, 2003. Formally, the Decision waives Article 31(f) (products produced under a compulsory license must be primarily for the domestic market) and Article 31(h) (the patentee is entitled to adequate remuneration) if matching compulsory licenses are issued in both the exporting country and the importing country.

<sup>17</sup> See TRIPS Article 31bis and associated annex, available at [https://www.wto.org/english/res\\_e/publications\\_e/ai17\\_e/trips\\_art31\\_bis\\_oth.pdf](https://www.wto.org/english/res_e/publications_e/ai17_e/trips_art31_bis_oth.pdf).

<sup>18</sup> See PhRMA Statement on the United Nations High Level Panel Report on Access to Medicines, September 14, 2016, <https://phrma.org/en/Press-Release/PhRMA-Statement-on-the-United-Nations-High-Level-Panel-Report-on-Access-to-Medicines>; U.S. Disappointed Over Fundamentally Flawed Report of the UN Secretary-General's High-Level Panel on Access to Medicines, September 16, 2016, <https://2009-2017.state.gov/r/pa/prs/ps/2016/09/262034.htm>.

From this silence we can infer at least grudging acquiescence to the existence of these two TRIPS flexibilities.

For the most part, this first set of flexibilities remains unaffected by the Free Trade Agreements, discussed above. A few of the FTAs that the United States has negotiated with other *developed* countries do set limits on compulsory licenses. For example, Article 16.7(6) of the agreement with Singapore provides, in pertinent part:

Neither Party shall permit the of the subject matter of a patent without the authorization of the right holder except in the following circumstances:

- (a) to remedy a practice determined after judicial or administrative process to be anti-competitive under the competition laws of the Party;
- (b) in the case of public non-commercial use or in the case of a national emergency or other circumstances of extreme urgency, provided that:
  - (i) such use is limited to use by the government or third parties authorized by the government;
  - (ii) the patent owner is provided with reasonable and entire compensation for such use and manufacture; and
  - (iii) the Party shall not require the patent owner to transfer undisclosed information or technical "know how" related to a patented invention that has been authorized for use without the consent of the patent owner pursuant to this paragraph.

The Agreements with Australia and Jordan (an upper-middle-income country) contain similar provisions.

Were the poorer countries of the world subject to similar restraints, their power to employ compulsory licenses to increase access to pharmaceutical products would be materially impaired. But thus far, the United States has not pressed any of them for such concessions.

#### b. Tightening Patentability Requirements

Flexibilities of the second type – opportunities to constrict the set of innovations that may be patented – have been invoked less often by developing countries. Partly as a result, their scope remains more contested. However, because they have the effect of eliminating patent protection for some drugs altogether, they are potentially more powerful and efficacious than the limitations on patentees' exclusive rights just discussed.

The most important flexibility in this group derives from the ambiguity of the term, "inventive step." As indicated above, Article 27 requires that patents "be available for any inventions ... in all fields of technology, provided that they are new, *involve an inventive step* and are capable of industrial application." An accompanying footnote permits countries to treat "inventive step" as synonymous with "non-obviousness." But TRIPS does not define either "inventive step" or "nonobviousness." This has prompted some commentators to argue that WTO members are free to define them in ways that would prevent the patenting of modest

improvements on existing drugs.<sup>19</sup> (As Chapter 2 explained, these are commonly referred to as “me-too” drugs.)

The only country that, to date, has invoked this option is India. When the government of India was finally obliged to recognize patent protection for pharmaceutical products, it tempered that recognition by adding to its patent statute section 3(d), which excludes from patentability “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” and further specifies that, “for the purposes of this clause, 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 regard to efficacy.”<sup>20</sup> In a series of cases involving the patentability of a recently developed variant of Novartis’ cancer drug, Glivec, the courts in India construed this provision to require patent applicants to demonstrate that a “new form” of an existing drug has greater therapeutic efficacy than the original. So, for example, a new form that has greater bio-availability but no therapeutic advantage would not pass muster.<sup>21</sup> As one might expect, most pharmaceutical firms, including Novartis, denounced this interpretation.

Thus far, no country has initiated a WTO dispute resolution proceeding to challenge section 3(d) of India’s statute. Perhaps mindful of the fate of the U.S. actions against Brazil and South Africa, the government of Switzerland, where Novartis is based, has indicated that it will not do so. However, there remains considerable disagreement concerning whether the Indian provision is compatible with TRIPS. Commentators who think not make two main arguments. First, they assert that, when the TRIPS Agreement was adopted, the terms, “inventive step” and “nonobvious,” had stable, well-recognized meanings, which the drafters of TRIPS meant to invoke. Far from being free now to adopt their own definitions of those terms, developing countries are obliged to extend patent protection to all inventions that satisfy the definitions in place *circa* 1994.<sup>22</sup> Second, commentators contend that India’s statute, by subjecting pharmaceutical product patents to an inventive-step requirement more stringent than that imposed on other types of inventions, violates the requirement of Article 27 that “patents shall be available and patent rights enjoyable without discrimination as to ... the field of technology.”

In our view, the first of these arguments is unpersuasive. The terms, “inventive step” and “nonobvious” have meant different things at different times and in different countries. In the leading history of the topic, John Duffy summarized as follows a few of the variations:

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<sup>19</sup> See, e.g., Carlos Correa, “Guidelines for Pharmaceutical Patent Examination: Examining Pharmaceutical Patents from a Public Health Perspective,” (United Nations Development Programme, 2015).

<sup>20</sup> <https://wipo.lex.wipo.int/en/text/128116>.

<sup>21</sup> Cf. *Novartis AG v. Union of India*, Civil Appeal Nos. 2706-2716 (Supreme Court of India 2013), available at <http://www.scribd.com/doc/133343411/Novartis-patent-Judgement>.

<sup>22</sup> See Eric M. Solovy and Pavan S. Krishnamurthy, “Trips Flexibilities and Their Limitations: A Response to the Un Secretary-General’s High-Level Panel Report on Access to Medicines,” *George Washington International Law Review* 50 (2017): 103.

[T]he history does not show steady progress toward the nonobviousness standard, even though this standard (or some closely related verbal equivalent) eventually becomes a worldwide standard. Rather, some concept of ingenuity was initially in the first patent law (Venice's), but the concept was lost when the idea of a patent system is transported to Great Britain. British practice required novelty or substantial novelty only for a long period of time. American law, most likely inspired by a French law, began to move away from a novelty-only standard in the early 1800's. American law invented the concept of "non-obviousness" as tested by the capabilities of a person having ordinary skill in a field, but American law also experimented with arguably more stringent standards. British law lagged behind American law in recognizing nonobviousness, but after latching onto nonobviousness in the late 19th century, British law never experimented with more rigorous tests. French law originated the statutory language that American common law judges would transform into the nonobviousness requirement, and yet France came late to adopting nonobviousness into its law. The development is spasmodic and irregular, with a general convergence requiring decades of time. Nor should this history suggest that the development process is complete. Rather, while a consensus on obviousness has been reached, nations continue to experiment in developing more accurate and more precise conceptions of obviousness.<sup>23</sup>

Even within the United States, the degree of inventiveness required for patentability has fluctuated dramatically. When the TRIPS Agreement was drafted, the Court of Appeals for the Federal Circuit was midway through a multi-year project seeking to harmonize (in the direction of leniency) the standards that, prior to 1986, had been adopted by the various geographically specific circuit courts. Since then, interventions by the Supreme Court have altered the standard in several respects, typically in the direction of stringency. Further adjustments in the coming years are nearly certain. In sum, to suggest that the meaning of "inventive step" was clear and stable as of 1994 (and thus now binds developing countries) is historically naïve.

The second of the two arguments advanced by the critics of section 3(d) is more colorable. India does seem to hold applicants for patents on pharmaceutical products to a higher standard of inventiveness than it does applicants for patents on innovations in other fields – something that TRIPS seems to forbid.

However, the United States is not free of criticism on this score. As Professors Burk and Lemley have shown, although U.S. patent law purports to be "technology neutral," in practice U.S. courts have applied different meanings of nonobviousness in different technological contexts. For example, applications for patents involving biotechnology have been treated more leniently than applications in other fields.<sup>24</sup> Were the U.S. to accuse India of discriminating among fields of technology, it would likely be met (as it was in the proceeding it brought against Brazil) by an accusation of hypocrisy.

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<sup>23</sup> See John F. Duffy, "Inventing Invention: A Case Study of Legal Innovation," *Texas Law Review* 86, no. 1 (2007).

<sup>24</sup> See Dan L. Burk and Mark A. Lemley, "Policy Levers in Patent Law," *Virginia Law Review* 89 (2003).

A more technical defense of the discriminatory aspect of section 3(d) would rely on a statement made (in *dictum*) in the Panel Report that resolved the WTO Dispute Resolution proceeding brought by the European Communities, challenging two Canadian statutory provisions that disfavored pharmaceutical firms. In a section of the report offering a general interpretation of the nondiscrimination provision of Article 27, the panel noted:

Article 27 prohibits only discrimination as to the place of invention, the field of technology, and whether products are imported or produced locally. Article 27 does not prohibit bona fide exceptions to deal with problems that may exist only in certain product areas.<sup>25</sup>

The second sentence in this passage might be invoked to argue that section 3(d) of India's statute is justified by the fact that it is designed to limit the socially pernicious practice of "evergreening," which in practice is largely limited to pharmaceutical products.

It must be acknowledged, however, that neither of these two defenses to the charge of discrimination is overwhelming. Unlike the bias in the United States in favor of biotechnological innovations and unlike the provisions at issue in the dispute between the EC and Canada, India's section 3(d) is an explicit statutory provision singling out pharmaceutical patents and imposing upon them a higher inventive-step requirement. Not only is the discrimination overt, it involves precisely the field of technology and the country with which the drafters of Article 27 were most concerned.<sup>26</sup>

Suppose, then, that a developing country less populous and powerful than India adopted a provision resembling Section 3(d) and that the United States challenged it in a WTO dispute resolution proceeding. Would the developing country prevail? The answer would depend in part on the strength of the arguments just summarized. But one of the lessons of the struggles over compulsory licensing in Brazil and South Africa is that the outcomes of such proceedings are likely to depend at least as much on the larger political environment, one aspect of which would be whether the provision could be characterized persuasively as necessary to save lives. In short, whether a developing country could win a fight with the U.S. would likely depend heavily on the political context and on the way in which its initiative were depicted in the media – factors over which it would have only partial control.

An alternative way of using the ambiguity of the term, "inventive step," to tighten patentability rules was proposed a few years ago in Brazil. Had it been adopted, Article 13 of Bill No. 5402/13 would have required a patent applicant to demonstrate not merely that his or her invention "does not derive in an obvious or evident manner from the prior art," but

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<sup>25</sup> Canada – Patent Protection of Pharmaceutical Products, WT/DS114/R (17 March 2000), paragraph 7.92. Helpful commentary on this crucial passage can be found in Maria Victoria Stout, "Crossing the Trips Nondiscrimination Line: How Cafta Pharmaceutical Patent Provisions Violate Trips Article 27.1," *Boston University Journal of Science and Technology Law* 14 (2008).

<sup>26</sup> Those features, in combination, unfortunately would increase the relevance of a sentence that appears at bit later in the Panel Report in the EU/Canada case: "It is quite plausible, as the EC argued, that the TRIPS Agreement would want to require governments to apply exceptions in a non-discriminatory manner, in order to ensure that governments do not succumb to domestic pressures to limit exceptions to areas where right holders tend to be foreign producers."

also that “it represents a significant technical advance compared with the prior art.”<sup>27</sup> By subjecting all technologies to the same standard, this provision would dodge the stronger of the two objections to India’s provision – namely that it discriminates against drugs. From a logical standpoint, that should reduce its vulnerability to a TRIPS challenge. From a political standpoint, however, its disconnection from health emergencies would increase the probability that, if adopted by a less powerful developing country, it would be challenged – and would not survive the challenge. Accordingly, our recommendation is that developing countries follow the lead of India on this particular issue, and not adopt the Brazilian proposal.

### c. Limiting Duration

Flexibilities of the third type are simpler and clearer. Article 33 of the TRIPS Agreement requires that the term of patents not be shorter than “twenty years counted from the filing date.” However, TRIPS neither requires that patent applications be processed within a specific period of time nor compels countries to extend patents to compensate applicants for the amounts of time they expend prosecuting their applications or securing regulatory approval. This means that developing countries are free to squeeze patents at both ends.

At the front end, they can drag their feet processing applications. Many developing countries have long done this semi-intentionally, simply by not allocating significant resources to the offices charged with evaluating applications. As we saw in Chapter 2, Thailand exemplifies this approach – although it has recently accelerated the processes associated with evaluation of applications. TRIPS creates no impediment to adopting this strategy more deliberately.<sup>28</sup>

Similarly, TRIPS does not require countries to extend patents on pharmaceutical patents beyond the 20-year line, regardless of how long it takes to process applications or secure regulatory approval. As we have seen, the U.S. patent system contains provisions enabling the holders of pharmaceutical-product patents to obtain term extensions sufficient to give them, on average, 12 years of commercial life. But developing countries are not obliged to follow suit. If, as we have suggested, they want to minimize the impediments that patents pose to the availability of medicines, they should not.

This is one zone where the Free Trade Agreements, discussed above, potentially have bite. A few of the existing agreements do contain requirements that the member countries either process patents reasonably expeditiously or extend their duration. For example, the Article 16:9, 6 of the FTA between the United States and Colombia provides, in pertinent part:

- (a) Each Party shall make best efforts to process patent applications and marketing approval applications expeditiously with a view to avoiding unreasonable delays.

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<sup>27</sup> See Roberto Romandini, “Flexibilities under Trips: An Analysis of the Proposal for Reforming Brazilian Patent Law,” *John Marshall Review of Intellectual Property Law* 15 (2016).

<sup>28</sup> In the United States, someone who is eventually granted a patent has a limited set of remedies against persons who, after the patent application was published but before the grant, made, used, or sold the invention in question. But TRIPS does not require countries to adopt such a regime – and, for the reasons outlined in the text, developing countries should not do so.

The Parties shall cooperate and provide assistance to one another to achieve these objectives.

- (b) Each Party shall provide the means to and shall, at the request of the patent owner, compensate for unreasonable delays in the issuance of a patent, other than a patent for a pharmaceutical product, by restoring patent term or patent rights. Each Party may provide the means to and may, at the request of the patent owner, compensate for unreasonable delays in the issuance of a patent for a pharmaceutical product by restoring patent term or patent rights. Any restoration under this subparagraph shall confer all of the exclusive rights of a patent subject to the same limitations and exceptions applicable to the original patent. For purposes of this subparagraph, an unreasonable delay shall at least include a delay in the issuance of the patent of more than five years from the date of filing of the application in the territory of the Party, or three years after a request for examination of the application has been made, whichever is later, provided that periods attributable to actions of the patent applicant need not be included in the determination of such delays.<sup>29</sup>

The Central American Free Trade Agreement (CAFTA), which binds Costa Rica, the Dominican Republic, El Salvador, Guatemala, Honduras, and Nicaragua, contains a similar provision.<sup>30</sup> Plainly, the options available to a country subject to an FTA of this sort are narrower than the options available to most developing countries. As yet, only a small minority of the nations with which we are concerned are so bound, but the number may increase.

#### d. Limiting Remedies

To date, flexibilities of the last type – opportunities to limit the *remedies* available to patentees whose rights have been infringed – have received almost no usage or attention. However, recent developments in U.S. patent law ironically have revealed a substantial zone of discretion that developing countries might use to increase the availability of drugs.

The relevant provisions of the TRIPS Agreement are Articles 42 to 49, which collectively require all WTO-member countries to make available to the holders of intellectual-property rights effective “civil and administrative procedures and remedies.” The crucial sections are set forth below.

42. Members shall make available to right holders civil judicial procedures concerning the enforcement of any intellectual property right covered by this Agreement....

44.1 The judicial authorities shall have the authority to order a party to desist from an infringement, *inter alia* to prevent the entry into the channels of commerce in their jurisdiction of imported goods that involve the

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<sup>29</sup> Free Trade Agreement between the United States and Colombia, Art. 16:9, available at <https://ustr.gov/sites/default/files/col-ipr.pdf>.

<sup>30</sup> CAFTA, Art. 15:9, 6(a) and (b), available at [https://ustr.gov/sites/default/files/uploads/agreements/cafta/asset\\_upload\\_file934\\_3935.pdf](https://ustr.gov/sites/default/files/uploads/agreements/cafta/asset_upload_file934_3935.pdf).

infringement of an intellectual property right, immediately after customs clearance of such goods. Members are not obliged to accord such authority in respect of protected subject matter acquired or ordered by a person prior to knowing or having reasonable grounds to know that dealing in such subject matter would entail the infringement of an intellectual property right.

44. 2. Notwithstanding the other provisions of this Part and provided that the provisions of Part II specifically addressing use by governments, or by third parties authorized by a government, without the authorization of the right holder are complied with, Members may limit the remedies available against such use to payment of remuneration in accordance with subparagraph (h) of Article 31. In other cases, the remedies under this Part shall apply or, where these remedies are inconsistent with a Member's law, declaratory judgments and adequate compensation shall be available.

45. 1. The judicial authorities shall have the authority to order the infringer to pay the right holder damages adequate to compensate for the injury the right holder has suffered because of an infringement of that person's intellectual property right by an infringer who knowingly, or with reasonable grounds to know, engaged in infringing activity.

45.2. The judicial authorities shall also have the authority to order the infringer to pay the right holder expenses, which may include appropriate attorney's fees. In appropriate cases, Members may authorize the judicial authorities to order recovery of profits and/or payment of pre-established damages even where the infringer did not knowingly, or with reasonable grounds to know, engage in infringing activity.

At the time the TRIPS Agreement was drafted, these provisions were widely regarded as onerous. One of the principal limitations of the Paris Convention, which TRIPS was intended to supplement, was its failure to require member countries to provide effective remedies for violation of patent rights; TRIPS was designed in part to fill that gap. Its impact in this regard was substantial; many countries soon amended their laws to increase the availability of preliminary injunctions and declaratory judgments, for example.

But lurking in these provisions are various opportunities for curtailing, rather than expanding the availability of remedies for patent infringement. A minor, but not trivial example is the second sentence of section 44.1, which seems to permit countries to deny injunctive relief to importers of patented goods who did not know – and had no reason to know – that they could be infringing. Much more general and important is the manner in which all of these provisions are phrased: they require countries to give their courts the power to issue injunctions and award compensatory damages, but do not specify the criteria that must govern the exercise of that authority. Silence in this respect is thus analogous to TRIPS' silence with respect to the meaning of "inventive step." Arguably, it leaves countries free to adopt provisions limiting the circumstances in which remedies must be available.

To this interpretation there is an obvious retort: As indicated above, the overarching purpose of the Agreement – and of Articles 41-49 in particular – was to provide patentees *effective* remedies for violation of their rights. Any interpretation of the pertinent clauses that would undermine that central objective cannot be right. Until recently, that retort would have been powerful. It has been significantly undermined, however, by the history of the portions of the U.S. patent regime pertaining to remedies.<sup>31</sup>

The crucial provision of the U.S. statute is section 283, which provides simply, “The several courts having jurisdiction of cases under this title may grant injunctions in accordance with the principles of equity to prevent the violation of any right secured by patent, on such terms as the court deems reasonable.” Before 1982, it was reasonably common for judges exercising the discretion they enjoyed under this provision to deny injunctions to prevailing patentees when, in their judgment, issuance would impair the public interest. Among the circumstances that would warrant denial was a threat to public health. Specifically, if entry of a permanent injunction would deprive the public of access to medicines or to devices that would be helpful in addressing public health challenges, a judge would be likely to deny it.

The Court of Appeals for the Federal Circuit, when it was formed, cut back sharply on this doctrine. Under the new court’s guidance, patentees successful in litigation could almost always secure an injunction, forcing the defendant to cease engaging in the activity in question.

In 2006, the Supreme Court decided the case of *eBay v. Mercexchange* in a way that radically altered the availability of injunctive relief. The holding of the case was that, when considering whether to grant injunctions in patent cases, judges should apply the traditional rules of equity that are applicable to all other kinds of disputes. Specifically, they should consider:

1. whether the plaintiff has suffered an irreparable injury;
2. whether monetary damages would be inadequate to compensate for that injury;
3. whether the balance of hardships favors the plaintiff; and
4. whether the public interest would not be adversely affected by a permanent injunction.

Only if the answers to all four questions are yes should the court should grant an injunction.

The impact of this decision on patent litigation was immediate and dramatic – perhaps more dramatic than the justices anticipated. The rates at which injunctions (both permanent injunctions and preliminary injunctions) dropped precipitously. Today, grants of injunctions are considered the exception, not the rule.<sup>32</sup>

To be sure, denial of an injunction ordinarily does not mean that the defendant is free thereafter to engage in the activity in question with impunity. Instead, the judge will ordinarily, at the patentee’s request, determine an “ongoing royalty” – an amount of money that the defendant has to pay the patentee if it wishes to continue. The amounts of such royalties vary

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<sup>31</sup> More detail concerning this history is available in the second half of a recorded lecture on patent remedies, available at <https://vimeo.com/311573281>.

<sup>32</sup> See, e.g., Kirti Gupta and Jay Kesan; Seaman.

substantially – in part because neither the Supreme Court nor the Federal Circuit has thus far given the trial judges guidance concerning how to calculate them.<sup>33</sup> The crucial point for our purposes is that the amount is under the control of the judge – and is almost always less than the license fee that the patentee, given its druthers, would demand.

Assuming, plausibly, that U.S. law governing patent remedies does not violate the TRIPS Agreement, the recent history of injunctive relief has two implications for developing countries. First, they are free to instruct their judges to deny injunctions in circumstances in which such injunctions would threaten “the public interest” – and, specifically, would endanger public health. Second, they are free to empower judges to determine the amounts of the “ongoing royalties” that generic firms must pay the patentees if they wish to manufacture and distribute products covered by their patents.

What criteria should be used to calculate those ongoing royalties? On this issue, the practice of U.S. courts provides less guidance. Recurring to the language of the TRIPS Agreement itself, a plausible answer would be: judges should select an amount “adequate to compensate for the injury the right holder [would] suffer[]” as a result of the generic firm’s conduct. As we have seen, in many developing countries, the revenues that patent owners are able to extract by enforcing their patents are modest. Consequently, the royalty that judges could order in lieu of injunctive relief should be comparably modest.

The availability of this option would be of limited value if, to determine how much it would have to pay, a generic firm were obliged to begin manufacturing and distributing the drugs at issue – and wait for the pharmaceutical firm to bring suit. But a developing country could avoid putting generic firms in this position. Notice that section 44.2 of TRIPS not only permits, but requires that “declaratory judgments” be made available. Declaratory judgments enable a party to test the legality of behavior before engaging in it. In the U.S., the courts have limited the availability of such suits because of the so-called “case or controversy” requirement derived from the federal Constitution, but most countries (including most developing countries) have no such requirement. As a result, they are free to adopt statutory provisions authorizing generic firms to ascertain, through declaratory judgment suits, the amounts of the “ongoing royalties” that they would be obliged to pay patentees.

The fruit of this inquiry is that, hidden in the structure of the TRIPS Agreement is an alternative mechanism by which developing countries can free up generic firms to make patented drugs. They need not rely upon compulsory licenses issued by statute or administrative decree – a process that, as we have seen, is fraught with controversy. Instead, they could follow the lead of the United States in limiting the availability of injunctive relief for patent violations – and then allow generic firms to use declaratory-judgment suits to determine the amounts of the license fees they have to pay.

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<sup>33</sup> See Gregory Sidak (finding that the median amount is 1.6 times of the amount of the “reasonable royalty” that the judge has ordered to compensate the patentee for the defendant’s past behavior).

### 3. Clearing the Paths

To summarize, there are four ways in which developing countries can limit patent protection for pharmaceutical products without violating their treaty obligations: (a) limit patentees' exclusive rights (e.g., by permitting parallel importation of patented drugs lawfully sold elsewhere or imposing compulsory licenses on the relevant patents); (b) require patent applications to meet a high inventive-step requirement (a technique pioneered by India); (c) limit the duration of patents, either by processing applications slowly or by renouncing term extensions (or both); and (d) limit the remedies available to patentees in ways suggested by the recent history in the United States.

Of these options, the only one that developing countries have used with any frequency is compulsory licensing – and recently even that device has been used less and less often. The peak in the issuance of compulsory licenses came in 2005. Approximately 20 were issued that year.<sup>34</sup> Since then, invocations have declined sharply. Starting in 2015, there has been an average of only two compulsory licenses issued per year – the large majority of which have been by high-income countries, not developing countries.<sup>35</sup>

One possible explanation for the paucity of recent invocations is that the governments of developing countries have discovered that use of the flexibilities is ineffective in reducing the prices or increasing the availability of drugs. Perhaps the critics of this strategy<sup>36</sup> are right.

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<sup>34</sup> Because there exists no official database pertaining to TRIPS flexibilities, we do not know the exact number. Ellen 't Hoen and her colleagues report that, in 2005, 24 compulsory licenses were either issued or threatened. See Ellen 't Hoen et al., "Medicine Procurement and the Use of Flexibilities in the Agreement on Trade-Related Aspects of Intellectual Property Rights, 2001–2016," *Bulletin of the World Health Organization* 96 (2018): 188. The "TRIPS Flexibilities Database," maintained by Medicines Law and Policy (available at <http://tripsflexibilities.medicineslawandpolicy.org>) identifies 16 compulsory licenses that were issued [Belarus, China, Congo, Gabon, Ghana, Guatemala, Guyana, Honduras, Italy, Liberia, Myanmar, Philippines, Swaziland, Taiwan, Tajikistan, Zimbabwe] and two that were threatened but not executed [Brazil, Cameroon]. (These lists include only invocations of the power to issue compulsory licenses under Article 31 of the TRIPS Agreement and excludes 14 instances during 2005 in which Least Developed Countries exercised their power under Paragraph 7 of the Doha Declaration to opt out of patent protection for pharmaceutical products altogether.)

<sup>35</sup> The following list of invocations during the past 7 years has been derived from the TRIPS Flexibilities Database," supra note \_\_\_\_\_. Developing Countries and Least Developed Countries (using the classifications of the World Trade Organization) are marked with asterisks.

2015: \*India; United Kingdom

2016: Germany

2017: \*Colombia; \*Malaysia

2018: Chile; Romania; Russia; Scotland

2019: \*Kazakhstan; United Kingdom

2020: Israel; Switzerland

2021: Russia

<sup>36</sup> See, e.g., Information Technology and Innovation Foundation, "Spread of Compulsory Licenses Threatens to Undermine Latin America's Innovation Ecosystem," August 24, 2018, <https://itif.org/publications/2018/08/24/spread-compulsory-licenses-threatens-undermine-latin-americas-innovation> ("Spurring local innovation, promoting competition by approving multiple types of treatments (such as for hepatitis C), promoting greater access to public healthcare to facilitate earlier detection of health risks, or

At least with respect to compulsory licenses, this hypothesis quickly collapses. Several recent empirical studies have examined the impacts of compulsory licenses in specific countries; all have concluded that they resulted in sharp price reductions, which in turn increased the set of patients who had access to the drugs in question, reduced the financial burdens borne by public health systems, or both.<sup>37</sup>

An alternative possible explanation for the declining usage of TRIPS flexibilities supposes that the strategic and high-profile initiatives between 2004 and 2008 by Brazil, South Africa and some other large developing countries (primarily to facilitate generic manufacture of patented ARVs)<sup>38</sup> convinced pharmaceutical firms of the willingness of all developing countries to use their powers. Since then, the firms may have taken that willingness into account when negotiating the prices they charge either the developing countries themselves or the international organizations that are providing them drugs. As a result, countries may no longer feel the need to use compulsory licenses; the threat – explicit or tacit – to use them is enough.<sup>39</sup> The dramatic recent decline, documented in Chapter 1, in the prices of most ARVs in the developing world is consistent with this hypothesis. However, the ability of pharmaceutical firms to maintain high prices in developing countries on many other patented drugs strongly suggests that this is not a complete explanation.

Three other factors seem to be at work. The simplest is that the relevant officials in some developing countries are simply unaware of the powers they enjoy. This is the most likely explanation of the fact that some of the poorest countries, who until 2033 have no duty to extend patent protection for drugs, currently do so.

Second, it is difficult, controversial, and time-consuming to use these powers on an ad-hoc basis. A country's ability to respond to threats to public health – some of which, as we have seen, arise suddenly – is maximized if, when they emerge, the administrative apparatus necessary to invoke these powers is already in place. Although the large majority of countries

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entering into good-faith price negotiations all represent far more effective public policy choices than issuing compulsory licenses on novel pharmaceutical drugs.”)

<sup>37</sup> See Eduardo Urias and Shyama V. Ramani, "Access to Medicines after Trips: Is Compulsory Licensing an Effective Mechanism to Lower Drug Prices? A Review of the Existing Evidence," *Journal of International Business Policy* 3 (2020); Frederick Abbott et al., "Using Competition Law to Promote Access to Health Technologies: A Guidebook for Low- and Middle-Income Countries," (UNDP, 2014), 153-54; Francisco Viegas Neves da Silva, Ronaldo Hallal, and Andre Guimaraes, "Compulsory License and Access to Medicines: Economics Savings of Efavirenz in Brazil," in *International AIDS Conference* (Washington, D.C.2012); Martin Khor, *Compulsory License and "Government Use" to Promote Access to Medicines: Some Examples* (Third World Network, 2014).

<sup>38</sup> See Germán Velásquez et al., "Improving Access to Medicines in Thailand: The Use of Trips Flexibilities," (2008), 20-23.; Sisule F. Musungu and Cecilia Oh, "The Use of Flexibilities in Trips by Developing Countries: Can They Promote Access to Medicines?," (Commission on Intellectual Property Rights, Innovation and Public Health, 2005), 18-19.

<sup>39</sup> For descriptions of situations in which threats to invoke compulsory licenses provoked substantial price reductions, see Carolinne Thays Scopel and Gabriela Costa Chaves, "Iniciativas De Enfrentamento Da Barreira Patentária E a Relação Com O Preço De Medicamentos Adquiridos Pelo Sistema Único De Saúde," (2016); Tatiana Andia, "The Inverse Boomerang Pattern: The Global Kaletra Campaign and Access to Antiretroviral Drugs in Colombia and Ecuador," *Studies in Comparative International Development* 50 (2015); William Flanagan and Gail Whiteman, "'Aids Is Not a Business': A Study in Global Corporate Responsibility – Securing Access to Low-Cost Hiv Medications," *Journal of Business Ethics* 73 (2006).

now have statutes (or adhere to regional agreements) that authorize the issuance of compulsory licenses, few of those provisions establish machinery sufficiently detailed to enable expeditious issuance of such a license.<sup>40</sup>

The third factor is that government officials in some developing countries have been deterred from using these tools by the prospect of retaliation, either by developed countries or by adversely affected pharmaceutical firms. As we have seen, the early exercises of these powers provoked fierce reactions. Brazil, South Africa, and Thailand were able eventually to weather the storms.<sup>41</sup> But their success did not prompt the United States, the European Union, or the firms whose patents were affected to cease their efforts to discourage or punish the use of compulsory licenses or other flexibilities.<sup>42</sup> The persistent and notoriety of these retaliations may have prompted most small developing countries – many of whom depend on the United States and the European Union for foreign aid – to refrain from poking the bears.

One of the most troubling instances of threatened retaliation may have occurred during the struggle during 2016 over Colombia's effort to impose a compulsory license on Glivec, a cancer drug sold by Novartis. Leaked correspondence between Colombia government officials suggests that they had been led to believe that imposition of the compulsory license might imperil the continuation of U.S. funding for the peace negotiations then underway between the Colombian government and the FARC guerillas.<sup>43</sup> The United States Trade Representative has denied making any such threat, and there is no independent evidence that it was indeed made. But the fact that high-level Colombian officials expressed anxiety on this score is a good indication of the deterrent effect of the pattern of pressure exerted by the United States on countries considering the use of compulsory licenses. Our interviews with officials in Namibia and Malawi suggest that they are indeed reluctant for this reason to use the powers they formally enjoy.

If, as we have urged, developing countries are to employ the flexibilities more aggressively, these obstacles must be dismantled. With respect to the first of the three factors, the principal reason why we have devoted so much attention to the arcane issues involving the interpretation of the TRIPS Agreement is to clarify, for officials in developing countries, the options currently available to them. As we have argued, some of the zones of discretion

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<sup>40</sup> See World Intellectual Property Organization, "Draft Reference Document on the Exception Regarding Compulsory Licensing," (2019), 20-45, 47-49.; Vwanda 2020

<sup>41</sup> See Chapter 2, pages \_\_\_\_.

<sup>42</sup> Examples of retaliation by the governments of developed countries or adversely affected patentees to the exercise of TRIPS flexibilities are described in Kevin Outterson, "Should Access to Medicines and Trips Flexibilities Be Limited to Specific Diseases?," *American Journal of Law & Medicine* 34 (2008): 320.; Cynthia Ho, "Patent Breaking or Balancing?: Separating Strands of Fact from Fiction under Trips," *North Carolina Journal of International Law & Commercial Regulation* 34 (2009): 447-48; Jacqui Wise, "Access to Aids Medicines Stumbles on Trade Rules," *Bulletin of the World Health Organization* 85, no. 4; Horace E. Jr. Anderson, "We Can Work It Out: Co-Op Compulsory Licensing as the Way Forward in Improving Access to Anti-Retroviral Drugs," (2010), 28; Christina Cotter, "The Implications of Rwanda's Paragraph 6 Agreement with Canada for Other Developing Countries," *Loyola University Chicago International Law Review* 5 (2008): 178, 87.

<sup>43</sup> See Letter from Andrés Flórez (a negotiator in the Colombian Embassy in Washington D.C.) to María Ángela Holguín (Minister of Foreign Affairs) (April 27, 2016), available at <https://big.assets.huffingtonpost.com/Glivec27April2016.pdf>.

have thus far received little or no attention. Our ambition has been to bring them to light – and thus encourage their use.

With respect to the second factor, lawmakers in developing countries can and should act now to create the machinery to enable them to respond most effectively to the threats on the horizon. For example, countries (such as Bangladesh) that have not yet adopted the necessary statutory authority to impose compulsory licenses on pharmaceutical patents, should do so.<sup>44</sup> The countries that do have such provisions can and should amend them to facilitate their efficient invocation. A sensible statute would have the following features:

- (a) a statement of the circumstances under which a compulsory license may be ordered that makes clear the legitimacy of using this device to ensure residents' access to crucial medicines;<sup>45</sup>
- (b) identification of the governmental entity (ideally, an administrative agency rather than a court) that has the authority to impose such a license;
- (c) a clear set of procedures for requesting, considering, and issuing such licenses;
- (d) guidelines for the calculation of the associated (modest) license fees; and
- (e) an appellate procedure that enables a patentee to challenge or amend a compulsory license, invocation of which does not suspend the operation of the license.<sup>46</sup>

More detailed recommendations concerning the components of an optimal compulsory-licensing system are available from the World Health Organization and the South Centre.<sup>47</sup> Less important than the details of such a statutory regime is that a country have one. That way, when a health crisis looms, they do not need to start from scratch.

Of the three factors, the most troubling – and perhaps the most powerful – is the threat of retaliation. There is little that the governments of developing countries can do to

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<sup>44</sup> See M. Monirul Azam, "Globalizing Standard of Patent Protection in Wto Law and Policy Options for the Ldcs: The Context of Bangladesh," *Chicago-Kent Journal of Intellectual Property* 13 (2014): 428-39.

<sup>45</sup> Most existing statutes identify one or more of the following grounds as justifications for the imposition of a license: (1) the patentee's persistent refusal to grant the applicant a voluntary license on reasonable commercial terms; (2) the "public interest"; (3) "public health"; (4) "emergency," such as war, famine, or natural catastrophe; (5) anti-competitive practices by the patentee; (6) that the patent is blocking use of a new or improved technology; (7) the patentee's failure to exploit or "work" the patent in the country in question. See Musungu and Oh, "Trips Flexibilities," 16-18. There is little doubt that the first six of these grounds are legitimate bases, under the TRIPS Agreement, for the imposition of domestic compulsory licenses. (We will discuss the seventh ground in section A.2., below.) Of these options, numbers 2, 3, and 4 most clearly authorize use of this tool to ensure that residents have access to crucial medicines.

<sup>46</sup> See "Commission on Intellectual Property Rights", "Integrating Intellectual Property Rights and Development Policy," (2002), 44.

<sup>47</sup> See James Love, "Remuneration Guidelines for Nonvoluntary Use of A Patent on Medical Technologies" (WHO and UNDP 2005); Carlos Correa, "Guide for the Granting of Compulsory Licenses and Government Use of Pharmaceutical Patents," (2020), <https://www.southcentre.int/wp-content/uploads/2020/04/RP-107.pdf>.

mitigate this hazard; that can only be achieved by the governments of the countries from which the threats emanate. We thus postpone our discussion of it until the second half of this chapter.

## **B. Developed Countries**

We turn now to the question of how developed countries might modify their intellectual property laws to help solve the problems before us. This shift in focus has an important implication: The laws of developed countries, unlike those of developing countries, do have a major impact on the creation of new drugs. Consequently, from this point forward, we must keep in mind both the incentive problem and the access problem, not just the latter.

For the reasons discussed in the preceding chapter, the country whose laws have the greatest impact on the creation and availability of vaccines and drugs is the United States. Consequently, the bulk of this section will concentrate on possible reforms of U.S. patent law. However, most of the recommendations we offer are equally applicable to other developed countries.

### *1. Constraints*

As we did in the previous section, we begin our analysis by identifying the constraints within which lawmakers considering modifications of the intellectual property system must operate. (It would do little good for us to advocate reforms that are unconstitutional or impracticable.) U.S. lawmakers must work within three such constraints.

First, they are of course bound by the terms of the pertinent multilateral treaties, the most important of which is the TRIPS Agreement. In the previous section, we examined in detail the complex combination of limitations and “flexibilities” produced by TRIPS. That combination binds the United States just as much as it binds developing countries.

To this generalization, there is an important qualification. In practice, the wealth and power of the United States has given it somewhat more latitude when deviating from the TRIPS Agreement than has been enjoyed by developing countries – and this imbalance is likely to persist. Although many provisions of U.S. intellectual-property laws might plausibly be challenged as violations of TRIPS, other countries have as yet only targeted a few of them in WTO dispute-resolution proceedings. And when such disputes have arisen and the United States has lost, the U.S. government has sometimes refused to modify its laws, choosing instead to pay the functional equivalent of an annual fine for continued noncompliance. Thus far, none of the instances in which the United States has sought to push against the envelope of TRIPS have involved pharmaceutical patents. But were the United States to test the pharma-related TRIPS provisions, it could probably get away with more than could a country in the developing world.

The second of the three constraints is that, when adjusting the patent regime, lawmakers in the United States are bound by the “takings” provision of the Fifth Amendment to the federal Constitution, which provides: “[N]or shall private property be taken for public use without just compensation.” Currently, the primary role of this provision is to limit

expropriations of “real” property – in other words, land and things attached to that land. As construed by the courts, the provision permits governments (federal, state, and local) to “take” such property only if both (a) the owners thereof are paid (roughly speaking, the fair market value of the property) and (b) the purpose of the confiscation is to benefit the public (interpreted broadly). These restrictions apply, not just to formal expropriations, but also to so-called “regulatory takings,” circumstances in which governments limit permissible uses of private property sufficiently severely to give rise to what the courts deem the functional equivalent of expropriation.

For many years, the applicability of the Fifth Amendment to intellectual property rights – and specifically to patents – was unclear, in large part because the degree to which patents constituted private property was uncertain. Some judicial decisions took the position that patents consisted of government grants, rather than property rights, and were therefore outside the zone covered by the takings provision; others took the opposite position. Commentators were also divided.

A recent decision by the Supreme Court removes some of the uncertainty. In *Oil States Energy Services v. Greene’s Energy Group*, the Court warned, “our decision [today] should not be misconstrued as suggesting that patents are not property for purposes of the Due Process Clause or the Takings Clause.”<sup>48</sup> Because the case did not directly implicate either clause, the Court’s statement does not cleanly resolve the issue before us. But the firmness of the declaration, combined with similar statements in the two prior decisions cited by the Court,<sup>49</sup> leave little doubt that governmental action with respect to patents must comply with the Takings Clause.

One implication of that principle is clear enough: an outright expropriation of a patent (or a group of patents) would surely be declared unconstitutional. So, for example, the federal government could not simply declare that the patent held by a private pharmaceutical firm on a newly developed COVID vaccine henceforth would belong to the government, which would assume responsibility for manufacturing and distributing the vaccine.

To be sure, the government could expropriate such a patent if it paid the firm the value of the patent. Indeed, a federal statute implicitly confirms that power by specifying a mechanism for determining the appropriate amount of the compensation. 35 USC 1498(a) provides, in pertinent part:

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<sup>48</sup> \_\_\_ U.S. \_\_\_ (2019).

<sup>49</sup> Specifically, the Court cited its prior decisions in *Florida Prepaid Postsecondary Ed. Expense Bd. v. College Savings Bank*, 527 U. S. 627, 642 (1999) (“Patents, however, have long been considered a species of property. ... As such, they are surely included within the “property” of which no person may be deprived by a State without due process of law.”) and *James v. Campbell*, 104 U. S. 356, 358 (1882) (“The United States has no such prerogative as that which is claimed by the sovereigns of England, by which it can reserve to itself, either expressly or by implication, a superior dominion and use in that which it grants by letters patent to those who entitle themselves to such grants. The government of the United States, as well as the citizen, is subject to the Constitution, and when it grants a patent, the grantee is entitled to it as a matter of right, and does not receive it, as was originally supposed to be the case in England, as a matter of grace and favor.”).

Whenever an invention described in and covered by a patent of the United States is used or manufactured by or for the United States without license of the owner thereof or lawful right to use or manufacture the same, the owner's remedy shall be by action against the United States in the United States Court of Federal Claims for the recovery of his reasonable and entire compensation for such use and manufacture.

But an uncompensated expropriation would be unconstitutional.

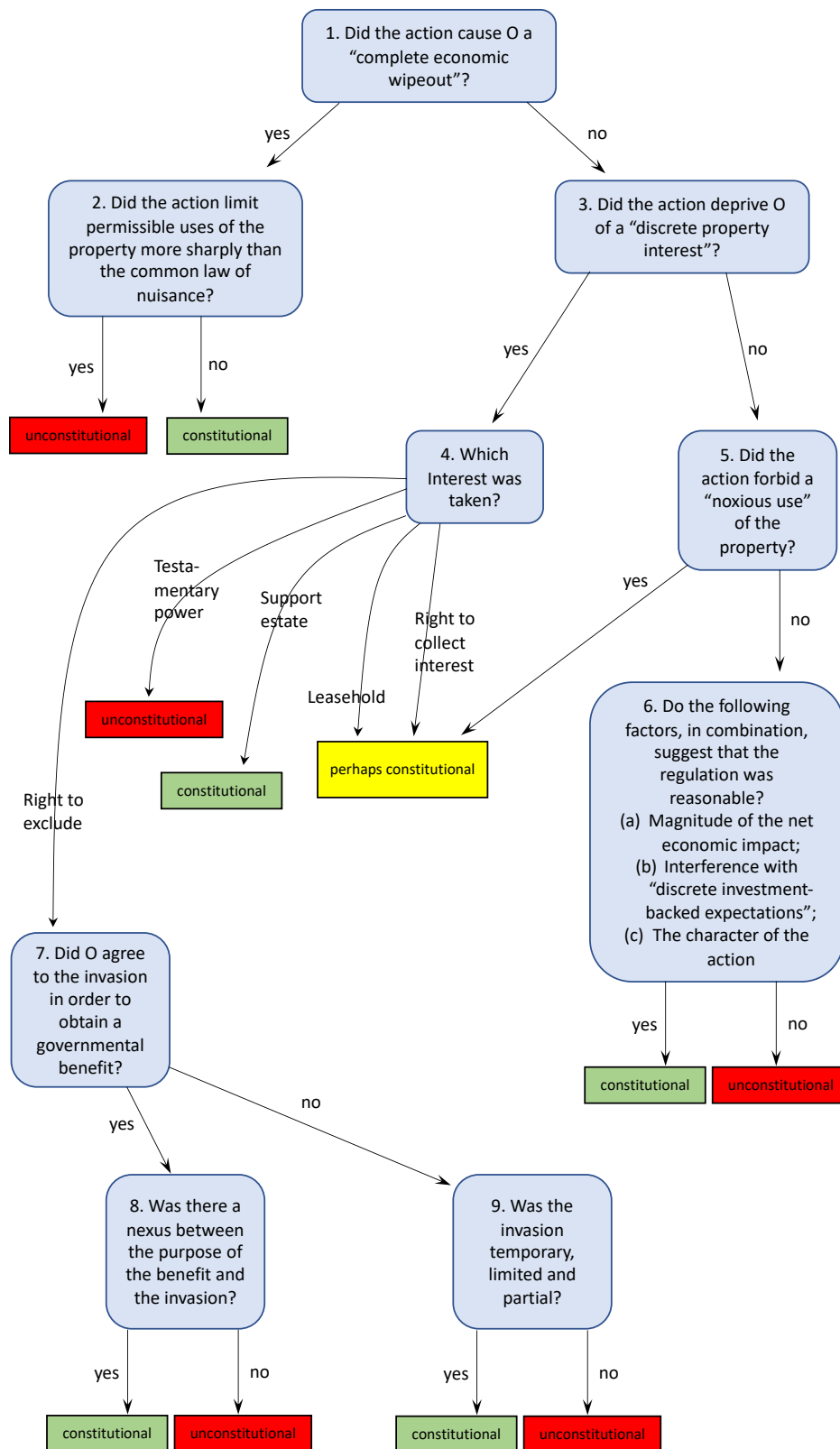
Much less clear is the degree to which the Supreme Court's extensive set of decisions concerning when a regulation of real property rises to the level of a *de facto* "taking" is applicable to patent rights. That at least some of that jurisprudence is applicable to patents was taken for granted by the Court of Appeals for the Federal Circuit in a recent decision upholding against a constitutional challenge the application of the America Invents Act to patents granted prior to its enactment. The challenger had contended that the statute, by increasing substantially the vulnerability of patents to invalidation through reexamination proceedings, "unfairly interferes with its reasonable investment-backed expectations without just compensation" and therefore constitutes a "regulatory taking" in violation of the Fifth Amendment. The court disagreed, not on the ground that adjustments of the patent statute could not give rise to "regulatory takings," but rather on the ground that the AIA did not alter the pre-existing reexamination procedures sufficiently to run afoul the Constitution.<sup>50</sup> In two subsequent cases, the Federal Circuit has reiterated this view, and in all three cases the Supreme Court declined to review the Federal Circuit's rulings.

From these decisions, we can safely conclude that retroactive changes in patent law *could* impair patentees' rights sufficiently to constitute regulatory takings, but as yet we have little guidance from the courts concerning the circumstances under which that would occur. What follows is our best effort to predict how the courts would be likely react to some of the kinds of retractive adjustments that lawmakers might consider if they sought in this way to combat the scourge of infectious diseases.

We begin with a summary of the case law concerning "regulatory takings" in the context of real and personal property. As any first-year law student can attest, this is a tangled and unstable field, but with some simplification, it can be reduced to the decision tree set forth in Figure 3, below. (To keep the figure manageable, it uses the following abbreviations: "action" is shorthand for a statute, regulation, or other governmental action; "property" is the tract of land adversely affected by the action; and "O" is the owner of the tract.)

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<sup>50</sup> Celgene Corp. v. Peter, 931 F.3d 1342 (CAFC 2019).



As is evident from its complexity, the middle branch of the tree (encompassing questions 4, 7, 8, and 9) has gotten a great deal of attention from the Court in the past 40 years, but is unlikely to have much bearing on which retroactive modifications of patent law give rise to regulatory takings. The reason is that the premise of this branch is that some of the “sticks” in the bundle of entitlements associated with ownership of a tract of land are more important than others – and thus that regulations burdening the crucial sticks are especially likely to give rise to unconstitutional takings. In the Court’s judgment, the premiere example of these special entitlements is the right to exclude – i.e., an owner’s right to prevent people or objects from “invading” the premises.<sup>51</sup> Patents – and pharmaceutical patents in particular – do not resemble real property rights in this way. To be sure, a patent right, like ownership of a parcel of land, can be thought of as a bundle of separate entitlements – specifically, the rights to prevent others from making, using, selling, or importing the patented invention.<sup>52</sup> But patentees do not ordinarily regard any one of those rights as especially important. Rather, what they care about is the aggregate financial return that the combination of entitlements enables. A reduction of that aggregate return concerns patentees, but typically not which rights are pruned to cause the reduction. The upshot is that constitutional challenges to retroactive modifications of patent law are likely to be resolved by asking questions analogous to questions 1, 2, 3, 5, and 6 in the chart, rather than 4, 7, 8, and 9.

The resolution of the recent challenges to the reexamination procedures of the AIA suggests how questions 1 and 2 are likely to interact. The nub of the courts’ rulings in those cases is that a retroactive change in patent law that reduces the value of a patent to zero (an “economic wipeout”) is presumptively unconstitutional unless the change can be characterized convincingly as enforcing a regulatory power that predated the grant of the patent. This is an old idea; the “vested-rights doctrine” in the early nineteenth century was founded upon it.<sup>53</sup> It still has appeal in the context of land-use regulations, and it is likely to be equally attractive in the context of patent-law adjustments. So, for example, although the recent judicial modification of the rules governing software patents resulted in the invalidation of thousands of pre-existing patents, a constitutional challenge to that modification by the holder of one of the invalidated patents would likely be rebuffed on the ground that the change merely clarified the long-standing principle that abstract ideas cannot be patented.<sup>54</sup>

Since 1978, landowners challenging regulations that hurt them financially but neither reduced the value of their holdings to zero nor impaired their “rights to exclude” have rarely prevailed. Question #6 in Figure 3 summarizes the multi-factor test that the courts have used in such cases. Occasionally, when a regulation has had an especially vivid impact on a “discrete investment-backed expectation,” an injured owner has been able to persuade a court to

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<sup>51</sup> See *Cedar Point Nursery v. Hassid*, \_\_\_ U.S. \_\_\_ (2021); *Loretto v. Teleprompter Manhattan CATV Corp.*, 458 U.S. 419 (1982).

<sup>52</sup> 35 U.S.C. 271.

<sup>53</sup> See William Fisher, “Ideology, Religion, and the Constitutional Protection of Private Property, 1760-1860,” *Emory Law Journal* 39 (1990).

<sup>54</sup> A nuance lurking in this example: Can changes in the law made by courts (rather than legislatures) give rise to constitutional violations? Probably. See James Krier, “Judicial Takings: Musings on Stop the Beach,” *Property Rights Conference Journal* 3 (2014).

invalidate it.<sup>55</sup> But generally speaking, the courts have been willing to give legislators the benefit of the doubt when assessing the strength of the public interest advanced by the challenged action and have tolerated reductions in the value of holdings of up to 80%.<sup>56</sup>

These attitudes are likely to carry over to the courts' responses to adjustments in patent law that hurt patentees but do not destroy the value of their holdings. Here are four (admittedly speculative) illustrations:

- Putting aside, for the moment, the TRIPS Agreement, suppose that Congress shortened the life of all patents from 20 years to 15 years – and made the change retroactive. There is a good chance that the courts would strike this down, reasoning that the 5-year interval thereby eliminated is “discrete” and that many patentees had made substantial investments relying on its availability.
- By contrast, a constitutional challenge to the recent adjustment of the rules governing “exhaustion” of patent rights,<sup>57</sup> which significantly reduced the value of patents on products that had been marketed globally using business models based on differential pricing, would almost certainly fail, because the net economic impact did not come close to a “wipeout.”
- As indicated in Chapter 2, many developed countries already limit the prices that pharmaceutical firms can charge for their patented products. Were Congress to institute such a system in the U.S., would the courts strike it down? Almost certainly not. The effect would not be an “economic wipeout,” and the multi-factor test would tilt in the government’s favor.<sup>58</sup>
- Finally, suppose that the government imposed a compulsory license on the patent on a particular drug – say, a patent held by Regeneron on a particular monoclonal antibody cocktail that promises to reduce COVID fatality rates. (Again, ignore for the moment the limits that TRIPS imposes on the use of this strategy.) This too would be likely to pass constitutional muster, at least if the compulsory license fee were adequate to permit Regeneron to recover its costs.

This concludes, for now, our analysis of the impact of the takings doctrine on the discretion of lawmakers in the United States, but we will return to this theme when discussing specific reform options below.

The last of the three constraints is political, rather than legal. In the United States, pharmaceutical firms spend more on lobbying (directed at legislators of both political parties) than do the firms in any other industry. Partly as a result, they enjoy substantial political power.

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<sup>55</sup> See, e.g., *Kaiser-Aetna v. United States*, 444 U.S. 164 (1979).

<sup>56</sup> See, e.g., *Hadacheck v. Sebastian*, 239 U.S. 394 (1915).

<sup>57</sup> See *Impression Products v. Lexmark*, 581 U.S. \_\_\_\_ (2017).

<sup>58</sup> The Supreme Court has already upheld against a constitutional challenge a municipal rent-control ordinance. It is unlikely that the Court would be more protective of the ability of pharmaceutical firms to charge what they want than it was of the analogous ability of landlords.

The prospects for any change in intellectual-property law that substantially disadvantages the firms are not good.

Although this barrier is formidable, two things make it less than insurmountable. First, popular hostility to the pricing practices of the firms has been rising in recent years, and the current pandemic has augmented it.<sup>59</sup> At some point, that hostility might be strong enough to offset the financial clout of the firms.

Second, although the firms would fiercely oppose any individual adjustment of the patent system that reduced their revenues, they might acquiesce in – or even support – a package of adjustments, some of which disadvantaged them, so long as the net impact of the combination left them at least equally well off. This has already occurred at least twice. Portions of both the Hatch-Waxman Act (discussed in Chapter 2) and of the Affordable Care Act hurt the pharmaceutical firms, but in each instance the overall package left them, roughly speaking, equally well off. That the firms did not oppose either initiative was crucial to their passage. When considering how to alleviate the health crisis in the developing world, we should look for similar combinations.

With these three constraints in mind, we can now turn to the reforms of patent law that developing countries might employ to help alleviate the health crisis in the developing world.

## *2. De-Biasing*

As Chapter 2 explained, the intellectual-property systems currently used by the United States and other developed countries create biases against research and development on three overlapping types of pharmaceutical products. Most directly relevant to the problem addressed in this book is the bias against drugs aimed at the subset of infectious diseases that have disproportionate impact on developing countries. The second disfavored category consists of vaccines, regardless of the type of disease they are designed to prevent. The third consists of “breakthrough” drugs of all sorts. The relationships among these categories might be depicted using a simple venn diagram:

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<sup>59</sup> All recent surveys support this generalization. See, for example, Nicholas Florko, "New Poll Shows Wide Support for Several Trump Drug Pricing Reforms, but Not Rebate Changes," *STAT*, <https://www.statnews.com/2020/08/28/poll-drug-pricing-trump/>; Kaiser Family Foundation, "Public Opinion on Prescription Drugs and Their Prices," <https://www.kff.org/slideshow/public-opinion-on-prescription-drugs-and-their-prices/>; Tal Axelrod, "Nearly 90 Percent of Americans Think Pharmaceutical Industry Will Use Coronavirus to Raise Drug Prices: Poll," *The Hill*, <https://thehill.com/policy/healthcare/503338-nearly-90-percent-of-americans-thinks-pharmaceutical-industry-will-use>.

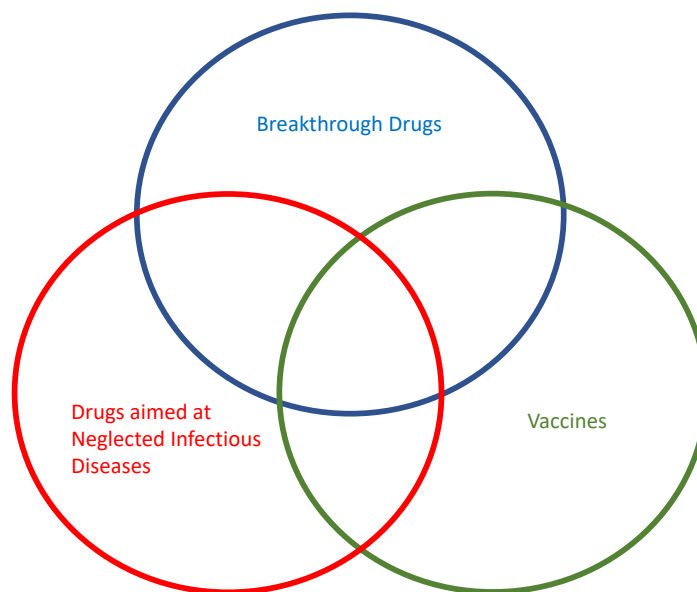


Figure 4

In this section, we identify some practicable reforms of the intellectual-property system that could offset these biases. Some of our recommendations entail augmenting incentives for innovations that fall into one or more of the three zones; others entail reducing incentives for innovations outside of them.

Before addressing what dials might be turned to achieve these effects, we pause to consider how the three categories might be defined. This is necessary because, if the relative strength of the IP rights associated with these three zones is increased, then pharmaceutical firms will surely try to characterize as many of their products as possible as falling into one or more of the privileged sectors. Reasonably sharp boundaries are thus essential both to minimize disputes and to ensure that the reforms are as efficient as possible.

The green circle is the easiest to draw. The meaning of the term, “vaccine,” is clear: “[a] product that stimulates a person’s immune system to produce immunity to a specific disease, protecting the person from that disease.”<sup>60</sup> Disputes concerning whether a particular concoction fits this definition are unlikely.

The red zone can and should be defined by using an administrative process to make (and periodically revise) a list of the diseases in question. The FDA has already developed such a list to implement its “priority review voucher” program (which we will describe in detail in Chapter 5). That list is follows:<sup>61</sup>

<sup>60</sup> Centers for Disease Control, “Vaccines and Immunizations,” <https://www.cdc.gov/vaccines/vac-gen/imz-basics.htm>.

<sup>61</sup> Source: <https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/tropical-disease-priority-review-voucher-program>.

- Tuberculosis
- Malaria
- Blinding trachoma
- Buruli ulcer
- Cholera
- Dengue
- Dracunculiasis  
(guinea-worm disease)
- Fascioliasis
- Human African trypanosomiasis
- Leishmaniasis
- Leprosy
- Lymphatic filariasis
- Onchocerciasis
- Schistosomiasis
- Soil transmitted helminthiasis
- Yaws
- Filovirus Diseases
- Zika Virus Disease
- Chagas disease
- Neurocysticercosis
- Chikungunya Virus Disease
- Lassa Fever
- Rabies
- Cryptococcal Meningitis
- Brucellosis
- Opisthorchiasis
- Paragonimiasis

Note that of the six diseases we examined in detail in Chapter 1, three – tuberculosis, malaria, and dengue – are on this list. The exclusion of two of the six – HIV/AIDS and COVID-19 – is sensible, because, as we saw, their adverse impact on developed countries is as great as their adverse impact on developing countries. The sixth – Ebola – should be on the list because, as we saw, its footprints in developing countries are much deeper than those in developed countries. In short, this particular list is not perfect, but it illustrates the methodology that should be used to define the category.

Incidentally, the list gives us an opportunity to reiterate an important limitation on the project of this chapter. The reforms of IP laws that we discuss below would reduce significantly the bias against infectious diseases that affect both developing countries and developed countries but have disproportionate impacts on the former. Unfortunately, those reforms would do little or nothing to boost production of drugs aimed at diseases on the list that have no impact at all in developed countries. An example is onchocerciasis (river blindness), whose current distribution is apparent from the map below.

Distribution of onchocerciasis, worldwide, 2013

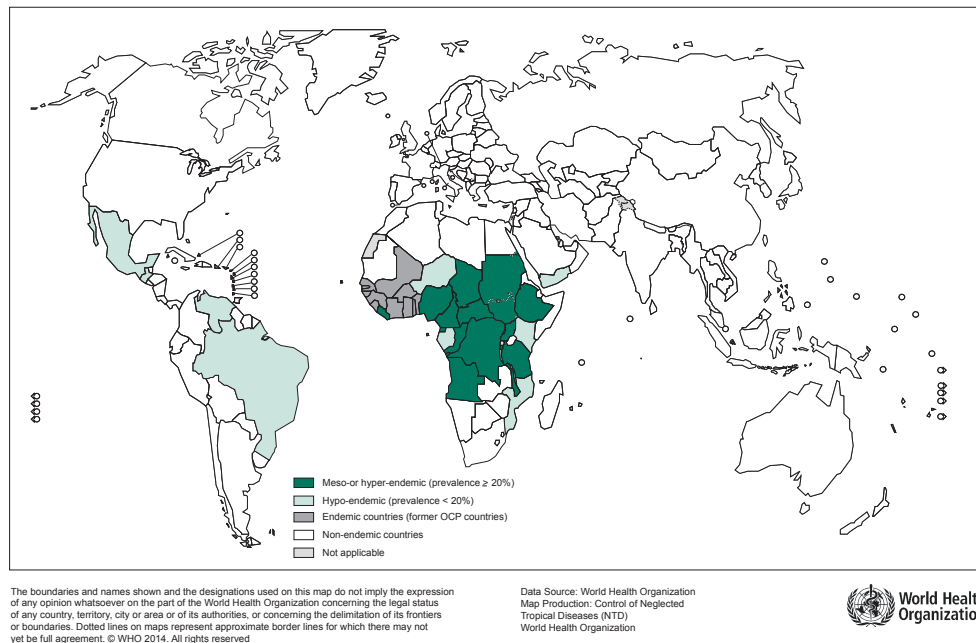


Figure 5

More than 99% of the persons infected by this diseases live in the 31 subSaharan African countries colored dark green in the map.<sup>62</sup> The reason why reform of intellectual property laws in developed countries would have minimal impact on drugs aimed at such diseases is the same as the reason, already mentioned, why IP law in developing countries currently has little impact on incentives: the markets in poor countries are not yet large enough to generate sufficient profit to stimulate the creation and testing of new drugs. (To address the diseases in this group, we will have to rely on mechanisms other than intellectual property – which we will take up in Chapters 5 and 6.)

The blue zone in Figure 4 (“breakthrough drugs”) would be the most difficult to define – and would surely give rise to the most disputes. At first glance, it might seem feasible to delineate it by invoking one or the other of two metrics already used by the FDA. As noted in the previous chapter, the agency currently separates drug applications into two main piles: those that promise sufficiently important health benefits that they are given “priority” review; and all others. To draw the boundary of the blue zone, we might simply equate “breakthrough” with “meriting priority review.” Although administratively simple, this approach would be overinclusive. The incentives for many of the drugs that fall into this box are already perfectly adequate; augmenting them would thus be socially wasteful. A subset of the applications that are given “priority” status are also deemed “breakthrough” by the FDA. Perhaps we should confine membership in the blue zone to drugs that meet this more stringent

<sup>62</sup> Source: World Health Organization, <https://www.who.int/onchocerciasis/distribution/en/>.

standard. Unfortunately, the way in which the agency defines “breakthrough” does not align well with how we have been using the term.

More administratively burdensome but better would be to create a new metric, which estimated the health benefits that would be associated with a particular drug (over and above the benefits of drugs already available) and treated all drugs above a particular number as “breakthrough.” In chapter 5, when analyzing prize systems, we consider in detail what such a metric might look like. For the time being, we assume that the complexities associated with this approach could be resolved.

Having defined the three zones (provisionally), we turn to the crucial question: how, without running afoul of the limitations discussed in the preceding section, could the IP rights associated with a drug falling into one or more of these categories be enhanced or the IP rights associated with a drug outside them be reduced?

With respect to enhancements, three options seem most promising. First, the duration of the IP rights at issue might be extended. This, in turn, might be achieved either by increasing the duration of the patent(s) on such an invention or by increasing the duration of the data-exclusivity protections given to the innovator. The first technique, as we saw in Chapter 2, was employed as one component of the Hatch-Waxman Act. The second, however, would be simpler and more effective. One of us has already advocated an extension of data-exclusivity protections to enhance incentives for breakthrough drugs focused on disorders of the central nervous system.<sup>63</sup> That reform has not yet been adopted, but we continue to support it. The same technique could be employed to buttress inventions falling into any of the three zones we have identified here.

The significance of the venn diagram in Figure 4 now becomes apparent. As it suggests, the biases are cumulative. Adjustments to the duration of IP rights thus ought to be cumulative as well. Suppose, for example, that the bonus associated with each category were three years. A breakthrough vaccine for a neglected infectious disease would then receive a bonus of nine years.

The second of the three ways of enhancing incentives for the currently disfavored categories is best explained historically. Until the late nineteenth century, an applicant for a U.S. patent was not obliged to indicate precisely what he “claimed.” He merely described the invention at issue, and the courts had the task of determining whether a competitor’s product or process resembled it sufficiently to constitute infringement. When exercising this responsibility, the courts commonly interpreted more expansively patents on what they deemed “pioneering” inventions than patents on so-called “mere improvements.” The rights associated with the former were said to be “broad,” while those associated with the latter were “narrow.” In other words, competitors were permitted to more closely approximate the latter than the former.<sup>64</sup>

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<sup>63</sup> See Dennis Choi et al., “Medicines for the Mind: Policy-Based “Pull” Incentives for Creating Breakthrough Cns Drugs,” *Neuron* 84, no. 3 (2014).

<sup>64</sup> See, e.g., *Evans v. Eaton*, 20 U.S. (7 Wheat.) 356, 361 (1822); *Odiorne v. Winkley*, 18 F. Cas. 581, 582 (C.C.D. Mass. 1814) (No. 10,432); *Woodcock v. Parker*, 30 F. Cas. 491, 492 (C.C.D. Mass. 1813) (No. 17,971); Brian

When the United States shifted to the current system of “peripheral claiming,” under which patentees were required to “particularly point out and distinctly claim” the aspects of their inventions for which they sought protection,<sup>65</sup> the preference that the courts had accorded pioneers survived but eventually morphed into two discrete doctrines. The first involved “claim interpretation,” the methodology that courts came to use when construing the language employed by patentees when marking out the territory they sought to control. One of the “canons” of claim construction came to be the principle that terms used in patents on pioneers should be read more broadly than the same terms used in other patents.<sup>66</sup> The second branch involved the doctrine of “equivalents,” which the courts used to extend patentees’ rights beyond the zone demarked “literally” by their claims. When they first developed the concept of “equivalents,” only the holders of patents on pioneers were permitted to invoke it.<sup>67</sup> When they later dropped this limitation, patents on pioneers continued to be accorded wider penumbras than patents on incremental improvements.<sup>68</sup>

The type of inventions that enjoyed this preferential treatment was never defined precisely. The language used by the Supreme Court in the venerable Westinghouse case has probably proven most influential; the Court there defined “pioneer” as follows:

This word, although used somewhat loosely, is commonly understood to denote a patent covering a function never before performed, a wholly novel device, or one of such novelty and importance as to mark a distinct step in the progress of the art, as distinguished from a mere improvement or perfection of what had gone before. Most conspicuous examples of such patents are the one to Howe, of the sewing machine; to Morse, of the electrical telegraph; and to Bell, of the telephone.<sup>69</sup>

As John Thomas has shown, other terminology appeared in the subsequent case law:

Courts have considered an invention to be a pioneer when it presents a “broad breakthrough,” “major advance,” or “basic operational concept”; or is “broadly new” or “devoid of significant prior art.” Pioneer inventions have

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Love, “Interring the Pioneer Invention Doctrine,” *North Carolina Law Review* 90 (2011): 390ff.; Dan L. Burk and Mark A. Lemley, “Fence Posts or Sign Posts? Rethinking Claim Construction,” *University of Pennsylvania Law Review* 157 (2009): 1746.

<sup>65</sup> See Jeanne C. Fromer, *Claiming Intellectual Property* (SSRN, 2008); Henry E. Smith, “Intellectual Property as Property,” *Yale L.J.* 116 (2007): 1807.

<sup>66</sup> See *Cimiotti Unhairing Co. v. An. Fur Ref. Co.*, 198 U.S. 399, 406 (1905); *Wright Co. v. Herring-Curtiss Co.*, 211 F. 654, 655 (CA2 1914).

<sup>67</sup> See *Morley Sewing Mach. Co. v. Lancaster*, 129 U.S. 263, 273 (1889); *Miller v. Eagle Mfg. Co.*, 151 U.S. 186, 207 (1894).

<sup>68</sup> See, e.g., *Price v. Lake Sales Supply R.M.*, 510 F.2d 388 (CA10 1974); *Thomas & Betts Corp. v. Litton Sys., Inc.*, 720 F.2d 1572, 1580 (Fed. Cir. 1983); Love, “Interring the Pioneer Invention Doctrine,” 393.

<sup>69</sup> *Westinghouse v. Boyden Power Brake Co.*, 170 U.S. 537, 561-62 (1898).

alternatively been called primary, basic, generic, “original,” or “key” inventions.<sup>70</sup>

Soon after the Court of Appeals for the Federal Circuit was established, the extra latitude given to patents on pioneers diminished sharply. Indeed, some of the new court’s opinion suggested that it had been eliminated altogether.<sup>71</sup> Although in practice trial courts and even some panels of the Federal Circuit continued to give pioneers special treatment,<sup>72</sup> the amount of preference was much reduced.

Some scholars lament the Federal Circuit’s diminution of the extra latitude enjoyed by pioneers and call for restoration of the doctrines that prevailed in the mid-twentieth century. Others contend that the Federal Circuit was right to demote pioneers. We need not resolve the debate between the two groups. Our contention, rather, is that the doctrines that courts formerly employed to boost the rights associated with pioneering inventions in all fields could and should be adapted to enhance the rights of the three types of pharmaceutical patents that we have identified as worthy of special treatment. Specifically, terms used in the claims of patents on breakthrough drugs, vaccines, and drugs aimed at neglected diseases should be construed especially liberally. Even when competitors’ products are found not to encroach upon the literal claims, they should more often be found to infringe under the doctrine of “equivalents.”

One context in which such a reform would make a difference concerns so-called “after-arising technology.” Courts have long struggled with the degree to which products or processes incorporating technologies that did not exist when the application for a patent was filed but that resemble the invention at issue should be deemed to infringe. Adoption of our proposal would make that more likely if the patent fell into one of the preferred zones than if it did not.

The third and last of the possible techniques for enhancement concerns the remedies for patent infringement. For the reasons we discussed in the first half of this chapter, the holders of U.S. patents now have a much harder time obtaining injunctions against infringers than was true at the turn of the century. The result has been to diminish significantly the magnitude of the royalties that they can extract from competitors. Like the flood and ebb of the extra latitude given pioneers, this doctrinal adjustment was made by the courts, not by Congress. Thus, it could be undone – in whole or in part – by the courts. Our suggestion is that the courts revive the availability of injunctive relief for patents falling into the three zones we have identified.

The tool by which they could make this adjustment is readily at hand. As we have seen, since the decision by the Supreme Court in the *eBay* case, courts have been paying greater attention to whether a grant of injunctive relief would advance or impair “the public interest.” For reasons that should now be apparent, augmenting the production of breakthrough

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<sup>70</sup> John R. Thomas, “The Question Concerning Patent Law and Pioneer Inventions,” *High Technology Law Journal* 10 (1995): 48.

<sup>71</sup> See *Texas Instruments, Inc. v. United States Trade Commission*, 846 F.2d 1369, 1370 (CAFC 1988).

<sup>72</sup> See Love, “Interring the Pioneer Invention Doctrine,” 394-404.

vaccines, particularly those aimed at neglected infectious diseases, would advance the public interest.

To summarize, in three ways incentives to produce innovations involving breakthrough drugs, vaccines, and neglected diseases could be increased: (i) by extending the duration of the data-exclusivity rights associated with drugs of the three sorts; (ii) by expanding the set of similar products and processes that would be deemed to infringe the patents on such innovations; and (iii) by awarding injunctions more often to the holders of such patents when infringement has been found. The first of these changes would require legislation, but the second and third could be implemented by the courts.

We hasten to emphasize that we are advocating such reforms only to the laws of the United States and other developed countries. For the reasons discussed in the first half of this chapter, developing countries need not and should not adjust their laws in this way. Doing so would do little or nothing to increase incentives for the creation of new medicines and vaccines and would seriously impair the availability of such drugs to their residents.

As noted at the outset of this section, an alternative way of reducing the current biases against the three zones in Figure 4 would be to curtail the rights associated with innovations that fall outside them. The ways in which this might be achieved are probably already apparent.

The most obvious is that the duration of the rights associated with so-called “me-too” drugs could be reduced. This is where the constraints upon U.S. lawmakers’ discretion become relevant. *Retroactive* reduction of patent terms – in other words, shortening the duration of existing patents on me-too drugs – would not run afoul the TRIPS Agreement unless the surviving term were shorter than 20 years from the date of the patent application. However, for the reasons we have discussed, in the United States such a change would likely be deemed unconstitutional. Whether retroactive reduction of the duration of data-exclusivity rights would violate the Constitution is much less clear, but it would undoubtedly provoke the ire of the pharmaceutical firms that hold such rights. Their opposition would doom any initiative of this sort. *Prospective* adjustments of the duration of these rights would not implicate the Constitution, but the resistance of the firms would be almost as adamant. The probability of prevailing against such opposition seems low enough that we put this option to one side.

The second approach would be to reduce the availability of injunctive relief in cases where the patents on me-too drugs have been found to be infringed. As noted above, securing an injunction in such a case is more difficult than it used to be, but not impossible. Patentees’ access to injunctions could be reduced further. The courts could do so by invoking the same criterion mentioned above: the “public interest.” In his concurring opinion in the *eBay* case, Justice Kennedy (joined by three colleagues) already identified three types of patents whose violation should be especially unlikely to trigger injunctions: those held by nonpracticing entities; business-method patents; and patents in fields susceptible to royalty stacking. Kennedy’s list has proven remarkably influential. To his set of disfavored types could be added a fourth: patents on me-too drugs.

The prospects of this recommendation are much better than those of the first option. For the reasons we have discussed, neither the TRIPS Agreement nor the federal Constitution

would stand in the way. And because this reform could be made by the courts and would entail merely an adjustment of an existing doctrine, opposition by the pharmaceutical firms would be much less efficacious. Indeed, if it were paired with the reform suggested above – namely, enhancement of their ability to obtain injunctions when the patents on pioneering drugs were infringed – the firms might well support it.

The final option would apply to the laws of developed countries the modification of the nonobviousness doctrine that we discussed at length when considering modifications of the laws of developing countries. Specifically, the bar could be raised to exclude from patentability “a new form of a known substance which does not result in the enhancement of the known efficacy of that substance.”<sup>73</sup>

The Fifth Amendment would likely not prevent such a reform in the United States. As we have noted, the U.S. nonobviousness standard has been raised and lowered several times. Against this background, even a retroactive adjustment of the sort we have proposed would likely pass constitutional muster. The current patentees applied for and acquired their patents aware of the government’s demonstrated habit of periodically redefining “nonobvious” to meet altered economic and social circumstances. For constitutional purposes, they could and should be deemed to have accepted that risk – in much the same way that landowners are deemed to have acquired their holdings with the knowledge that state and local governments, using their “police powers,” might change the rules governing permissible uses of the tracts in light of altered conditions. In any event, prospective reform of this sort would pose no constitutional problem.

However, the pharmaceutical firms would almost certainly oppose such a change – even if it were only prospective. As a result, its prospects would hinge upon whether it could be packaged with reforms that the firms would support, such as the expansion of the rights associated with patents on breakthrough drugs.

### *3. Respecting the TRIPS Flexibilities*

Our final recommendation is straightforward but important. In the first half of this chapter, we examined the “flexibilities” that developing countries have to limit patent protection for pharmaceutical products, and we encouraged the governments of those countries to exercise their discretion more often and aggressively. We noted that one of the reasons why they have used their powers infrequently is that they fear retaliation by the adversely affected pharmaceutical firms or by the United States Trade Representative. That fear is justified by the manner in which the firms and the USTR have frequently acted in the past.

A simple way in which the government of the United States could come to the aid of developing countries would be to forbid such retaliation. Specifically, all executive officers, including the USTR, could and should be instructed to cease imposing sanctions on countries that adjust or apply their IP regimes in ways that are permitted by the multilateral treaties to

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<sup>73</sup> See the text accompanying notes 20ff, above.

which those countries have agreed. In addition, pharmaceutical firms should be forbidden to retaliate against countries that make such adjustments.

This suggestion is not radical. After all, in many other contexts, we forbid private parties to retaliate against others for exercising their legal rights. For example, employees who seek to organize unions, persons who file civil-rights claims, and tenants who complain about the poor condition of their apartments are all shielded from retaliation from the parties disadvantaged by their actions.<sup>74</sup> Countries that exercise their legal authority to curtail IP rights to address health emergencies could and should be afforded similar protection.

Less obvious but equally important, the governments of developed countries, when they negotiate “free-trade agreements” with developing countries, should cease hobbling their exercise of the TRIPS flexibilities. For the reasons we have discussed, the powers retained by developing countries by the terms of TRIPS and by its subsequent interpretations and amendments are socially beneficial. Developing countries should not seek to limit them.<sup>75</sup>

If U.S. lawmakers wanted to maximize the freedom of developing countries to use the TRIPS flexibilities, they could go even further. In addition to forbidding the USTR to discourage or penalize exercises of those options, Congress (or the President) might require the USTR to provide developing countries advice that would assist them in using these tools. Several U.S. government agencies already routinely and conscientiously provide private parties with guidance concerning the permissibility of proposed courses of conduct. For example, the Internal Revenue Service issues “private revenue rulings” to individuals or firms who want assurance concerning the tax implications of business plans, and the Federal Trade Commission indicates in advance whether specific mergers would be permissible.<sup>76</sup> U.S. law could be amended to require the USTR to do something analogous when asked by a developing country.

Suppose, for example, that the government of Ghana was considering following the lead of Israel in imposing a compulsory license on a drug designed to alleviate COVID-19.<sup>77</sup>

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<sup>74</sup> See, e.g., *Edwards v. Habib*, 397 F.2d 687 (D.C.Cir. 1968), cert. denied, 393 U.S. 1016 (1969); EEOC Enforcement Guidance, “Unlawful Disparate Treatment of Workers with Caregiving Responsibilities” (2007), Section III, <http://www.eeoc.gov/policy/docs/caregiving.html#retaliation>. But cf. Hemphill and Suk, “The Fashion Originators’ Guild of America: Self-Help at the Edge of IP and Antitrust” (2013) (describing, in favorable terms, the use of boycotts “to mimic the effect of intellectual property protection that has not yet been granted by the legislature”).

<sup>75</sup> A crucial component of this modification of U.S. Policy would be recognition that the principles embodied in the Doha Declaration extend, not just to patent rights, but also to data-exclusivity rights. For persuasive discussion of the ambiguity of the FTAs on this issue – and the corresponding need for clarification of the flexibilities enjoyed by developing countries, see Burcu Kilic (Public Citizen), “Submission to the United Nations High-Level Panel on Access to Medicines” (February 2016), <http://www.unsgaccessmeds.org/inbox/2016/2/26/0cf4qijez0vtgr8fmrrc3we4ziaz01>.

<sup>76</sup> See Understanding IRS Guidance, <https://www.irs.gov/newsroom/understanding-irs-guidance-a-brief-primer>; Premerger Notification and Merger Review Process, <https://www.ftc.gov/tips-advice/competition-guidance/guide-antitrust-laws/mergers/premerger-notification-merger-review>.

<sup>77</sup> See Dani Kass, “Israel Defies AbbVie IP To Import Generic Drugs For COVID-19,” *Law 360* (March 19, 2020), <https://www.law360.com/articles/1255079/israel-defies-abbvie-ip-to-import-generic-drugs-for-covid-19>.

Prior to doing so, the Ghanaian government could submit a description of the plan to the USTR and request a ruling concerning the permissibility of the initiative in question. The ideal response would consist of a published, reasoned analysis of the compatibility of the proposed initiative with TRIPS and other multilateral agreements. A more modest and practicable response, in light of the limited resources and authority of the USTR, would consist of a simple statement that the agency would or would not initiate proceedings to challenge the initiative. The United States would be bound by the USTR's response, much as the IRS is bound by its "revenue rulings."

To be sure, the creation of such a mechanism would entail a significant adjustment of the USTR's responsibilities. For many years, the agency has staunchly defended the interests of the pharmaceutical firms based in the United States whenever they have objected to initiatives by developing countries to promote access to medicine.<sup>78</sup> To provide countries good-faith determinations of whether it intended to challenge proposed initiatives, the USTR would have to change its practices and culture considerably.

The reorientation might be justified in either of two ways. First, the USTR might be persuaded to take more seriously its current statutory charge. In its own mission statement, the agency interprets that charge as follows: "American trade policy works toward opening markets throughout the world to create new opportunities and higher living standards for families, farmers, manufacturers, workers, consumers, and businesses."<sup>79</sup> This statement appropriately recognizes that U.S. trade policy can and should be shaped to promote the welfare of all sectors of the population, not just businesses concerned with maximizing their export markets. As noted earlier in this article, it is not certain that increasing the ability of firms in developing countries to manufacture drugs will always directly benefit the United States, but surely the resultant improvements to public health and economic development in those countries would redound to the net benefit of U.S. residents in at least some cases. For example, if augmentation of local production significantly reduced the presence of substandard antibiotics in developing countries, the resulting inhibition of the development of drug-resistant strains of bacteria would be, in the long run, hugely beneficial to everyone on the planet, including U.S. residents. Similarly, the universal provision of vaccines can lead to a speedier recovery of the global economy from global pandemics, benefiting everyone in the long run, including U.S. residents. A declaratory-judgment system of the sort proposed above would enable the agency to identify such situations and thus to provide governments and firms in developing countries clarity concerning their authority to proceed.

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<sup>78</sup> See, e.g., Mike Palmedo, "Analysis of Special 301 Listings 2009-2020," (2020), [https://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=3680332](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3680332).

<sup>79</sup> See Office of the United States Trade Representative, <https://ustr.gov/about-us/about-ustr>. The way in which the USTR describes "the benefits of trade" is consistent with this mission statement: "Trade is critical to America's prosperity -- fueling economic growth, supporting good jobs at home, raising living standards and helping Americans provide for their families with affordable goods and services.... Trade expansion benefits families and businesses by: Supporting more productive, higher paying jobs in our export sectors; Expanding the variety of products for purchase by consumers and business; Encouraging investment and more rapid economic growth. Trade keeps our economy open, dynamic, and competitive, and helps ensure that America continues to be the best place in the world to do business." <https://ustr.gov/about-us/benefits-trade>.

The second route would be more sweeping in its implications and would likely require statutory change. Arguably, the aggressive way in which the USTR has been defining U.S. trade policy since at least 1988<sup>80</sup> is no longer consistent with U.S. foreign policy as a whole. The latter certainly includes some degree of attention to the welfare of the residents of the rest of the world. To consistently privilege the interests of U.S.-based businesses over the health of the residents of the developing world is no longer (if it ever was) compatible with the overall aspirations of the United States as a player on the world stage.

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<sup>80</sup> See, e.g., Statement of Michael Froman, United States Trade Representative, Hearing Before the House Committee on Ways and Means, July 18, 2013:

“As President Obama has made clear, our focus must be to promote growth, create American jobs and strengthen our middle class. USTR can contribute to this effort in three important ways: First, by opening markets around the world so we can expand our exports; second, by leveling the playing field so that our people can compete and win in the global economy; and third, by ensuring that the rights and trade rules we have fought so hard for are fully implemented and enforced.

Trade policy, negotiated and enforced vigorously to reflect both our interests and our values, gives our workers, farmers and ranchers, our manufacturers and service providers, our innovators, creators, investors in businesses of all sizes the best chance to compete around the world.”

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