

Harmonization and Its Discontents: A Case Study of TRIPS Implementation in India's Pharmaceutical Sector

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INTRODUCTION

The last few decades have seen a surge of new intellectual property (IP) treaties, part of a trend of “upward harmonization” aimed at making IP rights stronger around the world, and especially in developing countries. The most important of these treaties is the Trade-Related Aspects of Intellectual Property (TRIPS) Agreement, which requires all members of the World Trade Organization (WTO) to adopt and enforce relatively high minimum standards of IP protection.¹

Those who support upward harmonization argue that it will have positive effects on trade, foreign direct investment, and global innovation.² Opponents contend that such harmonization could ossify the imperfect IP system of the North and impede development.³ The most acute criticisms of the trend have focused on the potential impact of TRIPS on health. Because TRIPS requires developing countries to provide patents on pharmaceuticals, it has the potential

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

2. See, e.g., KEITH E. MASKUS, *INTELLECTUAL PROPERTY RIGHTS IN THE GLOBAL ECONOMY* 186–94 (2000) (describing and evaluating these claims).

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

to limit the access of patients in those countries to less expensive generic versions of new medicines.

The effects of the TRIPS Agreement, however, depend on empirical questions that have yet to receive much attention in the literature: Can TRIPS in fact oblige developing countries to “harmonize” their IP laws with those of developed countries?⁴ Will the Agreement achieve the primary goal that most agree was set for it—to require developing countries to adopt IP regimes comparable to those in developed countries?⁵ Conversely, how much flexibility does the legalistic framework of TRIPS offer developing countries, not only in theory but also in practice?⁶ This is an opportune moment to address these questions because we are entering a new age of implementation in international IP law. TRIPS transition periods for developing countries have mostly expired,⁷ new multilateral harmonization efforts have foundered,⁸ and conversations have shifted toward topics of implementation and enforcement.⁹

The refrain that TRIPS is a “harmonizing agreement” implies that the Agreement will bring the laws and practices of WTO members into substantial

4. “Harmonization” is not usually defined in the international IP literature and is susceptible to a variety of meanings. It may be thought of as “the adoption of an international standard that adjusts the regulatory standards or procedures of two or more countries until they are the same.” Sidney A. Shapiro, *International Trade Agreements, Regulatory Protection, and Public Accountability*, 54 ADMIN. L. REV. 435, 436 (2002). A looser definition would treat harmonization as the adoption of standards or agreements that bring state practices closer to one another. Here I intend the term to refer to whether the TRIPS Agreement can require developing countries to adopt developed-country-style IP protections, and produce standardization between countries that might reduce costs for applicants and patent offices.

5. See, e.g., John F. Duffy, *Harmony and Diversity in Global Patent Law*, 17 BERKELEY TECH. L.J. 685, 695–96 (2002).

6. I focus on TRIPS because it is the most comprehensive and important international IP treaty today, particularly because it is enforceable through the WTO’s dispute resolution process. Flexibilities available under TRIPS may be restricted by other international agreements, including new multilateral agreements and bilateral free trade agreements. The potential implications of such initiatives for the flexibilities addressed here are discussed *infra* at text accompanying notes 402–06.

7. See TRIPS, *supra* note 1, arts. 65–66; see also World Trade Organization, Ministerial Declaration of 14 November 2001, WT/MIN(01)/DEC/2, 41 I.L.M. 746 (2002) [hereinafter Doha Declaration] (extending the transition period for least-developed country members with respect to pharmaceutical products).

8. See Graeme B. Dinwoodie, *Some Remarks on the Limits of Harmonization*, 5 J. MARSHALL REV. INTELL. PROP. L. 596, 603 (2006) (“[T]he current political economy of intellectual property lawmaking nationally and internationally makes it hard to see much progress on substantive treaty-based harmonization in the next few years.”); Amy Kapczynski, *The Access to Knowledge Mobilization and the New Politics of Intellectual Property*, 117 YALE L.J. 804, 836 (2008) (discussing the collapse of broadcasting rights and substantive patent law treaty negotiations at the World Intellectual Property Organization (WIPO)).

9. See, e.g., Liza Porteus Viana, *US Lawmakers Seek to Fuel International IP Enforcement Activities*, INTELL. PROP. WATCH, Nov. 8, 2007, <http://www.ip-watch.org/weblog/index.php?p=816> (discussing various new enforcement initiatives supported by the United States, including a proposed Anti-Counterfeiting Trade Agreement, domestic bills on IP enforcement, and the recent dispute initiated at the WTO by the United States against China regarding copyright enforcement).

conformity with one another. There is, of course, room for skepticism. Some proponents of TRIPS suggest that developing countries will cheat by failing to enforce the Agreement or by ignoring its requirements.¹⁰ Experts in international IP law have emphasized instead that TRIPS leaves significant “wobble room” for developing countries, and that, if pressured, these countries may invoke its flexibilities to resist the Agreement’s objectives.¹¹

To date, the academic conversation about the harmonizing power of TRIPS has been largely theoretical, based on predicted effects and the formal flexibilities available under the Agreement.¹² This Article advances that literature by adopting an empirical case study approach, based on field research and interviews in one key location: the pharmaceutical sector in India. The location is well suited to an inquiry into the dynamics and limits of harmonization under TRIPS, for several reasons. It is in the domain of pharmaceuticals that the Agreement is arguably the most consequential and controversial. As we will see, India has exceptionally strong motivation and capacity to implement TRIPS in a fashion that responds to local needs.¹³ Many developing countries, particularly the poorest ones, have adopted IP laws that are more restrictive than TRIPS requires.¹⁴ India has instead mapped out an

10. See, e.g., Charles S. Levy, *Implementing TRIPS—A Test of Political Will*, 31 L. & POL’Y INT’L BUS. 789, 789 (2000) (“The real test of TRIPS and the WTO will be whether developing countries meet these obligations, and if they do not, whether developed countries will hold them accountable until they reach full compliance with TRIPS. Although it is still early, all indications point toward significant noncompliance by key developing countries.”); John Gladstone Mills III, *A Transnational Patent Convention for the Acquisition and Enforcement of International Patent Rights*, 88 J. PAT. & TRADEMARK OFF. SOC’Y 958, 961 (2006) (“The creation of the WTO and the signing of the TRIPs Agreement gave support to the complete harmonization approach. However, the first five years of TRIPs provide scant basis for optimism about prospects for complete harmonization. Of developed, developing, and least-developed countries, only the developed countries appear to be capable of compliance in the near term.”).

11. J.H. Reichman, *The TRIPS Agreement Comes of Age: Conflict or Cooperation with the Developing Countries?*, 32 CASE W. RES. J. INT’L L. 441, 458–59, 461 (2000). The term “TRIPS flexibility” designates domains of IP law that may be adjusted, consistently with the Agreement, to respond to local context and priorities. See *infra* p. 1588.

12. See, e.g., CAROLYN DEERE, *THE IMPLEMENTATION GAME: THE TRIPS AGREEMENT AND THE GLOBAL POLITICS OF INTELLECTUAL PROPERTY REFORM IN DEVELOPING COUNTRIES* 21 (2009) (noting that “[t]o date, WTO scholars have generally examined implementation from a legal or descriptive perspective, often overlooking the ways in which it is a dynamic political process and the scope for different interpretations of legal commitments” and noting that there has been “surprisingly little . . . analysis of the implementation process”). Deere’s new study is unusual for its focus on implementation, but adopts a survey approach rather than the in-depth case study used here. Janice Mueller has written a comprehensive guide to the new Indian Patents Act, but does not focus on the issues of implementation and harmonization that provide the impetus for the present Article. See Janice M. Mueller, *The Tiger Awakens: The Tumultuous Transformation of India’s Patent System and the Rise of Indian Pharmaceutical Innovation*, 68 U. PITT. L. REV. 491 (2007).

13. See *infra* Part I; see also DEERE, *supra* note 12, at 310 (citing India as one of the few developing countries that has had “access to national or regional experts capable of tailoring the implementation of international IP obligations to foster national development objectives”).

14. DEERE, *supra* note 12, at 13 (concluding from a review of formal legal implementation

extraordinary array of TRIPS flexibilities, some of which are unknown elsewhere in the world.

The primary aim of the Article is to contribute to the international IP literature by enriching our understanding of the nature and utility of TRIPS flexibilities, and of the potential for TRIPS to serve as a harmonizing force. It demonstrates, first, that TRIPS offers developing countries substantially more formal flexibility in the domain of pharmaceuticals than has commonly been recognized. To date, conversations about TRIPS flexibilities have focused largely on the mechanism of compulsory licensing.¹⁵ I use the Indian example to detail several other important flexibilities that have received much less attention in the literature, including limits on patentable subject matter, expansive procedural opportunities to challenge patents, and restrictions on injunctive remedies.¹⁶ Using these flexibilities, countries could facilitate substantial competition in the pharmaceutical sector without the need to ever issue a compulsory license.

Second, I demonstrate the substantial difficulties that developing countries face in implementing TRIPS flexibilities, contributing to the existing literature by providing a structured and detailed account of these obstacles and by demonstrating that they are not ancillary to the transnationalization of patent law, but intimately tied up with it.¹⁷ While TRIPS as a formal matter cannot produce deep harmonization, it nonetheless channels a strong harmonizing force, because it inserts countries into a transnational circuit that fills in the gaps in the Agreement and that works against the use of TRIPS flexibilities. Limits on administrative resources, the influence of transnational legal networks, and the threat of unilateral retaliation from high-protection jurisdictions all make it difficult for countries like India to implement an autonomous vision of patent law. The case study approach permits us to bring such obstacles into view, and to develop a more concrete account of the implications of the transnationalization of law in this domain, particularly for developing countries.

Third, I identify three compensating strategies that may facilitate the effective use of TRIPS flexibilities, responding to the transnationalized pressures that TRIPS implementation sets up.¹⁸ I call these strategies fragmentation, mimicry, and counter-harmonization. As I will describe, fragmentation identifies the ability of unique local legal requirements to introduce friction into transnational circuits of influence. Mimicry works these circuits against the grain by legitimating local law with reference to the law of

of TRIPS that more than one-third of developing country members implemented “a broad range of TRIPS-plus provisions in their laws”).

15. See *infra* note 99.

16. See *infra* Part II.

17. See *infra* Part III.

18. See *infra* Part IV.

high-protection countries while reinscribing the meaning of those texts and precedents. Counter-harmonization seeks to rewrite these transnational circuits by creating an alternative model of patent law that is coordinated among developing countries. As I demonstrate, the last strategy shows the most promise, because it offers countries safety in numbers, can lower the administrative costs of implementing an alternative patent law, and can generate a transnational legal counterculture.

Rather than reject TRIPS, India has entered fully into the Agreement, while also creatively interpreting its terms. (I deliberately avoid the terminology of “resistance” here, because that term presupposes that TRIPS means and requires what its proponents intended it to mean and require. The dynamics of TRIPS implementation in developing countries instead precisely call into question what it *means* to faithfully adhere to TRIPS.) This suggests that the age of TRIPS implementation will constitute a new kind of global community of disagreement about the terms of IP law. In previous work, I have discussed the potential of international law to constitute global publics, by drawing movements and counter-movements into its language and terms.¹⁹ Here I extend this perspective to governmental actors. TRIPS has pulled Indian parliamentarians and patent examiners alike into a transnational discourse of patent law. This has important implications for how India implements its new law, and for how we conceptualize the operation of international law more generally. Although India has incorporated an exceptionally broad range of flexibilities into its patent law, the dynamics identified here (related to resource limitations, transnational legal cultures, and the continued existence of extralegal pressure) make it difficult for India to implement these flexibilities. As I show, these dynamics are not ancillary to, but intimately bound up with, the legalization of the transnational domain of patent law. This suggests that legalization cannot simply be identified, as some prominent trade law scholars have suggested, with the substitution of politics for principle, and with the leveling of power differences between states. It also suggests a new perspective on the debate over whether the WTO has a “constitutional” form, and if so, what this means. To date, those who claim a constitutional nature for the WTO have identified that nature with a move beyond politics. The analysis offered here suggests that if the WTO has a constitutional nature, it lies in its capacity to mobilize and channel, rather than to suppress or transcend, political disagreement. While the implications of these points cannot be fully elaborated here, some possibilities are discussed in the Conclusion.

The Article proceeds in four Parts. Part I provides the background needed to understand the dynamics and implications of TRIPS implementation in India’s pharmaceutical sector. Part II identifies and explains the most important flexibilities emerging in India, which include novel subject matter limitations, a

19. See Kapczynski, *supra* note 8, at 879–83.

high threshold for obviousness, procedural limitations such as oppositions and disclosures, limits on injunctive remedies, and strong patent misuse standards. Part III leverages the case study approach to enumerate the dynamics that make it difficult for India to fully and autonomously make use of these flexibilities and demonstrates that these dynamics are not ancillary to, but are rather shaped by, the increasingly transnationalized nature of patent law. Part IV discusses three strategies emerging in India to counteract these barriers, strategies that I call fragmentation, mimicry, and counter-harmonization. The Conclusion elaborates on the contributions of the Article to the international IP literature, and to recent debates about the implications of the legalization and constitutionalization of the world trading order.

I

TRIPS AND THE EVOLUTION OF INDIA'S PATENT LAW

In 2005, in order to comply with the requirements of TRIPS, the Indian government introduced product patents on pharmaceuticals. For the previous three decades, such patents had been forbidden, allowing India to develop one of the most robust generic pharmaceutical industries in the world. Prior to TRIPS, Indian companies and global health advocates operated largely in ignorance of the relationship between patent law and pharmaceutical policy. Over the decade that followed the signing of TRIPS in 1995, these groups developed a new sophistication about patents, which they put to work in the debates concerning the shape of India's new patent law. Responding to their advocacy, the Indian government adopted several novel and far-reaching flexibilities in its new law, which Part II will describe in detail. Indian government officials thus were drawn into the language of TRIPS, seeking to implement its requirements in a manner that met local concerns about access to healthcare and the development of local industry. In the process, they were inserted into a circuit of transnational influences and dynamics that shape how India's patent law operates, as Parts III and IV will show.

A. The Pre-TRIPS Era

Pharmaceutical patents were first introduced to India by the British in the colonial era.²⁰ In 1970, concerned about the dominance of foreign pharmaceutical firms and the high price of medicines, India changed course, passing a patent law prohibiting product patents on medicines.²¹ At the time,

20. India's first patent law was passed in 1856, during the rule of the British East India Company and just prior to the formal beginning of the British Raj. P. NARAYANAN, PATENT LAW 5 (4th ed. 2006).

21. The Patents Act, 1970, No. 39, § 5 (India), *reprinted in* P. NARAYANAN, PATENT LAW 546 (3d ed. 1998) (excluding patents on "substances intended for use, or capable of being used, as food or as medicine or drug").

foreign firms controlled about 70 percent of the Indian market,²² and Indian drug prices were among the highest in the world.²³ Colonial era patent laws were an important factor: foreign firms used them to their advantage, winning victories in court that helped suppress competition from local companies.²⁴

The 1970 Act served as a substantial driver of three decades of growth in the domestic pharmaceutical industry.²⁵ In the years that followed it, the number of patents granted in India dropped precipitously.²⁶ Although the law permitted process patents related to medicines, they were very limited in scope²⁷ and rarely sought.²⁸ The law thus created significant space for the entry of local pharmaceutical firms,²⁹ and they rapidly increased their share of the

22. See SUDIP CHAUDHURI, *THE WTO AND INDIA'S PHARMACEUTICALS INDUSTRY: PATENT PROTECTION, TRIPS, AND DEVELOPING COUNTRIES* 1, 29 (2005) (estimating 68 percent); P. K. Ramachandran & B. V. Rangarao, *The Pharmaceutical Industry in India*, 7 *ECON. & POL. WKLY.* M-27, M-30 (1972) (estimating 75 percent).

23. STAFF OF S. COMM ON THE JUDICIARY, SUBCOMM. ON ANTITRUST AND MONOPOLY, 87TH CONG. 1ST SESS., REP. NO. 448 (June 27, 1961) 41 tbl.19 (showing India with the highest prices of the seventeen countries surveyed, which included the United States).

24. CHAUDHURI, *supra* note 22, at 128–32.

25. See, e.g., Jean O. Lanjouw, *The Introduction of Pharmaceutical Product Patents in India: "Heartless Exploitation of the Poor and Suffering"?* 3 (Nat'l Bureau of Econ. Research, Working Paper No. 6366, 1998), available at www.oiprc.ox.ac.uk/EJWP0799.pdf; Interview with Raghu Cidambi, Advisor, Dr. Reddy's Labs. Ltd., in Hyderabad, India (May 25, 2007) (notes and transcript on file with author); CHAUDHURI, *supra* note 22, at 39.

26. Lanjouw, *supra* note 25 (citing evidence that the number of patents granted fell by 75 percent in the decade after the 1970 Act was passed); Aradhna Aggarwal, *Strategic Approach to Strengthening the International Competitiveness in Knowledge Based Industries: The Indian Pharmaceutical Industry* 16 (Research & Info. Sys. for Dev. Countries, Discussion Paper No. 80, 2004), available at http://www.ris.org.in/Dp80_pap.pdf.

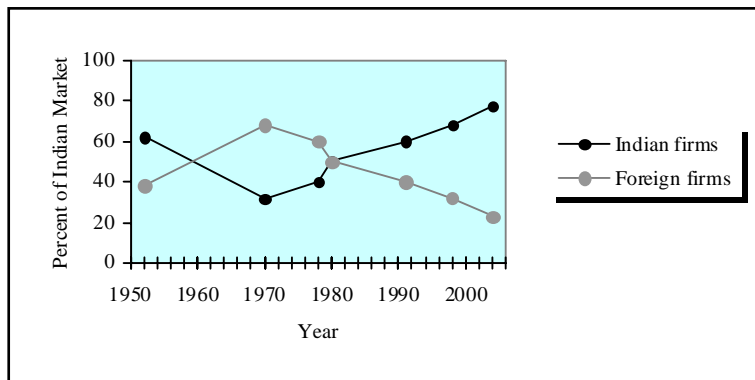
27. For example, such patents only lasted for the shorter of five years from the date of grant or seven years from the date the patent was filed. The Patents Act, 1970, No. 39, § 53(1)(a), reprinted in P. NARAYANAN, *supra* note 21, at 563. They were also automatically endorsed as "Licenses of Right" three years after their grant, permitting any person interested in working them to do so. *Id.* §§ 87–88, reprinted in P. NARAYANAN, *supra* note 21, at 574.

28. See H. Ashok Chandra Prasad & Shripad Bhat, *Strengthening India's Patent System: Implications for Pharmaceutical Sector*, 28 *ECON. & POL. WKLY.* 1037, 1053 tbl.20 (1993) (reporting, for example, that from 1972–89, Ranbaxy obtained eight such patents, while Pfizer obtained four). According to D.G. Shah, such patents were secured primarily for defensive purposes. Interview with Dilip G. Shah, Sec'y Gen., Indian Pharm. Alliance, in New Delhi, India (May 23, 2007) (transcript on file with author).

29. Other government policies likely also played a supportive role in the substantial growth that followed in the industry. Shortly after product patents were eliminated, the government imposed new regulations on foreign and domestic pharmaceutical companies designed to encourage the development of the local sector. Aggarwal, *supra* note 26, at 7; Interview with B.K. Keayla, Convenor, Nat'l Working Group on Patent Laws, in New Delhi, India (May 21, 2007) (transcript on file with author). For example, many drugs could be produced only by the Indian public sector or by companies with 60 percent or more Indian equity. CHAUDHURI, *supra* note 22, at 133; Aggarwal, *supra* note 26, at 7. Strict regulations were also imposed to encourage the local production of active pharmaceutical ingredients (APIs or "bulk drugs") which require the greatest technical sophistication. CHAUDHURI, *supra* note 22, at 133–36. These were supplemented by import restrictions on formulations and tariffs. Lanjouw, *supra* note 25, at 4. Price control regulations imposed in the 1970s reduced local prices on medicines, likely further diminishing foreign firms' interest in the Indian market. See *id.*; CHAUDHURI, *supra* note 22, at 276–78.

Indian market.³⁰

Table 1: Indian Pharmaceutical Market Sales³¹



Indian firms also rapidly became more technically sophisticated. For example, they first produced active pharmaceutical ingredients (APIs) in the mid-1970s, with production steadily increasing over the next three decades.³² Indian companies became skilled in reverse engineering and developing new processes for drug production.³³ Some launched foreign drugs locally before the originator did, apparently even in cases where the originator sought to be the first in the market.³⁴ Over time, the Indian industry also evolved to become extraordinarily competitive and diverse.³⁵ Although comprehensive price comparisons between countries are difficult to come by, numerous surveys indicate that Indian drug prices by the 1990s were among the lowest in the world.³⁶

30. CHAUDHURI, *supra* note 22, at 18 tbl.2.2; *cf.* Aggarwal, *supra* note 26, at 17 (citing evidence that Indian firms accounted for 70 percent of the bulk drugs and 80 percent of the formulations in 1991). Agrawal and Saibaba estimated that local firms supplied 95 percent of the Indian market in 2001, presumably measuring by volume rather than price. Pradeep Agrawal & P. Saibaba, *TRIPS and India's Pharmaceuticals Industry*, 36 *ECON. & POL. WKLY.* 3787, 3787 (2001).

31. CHAUDHURI, *supra* note 22, at 18 tbl.2.2. In 2001, the export market reached over \$1.5 billion, or more than 4 percent of India's total exports. Agrawal & Saibaba, *supra* note 30, at 3787.

32. CHAUDHURI, *supra* note 22, at 40–41 tbl.2.4; Aggarwal, *supra* note 26, at 23. APIs require significantly more technical sophistication to produce than do the subsequent drug formulations and are the most important determinant of the overall cost of production of a drug.

33. CHAUDHURI, *supra* note 22, at 52. This began in the 1970s, expanded in the 1980s, and achieved real success in the 1990s. Interview with Raghunath Cidambi, *supra* note 25. By 1995, the time needed to reverse engineer a drug dropped from three to four years to just one year. Dilip G. Shah, *Generic to Innovative: Transition of Indian Pharmaceutical Companies*, 5 *PHARMA FOCUS ASIA* 13, 14 (2007).

34. CHAUDHURI, *supra* note 22, at 54; Lanjouw, *supra* note 25, at 22.

35. By 2003, the Indian market was supplied by at least 5800 drug manufacturing units, more than one-fifth of which were involved in the production of bulk drugs. CHAUDHURI, *supra* note 22, at 15. Others put estimates of the number of local firms substantially higher, at 7000 to 8000 firms. Aggarwal, *supra* note 26, at 16.

36. See CHAUDHURI, *supra* note 22, at 53–58; K. Bala & Kiran Sagoo, *Patents and Prices*,

B. *The Era of Transition: 1995 to 2005*

Another era of transition began in 1995, when India joined the WTO and with it, the TRIPS Agreement. TRIPS was a bold initiative, one that radically altered the terrain of international IP law. It was the product of a concerted campaign by multinational firms in information-intensive industries that persuaded the United States, Europe, and Japan that their national trade supremacy depended on stronger protection for IP abroad, and especially in developing economies.³⁷ Supporters promoted TRIPS as a way to solve several problems in the existing international IP system. The incentive to join traditional IP treaties was often fairly limited for information-importing countries, but the “single undertaking” nature of the WTO ensured that countries would have to accept TRIPS if they wanted to be part of the WTO.³⁸ Treaties administered through the World Intellectual Property Organization (WIPO) had no effective enforcement mechanism, but the WTO incorporated a new dispute settlement system, allowing for adjudication of TRIPS disputes and for trade sanctions against countries found to be in violation of the Agreement.³⁹ Finally, TRIPS added substantially to the degree of IP protection required by existing treaties, particularly in the area of patents.⁴⁰

TRIPS has caused the most controversy in the domain of access to medicines because it requires patents on pharmaceutical products, which at

HAINews, Apr.–May 2000, available at <http://www.haiweb.org/pubs/hainews/Patents%20and%20Prices.html>; Prasad & Bhat, *supra* note 28, at 1046 tbl.15A, 1051 tbl.18A; Lanjouw, *supra* note 25, at 8–9. Some signs indicate that the private market in India may have become less competitive since these estimates were produced, perhaps attributable to the steady decline of the scope of price controls and/or in the number of small drug companies. Interview with Biswajit Dhar, Professor & Head, Ctr. for WTO Studies, Indian Inst. of Foreign Trade, in New Delhi, India (June 6, 2007) (transcript on file with author); see also CHAUDHURI, *supra* note 22, at 209–10; Anita Kotwani et al., *Prices & Availability of Common Medicines at Six Sites in India Using a Standard Methodology*, 125 INDIAN J. MED. RES. 645, 653–54 (2007).

37. For a discussion of the lobbying and negotiations that led to the TRIPS Agreement, and the catalytic role played by industry, see SUSAN K. SELL, *PRIVATE POWER, PUBLIC LAW: THE GLOBALIZATION OF INTELLECTUAL PROPERTY RIGHTS* (2003).

38. Previously, countries had chosen their IP commitments (for example, to treaties administered by WIPO) in *à la carte* fashion, with no implications for their participation in the world trading regime.

39. Prior to the WTO, multilateral treaties such as the Berne Convention referred parties to the International Court of Justice (ICJ) for the settlement of disputes. See, e.g., Berne Convention for the Protection of Literary and Artistic Works art. 33, Sept. 9, 1886, as last revised at Paris, July 24, 1971, S. TREATY DOC. No. 99-27, 828 U.N.T.S. 221. No actions under IP treaties were ever brought before the ICJ, suggesting that this was an unappealing venue for enforcement efforts. FREDERICK M. ABBOTT ET AL., *INTERNATIONAL INTELLECTUAL PROPERTY IN AN INTEGRATED WORLD ECONOMY* 330 (2007).

40. For example, TRIPS signatories must offer patents “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.” TRIPS, *supra* note 1, art. 27.1. The Agreement also establishes other important requirements, including minimum patent terms and limitations on members’ ability to derogate from patents. TRIPS, *supra* note 1, arts. 31, 33.

least fifty developing countries did not offer at the time of its adoption.⁴¹ Patents tend to generate deadweight social losses in the form of higher prices for consumers.⁴² In the domain of medicines, such losses translate into more limited access to medicines, particularly in developing countries.⁴³ The most important potential gain associated with stronger patent law is the marginal incentive for pharmaceutical innovation that will be provided by additional exclusivity in the new country.⁴⁴ But the marginal effects of patents in jurisdictions that are a very small portion of the world's market will be small, and not likely to outweigh the costs to local consumers.⁴⁵ It is thus fairly clear from the economics literature that higher patent standards for medicines will reduce welfare in developing countries.⁴⁶

Many developing countries strongly opposed the incorporation of TRIPS into the new WTO regime, because they understood its likely negative effects

41. See Carlos M. Correa, *Patent Rights*, in *INTELLECTUAL PROPERTY AND INTERNATIONAL TRADE: THE TRIPS AGREEMENT* 227, 229 (Carlos M. Correa & Abdulqawi A. Yusuf eds., 2d ed. 2008).

42. See, e.g., F. M. Scherer, *A Note on Global Welfare in Pharmaceutical Patenting*, 27 *WORLD ECON.* 1127, 1128 (2004). Perfect price discrimination could eliminate this deadweight loss but is not expected in practice.

43. Generic medicines are typically substantially less expensive than patented versions, and patients in resource-poor settings are particularly reliant on generic medicines. *WORLD HEALTH ORG., THE WORLD MEDICINES SITUATION* 31, 68–69 (2004).

44. Alan V. Deardorff, *Should Patent Protection Be Extended to All Developing Countries?*, 13 *WORLD ECON.* 497, 503 (1990). Extending patent protection to a new jurisdiction could produce gains other than innovation. For example, if a firm refuses to sell in a market and others cannot copy the product (e.g., because it requires closely held know-how), the introduction of patents could induce the firm to enter the market and thus improve social welfare. *Id.* at 502. In the pharmaceutical sector, however, reverse engineering is common and rapid. See *supra* text accompanying notes 33–34. Stronger IP protection could also stimulate foreign direct investment (FDI), but “[i]t is difficult to establish strong theoretical and empirical linkages between intellectual property rights and FDI and technology trade.” Keith E. Maskus, *Implications of Regional and Multilateral Agreements for Intellectual Property Rights*, 20 *WORLD ECON.* 681, 689 (1997).

45. See Carlos A. Primo Braga & Carsten Fink, *The Economic Justification for the Grant of Intellectual Property Rights: Patterns of Convergence and Conflict*, 72 *CHI-KENT L. REV.* 439, 442–43 (1996). Scherer shows that if extending patents to all low-income nations increased rents by these nations' share of global GDP (20 percent), the innovative effect would be far less than required to offset the projected deadweight loss. See Scherer, *supra* note 42, at 1128–29. If lesser patent protection in low-income countries eroded protection in wealthy countries, for example because of arbitrage between markets, it could lessen incentives to innovate in wealthy countries and thus diminish welfare for patients in poor countries who could benefit from cheap copies of these innovations. But evidence from the AIDS drugs context suggests that such arbitrage is still for the most part theoretical, despite substantial existing price differentials across countries. See Kevin Outterson, *Pharmaceutical Arbitrage: Balancing Access and Innovation in International Prescription Drug Markets*, 5 *YALE J. HEALTH POL'Y L. & ETHICS* 193, 262–65 (2005).

46. See Scherer, *supra* note 42, at 1128 (“It is reasonably well established in the economics literature that, especially in a world of AIDS and resistant tuberculosis epidemics, low-income nations enjoy higher economic welfare when they can free-ride on pharmaceutical innovations made and patented in the first world than when they must pay monopolistic prices for the newest and most effective drugs.”).

in this and other areas.⁴⁷ India opposed TRIPS, and particularly its patent provisions,⁴⁸ as did the bulk of the Indian pharmaceutical industry.⁴⁹ Faced with the alternative of remaining entirely outside the WTO framework, India nonetheless acceded to the Agreement, negotiating in the process for certain flexibilities that would limit the effects of the changes it required.

For example, India is often credited with the fact that developing countries were afforded “transition periods” of several years before they had to fully comply with TRIPS.⁵⁰ India was not required to comply with the product patent requirements of TRIPS until 2005,⁵¹ although it did have to create a “mailbox” for the filing of patent applications that would be examined when the 2005 changes came into effect.⁵² While the full legal effects of the Agreement were suspended during this transition period, its effects on India were nonetheless substantial, because of its impact on the behavior and thinking of industry and health advocates.

Facing the looming deadline of TRIPS and fearing that they would lose ground in the local market, Indian firms began to look for new markets. This led them in two directions: towards exports and towards research and development (R&D) targeted at developed-country markets. India first achieved a positive trade balance in pharmaceuticals in the late 1980s, but firms focused their exports largely on unregulated markets in developing countries.⁵³ Wealthy countries have the most lucrative markets for generic drugs,⁵⁴ but extensive regulation creates high barriers to entry.⁵⁵ Indian companies therefore

47. PETER DRAHOS & JOHN BRAITHWAITE, INFORMATION FEUDALISM: WHO OWNS THE KNOWLEDGE ECONOMY? 133–34, 136 (2002); SELL, *supra* note 37, at 108–11.

48. George K. Foster, *Opposing Forces in a Revolution in International Patent Protection: The U.S. and India in the Uruguay Round and its Aftermath*, 3 UCLA J. INT’L L. & FOREIGN AFF. 283, 311 (1998).

49. *Id.* at 307–11.

50. *Id.* at 312; *see also* TRIPS, *supra* note 1, arts. 65–66.

51. TRIPS, *supra* note 1, art. 65.4.

52. *Id.* art. 70.8(a); Appellate Body Report, *India—Patent Protection for Pharmaceutical and Agricultural Chemical Products*, WT/DS50/AB/R (Dec. 19, 1997) [hereinafter *India—Patents*] (requiring India to comply with Art. 70.8(a)). The mailbox was implemented by the Patents (Amendment) Act, 1999, No. 17, Acts of Parliament, 1999, §§ 2, 3. India took other steps towards complying with TRIPS requirements in 2002, when it extended a twenty-year term to all patents, reversed the burden of proof in process infringement cases, and introduced for the first time a definition of “inventive step.” The Patents (Amendment) Act, 2003, No. 38, Acts of Parliament, 2003, §§ 27, 43, 3(f).

53. CHAUDHURI, *supra* note 22, at 45 tbl.2.5; Aggarwal, *supra* note 26, at 26.

54. The United States makes up 50 percent of the global market in pharmaceuticals, and generic drugs make up about 63 percent of the U.S. market by volume. William Greene, *The Emergence of India’s Pharmaceutical Industry and Implications for the U.S. Generic Drug Market* 21–22 (U.S. Int’l Trade Comm’n Office of Econ., Working Paper No. 2007-05-A, 2007). This represented a generics market of \$54.1 billion in 2006. *Id.* at 21. By comparison, the entire Indian pharmaceutical market in 2005 was valued at approximately \$6.3 billion. GAUTAM KUMRA ET AL., MCKINSEY & CO., INDIA PHARMA 2015: UNLOCKING THE POTENTIAL OF THE INDIAN PHARMACEUTICALS MARKET 11 (2007).

55. CHAUDHURI, *supra* note 22, at 180–81, 188 (reporting that “Drug Master File” [DMF]

did not make a serious effort to enter the U.S. generics market until the mid-1990s.⁵⁶ Notably, the first time Indian companies directly encountered patent issues was when they entered U.S. markets.⁵⁷

As Indian companies gained expertise in navigating patent and regulatory filings, their share of U.S. drug filings skyrocketed. Today, Indian companies constitute 25 to 50 percent of all applications for generic drug approval in the United States.⁵⁸ The result has been new, cutthroat competition in some sectors of the U.S. generics market.⁵⁹ Paradoxically, it may be that, as a top executive of one of the largest Indian drug companies asserted, “U.S. consumers are the biggest beneficiaries, in value terms, of the Indian generics industry.”⁶⁰

Along the way, India has developed a significant trade advantage.⁶¹ It has become one of the largest suppliers of pharmaceutical formulations in the world by volume, as well as one of the top API suppliers.⁶² Top-tier Indian companies are also increasingly transnationalized. Leading Indian firms now make substantially more of their revenue through exports than they do through

applications cost up to \$200,000 and the more complex “Abbreviated New Drug Application” [ANDA] filing can cost up to \$1 million and take up to five years to complete); *cf.* Aggarwal, *supra* note 26, at 56.

56. Shah, *supra* note 33, at 11; Interview with Gopakumar Nair, Gopakumar Nair Assocs., in Mumbai, India (June 11, 2007) (transcript on file with author); *see also* Aggarwal, *supra* note 26, at 29 tbl.13 (explaining that the United States was less than 4 percent of India’s export market in 1989–90).

57. Interview with Raghu Cidambi, *supra* note 25; Interview with Gopakumar Nair, *supra* note 56.

58. Most Indian companies that sell into the U.S. market supply APIs under the DMF procedure. CHAUDHURI, *supra* note 22, at 196. The share of U.S. DMF filings made by Indian companies increased from 14 percent in 2000 to about 50 percent in 2007. Hitesh Gajaria, *India to Be Amongst Top Three Generic Makers in the World*, EXPRESS PHARMA, Jan. 16–31, 2008, available at <http://www.expresspharmaonline.com/20080131/indianpharmain202008.shtml>. Only a select group of top Indian companies file ANDAs, but here too, growth in recent years has been explosive. CHAUDHURI, *supra* note 22, at 196–97. The first ANDA filed by an Indian company was in 1998. Interview with Dilip G. Shah, *supra* note 28. Today, Indian companies are the second-largest filers of ANDAs in the United States, with a share of approximately 25 percent. Greene, *supra* note 54, at 17; Gajaria, *supra*.

59. Interview with Raghu Cidambi, *supra* note 25; *see also* Greene, *supra* note 54, at 23. The U.S. generics market has in fact become so competitive that profitability has declined and Indian companies have turned increasingly to higher margin export markets such as Europe and Japan. Greene, *supra* note 54, at 20.

60. Interview with Raghu Cidambi, *supra* note 25. Indian companies still represent a fairly small percentage of the U.S. generics market, Greene, *supra* note 54, at 23–25, but they are important in the markets where they compete, as well as in driving down the price of APIs. *Id.* at 26–27.

61. CHAUDHURI, *supra* note 22, at 45 tbl.2.5; Aggarwal, *supra* note 26, at 26.

62. Some estimate India as the largest supplier of drug formulations by volume and “one of the largest” producers of APIs. *See, e.g.*, Shubham Chaudhuri, Pinelopi K. Goldberg & Panle Jia, *Estimating the Effects of Global Patent Protection in Pharmaceuticals: A Case Study of Quinolones in India*, 96 AM. ECON. REV. 1477, 1481–82 (2006). Others rank India among the top five pharmaceutical producers in the world by volume and in the top twenty exporters of APIs. *See, e.g.*, Aggarwal, *supra* note 26, at 1–2. The reason for the discrepancy is not clear.

local sales.⁶³ Several of the biggest names have recently acquired companies in other markets, or have been acquired by companies based outside of India.⁶⁴

Intriguingly, key players in the Indian industry credit these recent successes to the globalization of IP norms. According to Gopakumar Nair, an expert on IP issues with four decades of experience in the Indian industry,

if the patent and product patent regime had not come to India, the tendency to learn more about patents would not have come . . . [and the industry would not have had the] ability to go to markets like Japan and Australia. . . . Indians have now become global players because global standards of intellectual property have come to India.⁶⁵

D.G. Shah, the secretary general of the Indian Pharmaceutical Alliance (IPA), contends that the progression towards export markets was a direct response to TRIPS, because the Agreement forced leading Indian companies to look outside of India when planning their strategy for growth.⁶⁶ According to him, when the “Indian industry saw that one of the drivers of growth, which was new product[s], [was] going to be hit with the patent regime, their response was ‘let’s go into the larger market’ They started going to [the] US in only ’98, not before.”⁶⁷

The entry of Indian companies into new product R&D was also triggered in part by the TRIPS Agreement.⁶⁸ Commentators often suggest that TRIPS will stimulate R&D because of the incentivizing power of patents,⁶⁹ but the Indian example suggests a different mechanism, where TRIPS acts not as a carrot but as a stick. Raghu Cidambi, a top advisor to Dr. Reddy’s, one of the

63. Greene, *supra* note 54, at 19. For example, more than 80 percent of the sales of the leading firm Ranbaxy occur outside of India. RANBAXY LABS. LTD., ANNUAL REPORT 12–14 (2007), http://www.ranbaxy.com/investorinformation/annual_pr2007.aspx.

64. Dr. Reddy’s recently purchased the German Betapharm, Ranbaxy purchased the Romanian Terapia, and Matrix acquired the Belgian Docpharma. *See Pharma Getting the Dose Right*, FINANCIAL EXPRESS (India), Oct. 29, 2006, available at <http://www.financialexpress.com/news/pharma-getting-the-dose-right/182225/0>. The U.S. company Mylan later purchased Matrix. *Id.* One of the largest Japanese drug firms recently acquired a controlling share of Ranbaxy. *See Ranbaxy Labs’ Singh Dynasty Comes to an End as Chief Executive Resigns*, DAILY TELEGRAPH (London), May 25, 2009, at 2.

65. Interview with Gopakumar Nair, *supra* note 56. Nair was a CEO, headed the Indian Drug Manufacturers’ Association, participated in the TRIPS negotiations, and now leads a top IP consulting firm. *See* About Dr. Gopakumar G. Nair, <http://www.gnaipr.com/gkgnair.php> (last visited Oct. 21, 2009).

66. Interview with Dilip G. Shah, *supra* note 28. The IPA is one of the two major lobbying groups for Indian generic companies, and represents mostly larger, export-oriented companies.

67. *Id.*; *see also* Interview with Gopakumar Nair, *supra* note 56 (stating that the threat of product patents in India accelerated the export orientation of Indian firms).

68. CHAUDHURI, *supra* note 22, at 157–60. Expenditure on R&D by Indian companies grew sharply in the decade after TRIPS, from approximately \$30 million a year in 1996 to nearly \$250 million a year in 2004. ERNST & YOUNG, UNVEILING INDIA’S PHARMACEUTICAL FUTURE 7 (2005) (on file with author). R&D expenditures as a proportion of sales had fallen from the 1960s to the 1990s. Aggarwal, *supra* note 26, at 22.

69. *See, e.g.*, Alan O. Sykes, *TRIPS, Pharmaceuticals, Developing Countries, and the Doha “Solution”*, 3 CHI. J. INT’L L. 47, 49 (2002).

first Indian firms to begin new product R&D, explained that knowing the company would “face limitations on the number of products that we [could] introduce and grow, we took a conscious decision in the early ’90s to expand our international presence and also to enter into the discovery and innovation businesses.”⁷⁰ Cidambi characterized the process as part of the natural progression of the industry, but one for which TRIPS “provided a trigger.”⁷¹

The orientation of R&D in India’s pharmaceutical sector supports the theory that TRIPS acted by threatening local markets rather than by creating the possibility of new profits in India. To date, Indian firms engaged in R&D have targeted their efforts on diseases prevalent in developed countries, rather than those specific to India.⁷² This is a predictable response to the comparative size of developed-country markets: in 2005, North America, Europe, and Japan accounted for 86 percent of the world’s pharmaceutical market, while India made up just 1.2 percent.⁷³ To the extent that Indian companies do begin to invest in R&D, then, we should not expect these R&D activities to be oriented to local markets and patent incentives, but rather to global markets and patent incentives.

TRIPS may thus have perverse implications for the multinational firms that advocated for it. Although they aimed to push Indian competitors out of the low-value Indian market, they may have also pushed Indian companies *into* the U.S. and EU markets on which their profits much more substantially rely. The desire to retain local markets also pushed Indian companies to advocate strongly in favor of expansive flexibilities during debates over the shape of the patent law, as will be demonstrated.

In the decade prior to TRIPS implementation in India, the Agreement also had a significant influence on local and international health activists, leading them for the first time to appreciate the relationship between patent protection and access to medicines in developing countries. As Ellen ‘t Hoen, long-time leader of the Access to Medicines Campaign at Médecins Sans Frontières (Doctors Without Borders or MSF) has noted, it was after TRIPS was signed

70. Interview with Raghu Cidambi, *supra* note 25. On Dr. Reddy’s leading role in Indian R&D efforts, see CHAUDHURI, *supra* note 22, at 160.

71. Interview with Raghu Cidambi, *supra* note 25.

72. See Interview with Dilip G. Shah, *supra* note 28 (noting that Indian companies engage in R&D for diseases that affect the West and Japan, because they depend for development on partnerships with multinational companies, who demand products with substantial sales potential). A recent review of the R&D activities of the major Indian firms involved in attempts to develop new drugs reported no projects that are clearly targeting diseases with markets predominantly in developing countries, and numerous projects for cancer, metabolic disorders (such as diabetes), asthma, and anti-infectives. See Aggarwal, *supra* note 26, at 49, 51. Anti-infectives could include projects relevant to tropical diseases, but it seems more likely that they would be tested at least initially on conditions prevalent in the North.

73. See COMM’N ON INTELLECTUAL PROP. RIGHTS, INNOVATION AND PUB. HEALTH, WORLD HEALTH ORG., PUBLIC HEALTH, INNOVATION AND INTELLECTUAL PROPERTY RIGHTS 15 (2006) (2005 data provided by IMS health).

that at an international meeting in 1995, for “the first time public health advocates raised the concern that the globalization of new international trade rules and the harmonization of regulatory requirements would restrict countries’ ability to implement drug policies that would ensure access to medicines for all.”⁷⁴ Some meeting participants responded in telling fashion, by suggesting that any problems could be remedied with generic substitution policies (which call for the replacement of patented drugs with generics in instances where patents pose no barrier). As ‘t Hoen has stated, such “comments made it apparent that even drug policy experts at the time had a very limited understanding of the ramifications of new international rules on intellectual property.”⁷⁵

Much changed from 1995 to 2005. Pushed by nongovernmental organizations (NGOs) such as Health Action International, the World Health Organization (WHO) began to study the relationship between the WTO and national essential medicines policies.⁷⁶ NGOs accelerated their activities in connection with the activities at the WHO, the 1999 WTO Ministerial Conference in Seattle, and flashpoints such as the lawsuit brought by thirty-nine pharmaceutical companies against the South African government over a law designed to facilitate access to generic medicines.⁷⁷ The HIV/AIDS crisis provided a focal point for access to medicines campaigners, who articulated TRIPS as a key barrier to affordable generic AIDS medicines in developing countries.⁷⁸ In 2000, India became central to the debate, because a leading Indian company, Cipla, offered breakthrough price discounts, promising to provide HIV therapy for \$385 per year rather than the \$10,000 per year charged by patent-holding companies.⁷⁹ The highpoint of health activists’ engagement with the WTO came in 2001, when NGOs working closely with developing countries secured the passage of the Doha Declaration on TRIPS and Public Health. The Declaration extended the transition period afforded to least-developed countries with regard to pharmaceuticals, addressed certain limitations on the export of generic medicines under compulsory license, and affirmed unequivocally that TRIPS “can and should be interpreted and implemented in a manner supportive of WTO members’ right to protect public

74. Ellen ‘t Hoen, *The Revised Drug Strategy: Access to Essential Medicines, Intellectual Property and the World Health Organization*, in *ACCESS TO KNOWLEDGE IN THE AGE OF INTELLECTUAL PROPERTY* (forthcoming 2010) (on file with author).

75. *Id.*

76. *Id.*

77. *Id.*

78. *See, e.g.*, James Love, Panel Discussion, *AIDS Drugs and the Developing World: The Role of Patents in the Access of Medicines*, 12 *FORDHAM INTELL. PROP. MEDIA & ENT. L.J.* 683, 705 (2002) (discussing the access to medicines crisis and suggesting that “[t]he WTO agreement is the most important thing”).

79. MÉDECINS SANS FRONTIÈRES, *UNTANGLING THE WEB OF ANTIRETROVIRAL PRICE REDUCTIONS* 6 (11th ed. 2008), available at http://www.msfaaccess.org/fileadmin/user_upload/diseases/hiv-aids/Untangling_the_Web/Untanglingtheweb_July2008_English.pdf.

health and, in particular, to promote access to medicines for all.”⁸⁰

By 2005, activists had successfully pushed for massive new HIV/AIDS treatment programs, which Indian generic medicines have played a significant part in sustaining.⁸¹ Thus, when the time came for India to enter fully into the TRIPS Agreement by implementing product patents for medicines, both local industry and local and global health advocates were poised to play a key role in the negotiations.

C. Implementing TRIPS in India

In order to meet the December 31, 2004, TRIPS deadline for the introduction of product patents, India passed an ordinance that temporarily brought its law into compliance.⁸² The measure was set to expire in approximately three months, setting the stage for a period of intense advocacy around the shape of the new bill. The Indian National Working Group on Patents, which had been seeking since 1998 to influence the government’s implementation of TRIPS, lobbied heavily,⁸³ as did the two major lobbying groups for the local generic industry.⁸⁴ The IPA, which represents the largest local generics companies, insisted that the Act include a specific limitation on patentability that would prevent the patenting of new uses of known substances, as well as the patenting of many new forms of known substances.⁸⁵ Local HIV/AIDS organizations such as the Delhi Network of Positive People (DNP+) organized local protests against the bill,⁸⁶ and worked with activist groups abroad who staged actions in the United States, France, Uganda, and Kenya.⁸⁷

80. Doha Declaration, *supra* note 7, ¶ 4. A compulsory license is granted by the government and overrides the exclusivity of the patent in exchange for a royalty. For more on compulsory licensing under TRIPS, see *infra* Part II.D.

81. For data on the role of generic competition in reducing prices of AIDS medicines, and current data on the price of generic versus patented AIDS medicines, see MÉDECINS SANS FRONTIÈRES, *supra* note 79, at 6, 67–70.

82. Patents (Amendment) Ordinance, No. 7 of 2004.

83. Interview with K. M. Gopakumar, Research Officer, Ctr. for Trade & Dev., in New Delhi, India (June 6, 2007) (transcript on file with author); Interview with B. K. Keayla, *supra* note 29.

84. Interview with Dilip G. Shah, *supra* note 28; Interview with Gajanan Wankankar, Executive Dir., Indian Drug Mfrs. Ass’n (IDMA), in New Delhi, India (June 19, 2007) (notes on file with author).

85. This resulted in the amendment of section 3(d) of the 1970 Act. See *infra* Part III.A.1. The ordinance was set to expire and the Congress Party needed the approval of either the BJP party or the left parties to pass the Amendment. See Amit Sen Gupta, *Mashelkan Committee Trips Again*, PEOPLE’S DEMOCRACY, Sept. 20, 2009, http://pd.cpim.org/2009/0920_pd/09202009_7.html. According to D.G. Shah, after lobbying, both the BJP and Left refused to ratify the ordinance as it was. “At that point, with back to [the] wall, Government said, ‘Okay, tell us what do you want.’ And [the local industry] gave six points. [section] 3(d) was one of those . . .” Interview with Dilip G. Shah, *supra* note 28.

86. Interview with Loon Gangte, President, Delhi Network of Positive People, in New Delhi, India (June 20, 2007) (transcript on file with author).

87. See, e.g., Press Release, Act Up-Paris, Global Access to Medicines is Threatened: The Indian Government Must Postpone Amending its Patent Law (Dec. 6, 2004), *available at*

The humanitarian group MSF also weighed in, sharply criticizing the ordinance for failing to include sufficient safeguards to prevent increases in the price of medicines. In particular, MSF urged that the bill should prohibit patenting of new uses of known substances, make full use of TRIPS provisions permitting export under compulsory license, and restore the system of pre-grant oppositions that the ordinance had removed.⁸⁸ Representatives from the WHO and the Joint United Nations Programme on HIV/AIDS (UNAIDS) also wrote to the government, urging it to implement a law that would facilitate access to medicines and that did not go beyond the minimum required by TRIPS.⁸⁹

The debates in Indian Parliament reflected the messages voiced by these local and transnational groups. Parliamentarians referred to the interventions of international organizations, called for the amendments that industry and activists urged, and emphasized the stakes of the decision for patients in India and in other developing countries.⁹⁰ Throughout, many members noted the importance of TRIPS compliance, but also urged that India should not go beyond what TRIPS required.⁹¹

The exceptionally globalized advocacy efforts around the bill resulted in several consequential changes in the new law. These changes consisted of, most importantly, new subject matter exclusions with significant import in the domain of pharmaceuticals, and the resurrection of a full pre-grant opposition

<http://www.cptech.org/ip/health/c/india/actupparis12062004.html>; *African AIDS Sufferers Plea for India to Drop Patents Bill*, AGENCE FRANCE PRESSE, Mar. 21, 2005.

88. MÉDECINS SANS FRONTIÈRES, WILL THE LIFELINE OF AFFORDABLE MEDICINES FOR POOR COUNTRIES BE CUT? 5–6 (2005), available at <http://www.msf.fr/drive/2005-02-01-msf.pdf>.

89. Letter from Jim Yong Kim, HIV/AIDS Dir., World Health Org., to Dr. A. Ramadoss, Minister of Health and Fam. Welfare, Gov't of India (Dec. 17, 2004), available at <http://www.cptech.org/ip/health/c/india/who12172004.html>; Letter from Achmat Dangor, Dir. of Advocacy, Comm. and Leadership, UNAIDS, to Kamal Nath, Minister of Com. and Indus., Gov't of India (Feb. 23, 2005), available at <http://www.cptech.org/ip/health/c/india/unaid02232005.html>.

90. See, e.g., LOK SABHA DEBATES, 4th Sess. (14th Lok Sabha, Vol. VII No. 18), Mar. 22, 2005, at 684, (statement of Shri Suresh Kurup referring to the interventions of the WHO and UNAIDS); *id.* at 632 (statement of Shri Uday Singh noting that “the livelihood of millions of people not only in India but in the lesser developed countries which are dependent on India for medical treatment” were implicated by the bill); *id.* at 675–79 (statement of Shrimati Maneka Gandhi urging a series of points also demanded by industry and activists); see also *id.* at 649 (statement of Shri Rupchand Pal noting calls of concern received from developing countries such as South Africa).

91. See, e.g., *id.* at 633 (statement of Shri Uday Singh); *id.* at 641–42 (statement of Shri Pawan Kumar Bansal); *id.* at 701–04 (statement of Shri Kinjarapu Yerrannaidu); see also *id.* at 647 (statement of Shri Rupchand Pal: “We cannot wish away TRIPS. But, our endeavour, struggle and position have all along been to derive as much benefit as possible using the flexibility clauses of the TRIPS.”); *id.* at 675–78 (statement of Shrimati Maneka Gandhi that the “WTO gives us the right to protect our consumer rights in the name of public health” and urging maximal use of flexibilities); *id.* at 717, 719 (statement of Shri Kamal Nath, Minister of Com. and Indus., noting that “whenever we have to meet a commitment . . . if we can, then we should,” but also that other developing countries “are looking at us to find out whether we have got the maximum flexibility” and assuring members that the amendments “use[] the maximum flexibility”).

system.⁹² The resulting law substantially limits the implications of the introduction of product patents on pharmaceuticals, providing a road map to TRIPS flexibilities in this area that is more varied, and that has much more potential to limit exclusivity, than the existing academic literature suggests.

II

TRIPS FLEXIBILITIES IN THE INDIAN CONTEXT

As scholars have noted, “All intellectual property rights regimes . . . have certain policy levers in common, wielded to a greater or lesser extent. All establish, for example, a length of protection, a breadth of protection . . . , and some fair use or policy-based limitations on the scope of protection.”⁹³ In the area of patent law, even seemingly minor adjustments in patent scope can have substantial economic effects.⁹⁴ In the domestic context, such domains of adjustment are often referred to as “policy levers” that can be used to calibrate the law’s application to particular contexts.⁹⁵ In the TRIPS literature, such domains are typically called “flexibilities,” denoting where patent law may be adjusted, consistent with TRIPS, to adapt to different domestic innovation and IP policies.

While TRIPS includes many relatively clear obligations, such as the requirement that patents last at least twenty years,⁹⁶ it also includes many vague and undefined commitments, such as the requirement to engage in “reasonable” efforts to negotiate with patent holders before overriding a patent.⁹⁷ Given the stakes of the Agreement, its flexibilities have been the subject of substantial attention in recent years, particularly in the context of developing-country access to pharmaceuticals. The mechanism of compulsory licensing⁹⁸ has received the lion’s share of attention in this regard, in both academic and policy circles.⁹⁹ A close examination of the Indian context, however, reveals several

92. The 1970 Act had included pre-grant oppositions, but the Ordinance had significantly curtailed them. *Compare* Patents (Amendment) Act, 2005, No. 15, Acts of Parliament, 2005, § 23, with Patents (Amendment) Ordinance, No. 7 of 2004, § 23, and Patents Act, 1970, No. 39, § 25, reprinted in P. NARAYANAN, *supra* note 21, at 553–54.

93. See Pamela Samuelson & Suzanne Scotchmer, *The Law and Economics of Reverse Engineering*, 111 YALE L.J. 1575, 1649 (2002).

94. See Robert P. Merges & Richard R. Nelson, *On the Complex Economics of Patent Scope*, 90 COLUM. L. REV. 839, 839 (1990).

95. See, e.g., Samuelson & Scotchmer, *supra* note 93, at 1649 (introducing the term); Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 VA. L. REV. 1575 (2003) (further developing the concept).

96. TRIPS, *supra* note 1, art. 33.

97. *Id.* art. 31(b).

98. For a definition of compulsory licensing, see *supra* note 80.

99. See, e.g., Frederick M. Abbott, *The WTO Medicines Decision: World Pharmaceutical Trade and the Protection of Public Health*, 99 AM. J. INT’L L. 317 (2005); Frederick M. Abbott, *The TRIPS-Legality of Measures Taken to Address Public Health Crises: A Synopsis*, 7 WIDENER L. SYMP. J. 71 (2001); Nabila Ansari, *International Patent Rights in a Post-Doha World*, 11 CURRENTS INT’L TRADE L.J. 57 (2002); Aditi Bagchi, *Compulsory Licensing and the Duty of*

other flexibilities with expansive potential that have received far less attention in the literature.

In the process of interpreting the TRIPS Agreement, and in part through the intervention of local industry and health advocates, India introduced robust versions of familiar flexibilities such as compulsory licensing, but also introduced some less common and even entirely new flexibilities. Among those innovations are novel limitations on subject matter, an exceptionally high inventive step standard, procedural requirements that could substantially decrease the grant rate, a patent misuse standard that may sharply constrain voluntary licensing activity, and perhaps most strikingly, limits on injunctive remedies. Rather than rejecting TRIPS, India has entered fully into its terms. In the process, it has demonstrated that, at least formally, TRIPS leaves developing countries with far more expansive flexibility in the area of medicines than has generally been recognized.

A. *Subject Matter and Inventive Step*

India has adopted a set of exclusions to patentability unknown elsewhere in the world and which could sharply limit the number of patents granted in the pharmaceutical context. It has also adopted an exceptionally high threshold for inventive step (or obviousness), which if applied rigorously would have the same effect. These two moves alone could invalidate a substantial percentage of the patents on medicines that would be granted in a jurisdiction such as the United States. And yet they appear to be fully TRIPS compliant.

Good Faith in TRIPS, 55 STAN. L. REV. 1529 (2003); Paul Champ & Amir Attaran, *Patent Rights and Local Working Under the WTO TRIPS Agreement: An Analysis of the U.S.-Brazil Patent Dispute*, 27 YALE J. INT'L L. 365 (2002); Sykes, *supra* note 69; Sara Germano, Note, *Compulsory Licensing of Pharmaceuticals in Southeast Asia: Paving the Way for Greater Use of the TRIPS Flexibility in Low- and Middle-Income Countries*, 76 UMKC L. REV. 273 (2007); SISULE F. MUSUNGU & CECILIA OH, WORLD HEALTH ORG., THE USE OF FLEXIBILITIES IN TRIPS BY DEVELOPING COUNTRIES: CAN THEY PROMOTE ACCESS TO MEDICINES? (2005), http://www.who.int/intellectualproperty/studies/TRIPS_flexibilities/en/index.html. Experts in international IP have noted that other levers exist, but generally have not examined their operation in detail or in context. See, e.g., Rochelle Cooper Dreyfuss & Andreas F. Lowenfeld, *Two Achievements of the Uruguay Round: Putting TRIPS and Dispute Settlement Together*, 37 VA. J. INT'L L. 275 (1997) (discussing the flexibility developing countries have with respect to, *inter alia*, the idea/expression distinction, inventive step, antitrust, patent misuse, and compulsory licensing); J. H. Reichman, *From Free Riders to Fair Followers: Global Competition Under the TRIPS Agreement*, 29 N.Y.U. J. INT'L L. & POL. 11, 30–35 (1996–1997) (noting that developing countries could choose, *inter alia*, restrictive standards for novelty, high standards for non-obviousness, oppositions, and disclosure requirements). The Indian example has spurred new interest in policy circles in some of the policy levers discussed here. See CARLOS CORREA, GUIDELINES FOR THE EXAMINATION OF PHARMACEUTICAL PATENTS: DEVELOPING A PUBLIC HEALTH PERSPECTIVE 6–25 (Jan. 2007), available at http://www.iprsonline.org/resources/docs/Correa_Patentability%20Guidelines.pdf (drawing heavily on the Indian example, and offering developing countries comprehensive recommendations for strict patentability standards, e.g., that they treat new formulations, compositions, salt patents, and enantiomers as obvious, and employ opposition systems).

1. *Subject Matter Exclusions*

Patent laws typically exclude certain things *a priori* from the scope of patentability, making the definition of patentable subject matter an issue of substantial importance.¹⁰⁰ India's subject matter exclusions are for the most part quite conventional,¹⁰¹ but a few are novel and have significant implications in the area of pharmaceuticals.

The most important exclusion is section 3(d), which forbids patents on both new uses of known substances and on new forms of known substances that do not enhance "efficacy."¹⁰² An important explanatory note clarifies the restriction on patents on new forms:¹⁰³ "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."¹⁰⁴ Other countries have limited patents in some of the ways included in section 3(d), for example, restricting patents on new uses of known substances.¹⁰⁵ But the scope of section 3(d), and in particular its expansive exclusion of patents on new forms of known substances, is new to patent law.¹⁰⁶ It can be explained as a classic act of legal borrowing:¹⁰⁷ the definition was taken virtually word-for-word from an EU drug regulatory directive.¹⁰⁸ The motivation was to enhance access to medicines and prevent so-called "evergreening" (where companies secure

100. See, e.g., *Diamond v. Diehr*, 450 U.S. 175, 185 (1981) (excluding "laws of nature, natural phenomena, and abstract ideas"); Convention on the Grant of European Patents arts. 52–53, Oct. 5, 1973, 1065 U.N.T.S. 199 [hereinafter EPC] (excluding patents on inventions contrary to "ordre public," "plant or animal varieties," "discoveries, scientific theories and mathematical methods," "aesthetic creations," "schemes, rules and methods for performing mental acts, playing games or doing business, and programs for computers," and "presentations of information").

101. These cover, for example, public order, discoveries of scientific principles or natural substances, plants and animals other than microorganisms, business methods and algorithms, computer programs "*per se*," and "any process for the medicinal, surgical, curative, prophylactic [diagnostic, therapeutic] or other treatment of human beings." The Patent Amendment Act, No. 15 of 2005, § 3, INDIA CODE (2005) [hereinafter India Patents Act]. Compare these, for example, to the exclusions in the EPC, *supra* note 100.

102. India Patents Act, *supra* note 101, § 3(d) (prohibiting, in relevant part, patents on "the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance").

103. Explanatory notes are common in Indian legislative practice and are used to avoid or dispel any ambiguity about a provision's application. See, e.g., *Hardev Motor Transport v. State of M.P.* (2006) 8 S.C.C. 613.

104. India Patents Act, *supra* note 101, § 3(d).

105. See *infra* note 150.

106. See Mueller, *supra* note 12, at 550.

107. See, e.g., ALAN WATSON, LEGAL TRANSPLANTS 21–22 (2d ed. 1993).

108. See Council Directive 2004/27/EC, Amending Council Directive 2001/83/EC on the Community Code Relating to Medicinal Products For Human Use, art. 10(2)(b), 2004 O.J. (L 136) 34, 39. For a description of how the act of borrowing occurred, see *supra* note 85.

successive patents to extend the effective period of their exclusive control over a drug).¹⁰⁹

The significance of the provision can only be appreciated when situated in the context of contemporary pharmaceutical patent practice. In the United States and European Union, for example, pharmaceutical compounds are rarely protected only with a patent on the active ingredient itself. Companies frequently seek other forms of patents, in order to generate or extend their exclusive rights over a medicine.¹¹⁰

Patents on the new use of a known substance (for example, claiming the use of a given compound to treat HIV) are common in the United States and Europe today, and do not cover a compound but rather a compound's use in a particular way.¹¹¹ New forms of known substances that have pharmaceutical applications are also commonly patented. Such patents may claim new structural forms of a compound with different properties, such as polymorphs (new crystalline forms)¹¹² or enantiomers (mirror-image isomers).¹¹³ They may also claim particular salts, esters, or ethers of a base compound. Salts, for example, are formed in a reaction between acids and bases; adding different acids to a base will produce different salts with potentially distinct properties. Pharmaceuticals are typically administered in salt form because salts dissolve more easily into the bloodstream and are thus more "bioavailable" than base compounds.¹¹⁴ Different salts of the same base compound may also differ substantially in properties that are important to manufacturing and storage, such as yield, hygroscopicity (attraction to water), stability, and stickiness.¹¹⁵

Salt selection is a straightforward, trial-and-error process, one that has been well described in the field of pharmaceuticals for more than thirty years.¹¹⁶ Nonetheless, patents on pharmaceutical salts have been granted for

109. See *Novartis AG v. Union of India*, W.P Nos. 24759 & 24760 of 2006, at ¶ 10 (Madras H.C., Aug. 6, 2007), available at <http://www.scribd.com/doc/456550/High-Court-order-Novartis-Union-of-India>; LOK SABHA DEBATES, *supra* note 90, at 684–85 (statement of Shri Suresh Kurup).

110. See, e.g., Michael Burdon & Kristie Sloper, *The Art of Using Secondary Patents to Improve Protection*, 3 INT'L J. MED. MARKETING 226 (2003); EUROPEAN COMMISSION, PHARMACEUTICAL SECTOR INQUIRY: FINAL REPORT 184–92 (2009), available at http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff_working_paper_part1.pdf.

111. JOHN R. THOMAS, PHARMACEUTICAL PATENT LAW 44–49 (2005); see also INT'L CENTRE FOR TRADE & SUSTAINABLE DEV. (ICTSD) & UNITED NATIONS CONFERENCE ON TRADE & DEV. (UNCTAD), RESOURCE BOOK ON TRIPS AND DEVELOPMENT 356–57 (2005).

112. See Dean L. Fanelli, *Claiming Novel Polymorphic Forms of Drug Products*, 88 J. PAT. & TRADEMARK OFF. SOC'Y 1053, 1054 (2006).

113. Jonathan J. Darrow, *The Patentability of Enantiomers: Implications for the Pharmaceutical Industry*, 2007 STAN. TECH. L. REV. 2, ¶ 3.

114. Stephen M. Berge et al., *Pharmaceutical Salts*, 66 J. PHARMACEUTICAL SCI. 1, 10 (1977).

115. Philip L. Gould, *Salt Selection for Basic Drugs*, 33 INT'L J. PHARMACEUTICS 201, 201 (1986).

116. See, e.g., *id.*; Berge et al., *supra* note 114.

decades in the United States, upon a showing that the salt differed from the previously disclosed compound in an unexpectedly beneficial way.¹¹⁷ Patents on enantiomers were rejected by U.S. courts in the 1940s, because enantiomers are necessarily present in the disclosed “racemic” mixtures from which they are derived.¹¹⁸ Such patents nonetheless have been accepted in recent years, also on a showing that they possessed surprisingly superior properties over the prior art.¹¹⁹

Section 3(d) imposes substantial limits on these kinds of claims, excluding patents on new uses outright, and limiting patents on new forms of known substances to those that have increased efficacy. The definition of the term “efficacy” is of enormous importance, as illustrated by a recent dispute in India. The multinational firm Novartis sought a patent on the beta crystalline form of the salt imatinib mesylate, covering its powerful anti-cancer drug Gleevec. Novartis contended that the beta crystalline form had several qualities that made it more “efficacious” than the base compound imatinib (which was invented before 1995 and therefore could not be patented in India). It was allegedly easier to store and process, and also 30 percent more bioavailable than imatinib.¹²⁰ These are common advantages of new salt and crystalline forms, so if Novartis had won the argument, section 3(d) would have had little bite. So far, however, the two lower courts to address the matter both decided in favor of a narrower “therapeutic” efficacy standard that requires the new form to show improved healing effect in the body.¹²¹ This standard has been incorporated into the Draft Patent Manual.¹²² If it holds, few new forms are

117. See, e.g., *In re Papesch*, 315 F.2d 381, 391 (C.C.P.A. 1963). In a decision widely regarded as departing from previous precedent, the Federal Circuit recently invalidated a salt-selection patent as obvious, relying on the relatively small number of pharmaceutically acceptable acid-addition salts known in the art and on the reasonable expectation that the salt would have the desired properties. *Pfizer v. Apotex, Inc.*, 480 F.3d 1348, 1362 (Fed. Cir. 2007), *panel reh'g & reh'g en banc denied*, 488 F.3d 1377 (Fed. Cir. 2007). Some suggested that the case cast doubt on the future viability of a substantial number of patents in the pharmaceutical sector. See, e.g., *Pfizer*, 488 F.3d at 1384 (2007) (Rader, J., dissenting from denial of rehearing en banc). Subsequent decisions may, however, have limited its scope. See, e.g., *Sanofi-Synthelabo v. Apotex, Inc.*, 550 F.3d 1075, 1089 (Fed. Cir. 2008) (upholding a district court's finding of non-obviousness of an enantiomer patent, despite the obviousness to try enantiomer isolation, because the properties of the enantiomer were “unexpected and unpredictable”).

118. See *In re Williams*, 171 F.2d 319, 320 (C.C.P.A. 1948); see also Darrow, *supra* note 113, ¶ 12.

119. See, e.g., *Ortho-McNeil Pharm., Inc. v. Mylan Labs, Inc.*, 348 F. Supp. 2d 713, 749 (N.D.W. Va. 2004). After *KSR*, the Federal Circuit also rejected an enantiomer patent as obvious. *Aventis Pharma Deutschland GmbH v. Lupin, Ltd.*, 499 F.3d 1293, 1301 (Fed. Cir. 2007). *But see Sanofi-Synthelabo*, 550 F.3d at 1089.

120. *Novartis AG v. Union of India*, Order No. 100/2009 (Intellectual Prop. App. Board, June 29, 2009) at 14, 23, available at <http://www.i-mak.org/pharma-patent-decisions> (reviewing Novartis's arguments).

121. *Id.* at 184–89; See *Novartis AG v. Union of India*, W.P. Nos. 24759 & 24760 of 2006, ¶ 19 (Madras H.C., Aug. 6, 2007), available at <http://www.scribd.com/doc/456550/High-Court-order-Novartis-Union-of-India>.

122. PATENT OFFICE (INDIA), DRAFT MANUAL OF PATENT PRACTICE AND PROCEDURE 58

likely to be eligible for patents in India, creating substantial scope for competition in the pharmaceutical sector.

2. *Inventive Step Threshold*

A second novel aspect of the patentable subject matter lever in India's new patent law is its unusually high threshold for "inventive step." India's law defines inventive step as "a feature of an invention that involves technical advance as compared to the existing knowledge or having economic significance or both *and* that makes the invention not obvious to a person skilled in the art."¹²³ The requirement that an invention be "non-obvious to a person skilled in the art" is standard in patent law,¹²⁴ but the requirement that the invention also represent a technical advance or have "economic significance" is unusual, and perhaps unique.¹²⁵ Technical and economic effects are often considered relevant to obviousness jurisprudence,¹²⁶ but India's law *requires* one of the two. This heightened standard appears to narrow the class of inventions that may be granted protection in India, although by precisely how much is not clear.¹²⁷

The standard adopted for obviousness jurisprudence can have a substantial impact on the scope of exclusivity offered by a patent law.¹²⁸ A new form of a known substance with increased efficacy, for example, could survive section 3(d) but fail a robust inventive step requirement. Section 3(d) imposes no restrictions on new compound patents, but a new compound that was obvious to synthesize in light of prior art might fail a strict inventive step standard. India could thus exclude a very extensive range of patents in the pharmaceutical and biotechnology domains by applying its obviousness requirement strictly.

(2008). The draft manual is not the result of formal rule-making and does not have the force of law. *See id.* at 3. But it will play a substantial role in guiding examiner decisions, as affirmed by the eager anticipation of the manual in the patent offices I visited.

123. India Patents Act, *supra* note 101, § 2(ja) (emphasis added).

124. *See, e.g.,* EPC, *supra* note 100, art. 56 ("An invention shall be considered as involving an inventive step if, having regard to the state of the art, it is not obvious to a person skilled in the art.").

125. India Patents Act, *supra* note 101, § 2(ja); *see also* Mueller, *supra* note 12, at 563–64.

126. The "secondary effects" doctrine in the United States, for example, incorporates consideration of factors such as "commercial success." *See, e.g.,* Graham v. John Deere Co., 383 U.S. 1, 17–18 (1966); 2 DONALD CHISUM, CHISUM ON PATENTS § 5.05. European courts also consult such factors when assessing obviousness. *See, e.g.,* Haberman v. Jackel Int'l, Ltd., [1999] F.S.R. 683, 699–701 (Ch. (Pat. Ct.)) (U.K.).

127. For a discussion of the narrow interpretation so far given to this provision, see *infra* text accompanying notes 340–41.

128. *See, e.g.,* Robert P. Merges, *Commercial Success and Patent Standards: Economic Perspectives on Innovation*, 76 CALIF. L. REV. 805, 812 (1988); Burk & Lemley, *supra* note 95, at 1648–50.

3. *Implications and Consistency with TRIPS*

India's law, if interpreted and enforced in its most expansive fashion, could substantially curtail the number of pharmaceutical patents in India and thus facilitate substantial competition in the pharmaceutical market. D.G. Shah, for example, estimated that very few of the almost seven thousand pharmaceutical patents pending in India's mailbox claim new chemical entities, and that the vast majority are thus likely to be invalidated by section 3(d).¹²⁹ Section 3(d) is also supplemented by other important subject matter exclusions, such as the prohibition on patents on "mere admixture[s],"¹³⁰ which could preclude patents on combinations of known therapies as well as formulations.¹³¹ Also potentially important is India's exclusion applied to "an invention which, in effect, is traditional knowledge or which is an aggregation or duplication of known properties of traditionally known component or components."¹³²

The impact of these subject matter exclusions is difficult to estimate with precision because we lack detailed empirical data regarding the role of different types of patents in providing exclusivity in the pharmaceutical sector. (We also currently know little about the percentage of drugs derived from traditional knowledge, in part because the term is subject to different interpretations, but also because patent systems in the global North do not require such information.) A precise estimate of the degree to which section 3(d) will narrow exclusivity in India's pharmaceutical industry must await research that can tell us (1) how often a new drug is covered only by patents regarding new uses, new forms of known substances, or combinations; and (2) where compound patents are combined with these other patent types, how many additional years of exclusivity the latter types typically grant.¹³³ It is clear, however, that India's restrictions, if interpreted in robust fashion, should substantially diminish the extent of exclusive rights over medicines in India. India's inventive step standard, if applied expansively, could do all of this and more.

India's innovative lawmaking also creates a potential model for other developing countries. Whether India ultimately interprets "efficacy" in section 3(d) as the more demanding "therapeutic efficacy" standard, and whether it interprets its inventive step standard as more stringent than inventive step standards in, for example, Europe, remains to be seen. But other countries could do both, and thereby sharply reduce exclusivity in the domain of medicines. With this lever, governments can render a substantial percentage of medicines open to generic competition without ever needing to consider a compulsory license.

129. Interview with Dilip G. Shah, *supra* note 28.

130. India Patents Act, *supra* note 101, § 3(e).

131. Such patents are well-known in the United States. THOMAS, *supra* note 111, at 44.

132. India Patents Act, *supra* note 101, § 3(p).

133. Colleagues and I are seeking to produce estimates of both figures in an ongoing research project.

Such a move also appears to be fully consistent with TRIPS. TRIPS is interpreted according to standards set forth in the Vienna Convention on the Law of Treaties.¹³⁴ The treaty's terms must thus be understood "in accordance with the ordinary meaning . . . in their context and in the light of its object and purpose."¹³⁵ Subsequent agreements of the parties "regarding the interpretation of the treaty or the application of its provisions" are relevant in interpreting its terms, as is subsequent state practice that "establishes the agreement of the parties" regarding the interpretation of TRIPS.¹³⁶ Treaty preparatory work and other "supplementary means of interpretation" may be used only to confirm a meaning, or to guide interpretation in cases where the meaning is "ambiguous and obscure" or "manifestly absurd."¹³⁷

Rulings of WTO Panels and especially the Appellate Body are typically treated as authoritative guidance on the meaning of WTO treaty requirements, although most experts contend that these decisions have no official *stare decisis* effect.¹³⁸ Unfortunately, there are few dispute settlement decisions addressing TRIPS, and even fewer addressing the more significant provisions of the Agreement. As such, interpretative efforts turn largely on the tools outlined in article 31 of the Vienna Convention and on the views of commentators. Absent an authoritative dispute resolution addressing a particular flexibility, all interpretations necessarily carry with them some uncertainty. I therefore limit myself to the conclusion that India's flexibilities "appear" to comply with TRIPS. It is important to recall, however, that the dispute resolution system does not authorize retroactive sanctions, thus providing an incentive for countries to utilize fully the flexibilities that they believe the Agreement permits.

Turning to the issue at hand, TRIPS article 27.1 requires all signatories to provide patent protection for inventions "in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application."¹³⁹ The Agreement nowhere defines these terms. However, article 1 states that members are not required to give more extensive protection than required by the treaty, and "shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice."¹⁴⁰ This suggests that the treaty should not be read to impose obligations stricter than those present on its face. Commentators widely

134. See, e.g., *India—Patents*, *supra* note 52, ¶ 43.

135. Vienna Convention on the Law of Treaties art. 31(1), May 23, 1969, 8 I.L.M. 679.

136. *Id.* art. 31.3(a)–(b).

137. *Id.* art. 32.

138. See, e.g., Pierre Pescatore, *Drafting and Analyzing Decisions on Dispute Settlement*, in 1 HANDBOOK OF WTO/GATT DISPUTE SETTLEMENT pt. 2 at 32 (Pierre Pescatore et al. eds., 1998); William J. Davey, *The WTO/GATT World Trading System: An Overview*, in 1 HANDBOOK OF WTO/GATT DISPUTE SETTLEMENT, *supra*, at 13, 20.

139. TRIPS, *supra* note 1, art. 27.1.

140. *Id.* art. 1.

interpret the openness of the terms of article 27.1 as indicating that countries have substantial leeway in implementing its three patentability requirements.¹⁴¹ Indeed, countries do diverge in the way they implement these requirements.¹⁴²

Articles 7 and 8, which set forth the Agreement's "objectives" and "principles," respectively, also lend support to India's interpretation.¹⁴³ Both articles are part of the TRIPS Agreement itself, included at the insistence of developing countries.¹⁴⁴ Following the general interpretive principle that all of a treaty's terms should be given effect,¹⁴⁵ both provisions must be allocated some meaning. Additionally, neither can be read to negate other provisions in the Agreement. These dual objectives are achieved by treating these articles as a lens through which to interpret other terms of the Agreement. The Doha Declaration specifically affirmed this approach,¹⁴⁶ as did the panel in *Canada—Generics*.¹⁴⁷

141. See, e.g., Correa, *supra* note 99, at 3; ICTSD & UNCTAD, *supra* note 111, at 358; Mueller, *supra* note 12, at 357–58, 562; Reichman & Dreyfuss, *supra* note 3, at 97–98.

142. For example, countries have taken various approaches to defining novelty, particularly with regard to the role of prior art and the availability of a grace period for disclosures made by inventors. See F. SCOTT KIEFF ET AL., *PRINCIPLES OF PATENT LAW: CASES AND MATERIALS* 335–41 (4th ed. 2008). Standards for inventive step or obviousness have also diverged, sometimes with important consequences. See, e.g., Amy Nelson, *Obviousness or Inventive Step as Applied to Nucleic Acid Molecules: A Global Perspective*, 6 N.C. J.L. & TECH. 1, 30–31 (2004) (contrasting U.S. obviousness standards in the area of nucleic acid sequence patents with the stricter standards of Europe and Japan).

143. Article 7 states that IP rights should “contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.” TRIPS, *supra* note 1, art. 7. Article 8 states that TRIPS members can, when shaping their domestic laws and regulations, “adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.” It also declares that “[a]ppropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.” *Id.* art. 8.

144. See Abdulqawi A. Yusuf, *TRIPS: Background, Principles, and General Provisions*, in *INTELLECTUAL PROPERTY AND INTERNATIONAL TRADE: THE TRIPS AGREEMENT*, *supra* note 41, at 3, 12–16; DANIEL GERVAIS, *THE TRIPS AGREEMENT: DRAFTING HISTORY AND ANALYSIS* 203 (3d ed. 2008); see also Peter K. Yu, *The Objectives and Principles of the TRIPS Agreement*, 46 HOUSTON L. REV. (forthcoming 2009), available at <http://ssrn.com/abstract=1398746> (describing the genesis of articles 7 and 8 and suggesting possible interpretive uses of the articles).

145. See, e.g., Appellate Body Report, *Argentina—Safeguard Measures on Imports of Footwear*, ¶ 88, WT/DS121/AB/R (Dec. 14, 1999).

146. Doha Declaration, *supra* note 7, ¶ 5(a). The precise legal status of the Doha Declaration is debatable, but at a minimum it should be treated as an important interpretive tool. See, e.g., James Thuo Gathii, *The Legal Status of the Doha Declaration on TRIPS and Public Health Under the Vienna Convention on the Law of Treaties*, 15 HARV. J.L. & TECH. 291, 292–317 (2002); cf. Steve Charnovitz, *The Legal Status of the Doha Declarations*, 5 J. INT'L ECON. L. 207, 211 (2002).

147. Panel Report, *Canada—Patent Protection of Pharmaceutical Products*, ¶ 7.23, WT/DS114/R (Mar. 17, 2000) [hereinafter *Canada—Generics*] (stating that “[b]oth the goals and

What this means in practice likely depends upon the provision in question. For example, one objection that might be leveled against section 3(d) is that India is imposing “additional” criteria for the grant of a patent, beyond the approved criteria of novelty, inventive step, and utility. But the section’s requirements can all be characterized as per se articulations of the standards expressed in article 27.1. The restriction on patents on new forms that lack significantly enhanced therapeutic efficacy, for example, can be understood as a codification of a particular approach to the law of obviousness.¹⁴⁸ Article 7 suggests that the article 27.1 requirements for patentability are not ends in themselves, but rather should be crafted to respond to the objectives incorporated into TRIPS. This in turn counsels against the kind of formalism that would require countries to explicitly label an application of the inventive step standard as such in their local laws.

It could be argued, alternatively, that per se subject matter exclusions such as those found in section 3(d) run afoul of the article 27.1 prohibition on discrimination by field of technology. If pharmaceuticals qualify as a field of technology, then it is notable that nothing in section 3(d) explicitly restricts its application to pharmaceuticals.¹⁴⁹ TRIPS members also frequently adopt subject matter exclusions that apply to certain technological fields,¹⁵⁰ and differentiate between technological fields in the way they apply basic patent law standards such as inventive step.¹⁵¹ Further, the *Canada—Generics* decision concluded that the article 27.1 nondiscrimination provision does “not prohibit bona fide exceptions to deal with problems that may exist only in

the limitations stated in Articles 7 and 8.1 must obviously be borne in mind” when considering the meaning of other provisions in the Agreement).

148. See *Novartis AG v. Union of India*, Order No. 100/2009 (Intellectual Prop. Appellate Board, June 29, 2009) at 190, available at <http://www.i-mak.org/pharma-patent-decisions> (describing section 3(d) as a “higher standard of inventive step”); see also Interview with Raghu Cidambi, *supra* note 25 (“[G]iven the national stage of understanding of patents in India, the fact that the patent office has just been set up and the patent examiners have just been trained, I think what the government has done is actually set a standard of obviousness in the statute . . .”). In fact, a recent Federal Circuit decision in the United States, decided on obviousness grounds, bears striking resemblance to the Indian standard. See *Pfizer v. Apotex, Inc.*, 480 F.3d 1348 (Fed. Cir. 2007); see also Brief of Amicus Curiae Pharmaceutical Research and Manufacturers of America In Support of the Combined Petition of Plaintiff-Appellee Pfizer Inc. for Rehearing and Rehearing En Banc at 2, *Pfizer*, 480 F.3d 1348 (No. 2006-1261) (arguing that the panel’s holding “inappropriately requires that patentability in the pharmaceutical field must be derived from improvements in therapeutic effects”).

149. See *Novartis AG*, Order No. 100/2009, at 188.

150. For example, the EPC excludes patents on software and business methods “as such,” EPC, *supra* note 100, art. 52 ¶ (2), (3), and many developing countries exclude patents on new or second uses of known substances, a restriction with particular importance in the pharmaceutical context, DEERE, *supra* note 12, at 79; Laurence R. Helfer, Karen J. Alter & M. Florencia Guerzovich, *Islands of Effective International Adjudication: Constructing an Intellectual Property Rule of Law in the Andean Community*, 103 AM. J. INT’L L. 1, 30 (2009).

151. See, e.g., Dan L. Burk & Mark A. Lemley, *Is Patent Law Technology-Specific?*, 17 BERKELEY TECH. L.J. 1155, 1156 (2003).

certain product areas.”¹⁵² The nature of a “bona fide exception” has not been elaborated upon, but should be informed by the areas given special solicitude under article 8. Thus, exceptions to patentability adopted in order to protect public health might not be deemed to discriminate by field of technology, even if they have applications only to particular fields.¹⁵³

The same arguments apply to India’s unusually stringent inventive step test. TRIPS does not define “inventive step,” and thus does not restrict countries to a single articulation of that requirement. Countries formulate their inventive step requirements in different ways, suggesting that signatories understand the Agreement to permit flexibility in this regard.¹⁵⁴ Reading article 27.1 in light of article 7 suggests that different formulations of an inventive step test are appropriate if they are necessary to respond to different contexts in a way that meets the goals of the Agreement. Each interpretive tool thus points to the same conclusion: India’s subject matter exclusions and inventive step standard appear to be consistent with the terms of the TRIPS Agreement. They thus map out a novel set of flexibilities that developing countries could adopt that would, if applied rigorously, substantially reduce the scope of exclusive rights in medicines in such countries.

B. Procedural Mechanisms: Patent Oppositions and Disclosure Requirements

India has also introduced several innovative procedural mechanisms that could help examiners identify suspect patents and that could create hurdles for applicants. These also offer examples of rarely discussed TRIPS flexibilities that could be adopted by other developing countries and that appear to fully comply with the Agreement.

1. Oppositions and Revocation Proceedings

India offers three administrative opportunities to challenge the grant of a patent: pre-grant and post-grant oppositions before the patent offices¹⁵⁵ and patent revocation proceedings that may be initiated before the Intellectual Property Appeal Board or via a counterclaim in an infringement suit.¹⁵⁶

The pre-grant procedure has been the most important of these, in part because of the substantial backlog of patents pending in the mailbox. Pre-grant opposition proceedings are not new to patent law, but high-protection

152. *Canada—Generics*, *supra* note 147, ¶¶ 7.91–92.

153. *Cf. Gervais*, *supra* note 144, at 358 (noting that the Doha Declaration specifically singles out pharmaceutical products for special treatment, suggesting that this may be a domain where “compelling public interests” constitute bona fide reasons for differentiation).

154. *See supra* note 142.

155. For historical reasons, India has four separate regional patent offices, located in Kolkata, New Delhi, Chennai, and Mumbai. OFFICE OF THE CONTROLLER GEN. OF PATENT DESIGNS & TRADEMARKS, GOV’T OF INDIA, ANNUAL REPORT 2007–2008, at 3 (2008), <http://www.patentoffice.nic.in/> [hereinafter IPO ANNUAL REPORT 2008].

156. *India Patents Act*, *supra* note 101, § 64.

jurisdictions have almost uniformly rejected them in favor of post-grant oppositions or no opposition proceedings.¹⁵⁷ The posture of pre-grant oppositions tends to favor opponents, because the patent's grant may be avoided entirely or at least delayed for a period in which competitors may work the invention without threat of penalty.¹⁵⁸ It is not yet clear how long it will take, on average, for India's patent offices to resolve pre-grant oppositions. To date, periods of two years or longer are not unusual.¹⁵⁹

India's pre-grant procedure is notable for its expansive standing provision: "any person" can file a pre-grant opposition with the relevant patent office, which the patent offices have interpreted to mean not only potential generic competitors but also groups representing patients' interests in affordable medicines.¹⁶⁰ The available grounds for pre-grant opposition are also broad.¹⁶¹ The Act does not directly state whether any of the grounds are curable, but courts could conclude that any legitimate grounds for opposition, including, for example, the fact that an applicant has failed to disclose the fate of parallel patent applications in other jurisdictions, is grounds for denial of the patent.¹⁶²

Nearly 200 pre-grant oppositions had been filed in India by mid-2007, not only by Indian companies, but in a substantial number of cases, by public

157. See, e.g., Jay P. Kesan, *Carrots and Sticks to Create a Better Patent System*, 17 BERKELEY TECH. L.J. 763, 781–82 (2002) (Germany and Japan abandoned pre-grant systems for post-grant systems in 1981 and 1994 respectively). Notably, Australia retains both pre- and post-grant patent oppositions. See Patents Act, 1990, § 59 (Austl.); IP AUSTRALIA, PATENT OPPOSITIONS (2005), <http://www.ipaustralia.gov.au/pdfs/patents/specific/oppositn.pdf>. Brazil and Jordan also permit pre-grant oppositions. See Mueller, *supra* note 12, at 568. The Andean Community also has an active opposition system. Helfer, Alter, & Guertzovich, *supra* note 150, at 19.

158. Furthermore, pre-grant oppositions may produce more accurate results than post-grant oppositions because the patent office has not already entrenched its position by approving the patent. Kesan, *supra* note 157, at 777. Data from the periods where Germany and Japan had pre-grant opposition proceedings also suggest that pre-grant procedures are much more likely than post-grant procedures to be used. *Id.* at 781–82.

159. As of this writing, several patent oppositions filed in 2006 had not been acted upon. Some oppositions have, however, been decided within one or two years. See *Boehringer Ingelheim Pharma v. Cipla Ltd.*, Delhi Patent Office (2008), available at <http://www.i-mak.org/pharma-patent-decisions> (opposition filed Aug. 29, 2007 and granted June 11, 2008); *Novartis AG v. Torrent Pharmaceuticals Ltd.*, Chennai Patent Office (2007), available at <http://www.i-mak.org/pharma-patent-decisions> (opposition filed Dec. 1, 2005 and granted Oct. 24, 2007).

160. One of the opponents to the patent on Gleevec, for example, was the Indian Cancer Patients' Aid Association. See *Novartis AG*, Chennai Patent Office, at 1.

161. They include the contention that the invention does not meet the statutory requirements for novelty and inventive step, that it is covered by an exclusion such as 3(d), that it fails the requirements of specification, and that the applicant has not disclosed the status of parallel applications in other jurisdictions or the geographical origin or source of biological materials used. India Patents Act, *supra* note 101, § 25.

162. The text of the Act suggests this interpretation, because no distinction is made in article 25 between grounds that would clearly result in denial of a patent (say, lack of inventive step) and grounds such as failure to comply with disclosure requirements. A strict penalty is also arguably necessary to enforce provisions that require the applicant to produce information, given that a patent office with limited resources can only detect violations with difficulty.

interest organizations.¹⁶³ No source provides systematic information about oppositions filed or their dispositions, but an NGO has collected and made available those decisions that it has been able to identify to date.¹⁶⁴ This sample does not purport to be comprehensive or representative, but it is nonetheless informative. Of the twenty-two substantive decisions on pre-grant oppositions to product patents in the area of pharmaceuticals represented there, opponents were successful 77 percent of the time.¹⁶⁵ Oppositions sometimes also lead firms to abandon patent applications.¹⁶⁶ The effects of these oppositions have reached far beyond this handful of cases, shaping the emerging jurisprudence of pharmaceutical patents. The “therapeutic” efficacy interpretation adopted by the High Court in *Novartis*, for example, was urged by opponents in that case, and now guides activities in the patent offices.¹⁶⁷

India’s law also permits post-grant oppositions and patent revocation proceedings on similar grounds as are provided for pre-grant oppositions.¹⁶⁸ However, the parties that may pursue post-grant oppositions and revocation proceedings are more limited: “any person interested” may file a post-grant opposition or revocation proceeding while “any person” may file a pre-grant opposition.¹⁶⁹ The implication of this difference has not yet been determined, and is perhaps the most important outstanding legal question with respect to these two proceedings.¹⁷⁰ Also important, and unclear, is whether any rule of issue or claim preclusion will apply to patent oppositions.¹⁷¹

163. Interview with Dilip G. Shah, *supra* note 28. The latest IPO Report indicates that sixty-four pre-grant opposition proceedings were initiated in 2007–2008. IPO ANNUAL REPORT 2008, *supra* note 155, at 9.

164. See I-MAK, Pharmaceutical Patent Decisions, <http://www.i-mak.org/pharma-patent-decisions> (last visited July 16, 2009). The Indian government has recently made a search interface available where one can look for decisions, but it can only be browsed with criteria such as patent number, making any systematic assessment of outcomes difficult. See Indian Patent Office, Patent Decision Search, <https://www.ipindiaonline.gov.in/patentdecisionsearch/patentsearch.aspx> (last visited Nov. 11, 2009).

165. Information collated from decisions available at <http://www.i-mak.org/pharma-patent-decisions> (last visited July 16, 2009). The most common grounds for denial of patents involved inventive step and section 3(d).

166. For example, GlaxoSmithKline abandoned applications on two of its HIV drugs, Combivir and Abacavir. See Priti Radhakrishnan, *Access to Anti-Retrovirals (ARVs) in India: Patents and the Way Forward*, INFOCHANGE, Sept. 2008, <http://www.hivaidsonline.in/index.php/Response/access-to-anti-retrovirals-arvs-in-india-patents-and-the-way-forward.html>.

167. See *supra* text accompanying notes 120–22.

168. India Patents Act, *supra* note 101, §§ 25(2), 64.

169. Compare *id.* § 25(2) (post-grant opposition), with § 25(1) (pre-grant opposition).

170. In at least one post-opposition case, a patent controller expressed doubt that NGOs have standing to file post-grant oppositions on the grounds that they have an interest in affordable medicines, but the issue was not decided because the patent holder had not raised an objection on standing grounds at the appropriate time. See *F. Hoffmann-La Roche AG v. Wockhardt Ltd.*, Chennai Patent Office (2009), at 20–21, available at <http://www.i-mak.org/pharma-patent-decisions>. The same case concluded that pharmaceutical companies do have standing as “interested persons” to file post-grant oppositions. *Id.* at 4.

171. Interview with Biswajit Dhar, *supra* note 36; Interview with Ms. H. Rajeshwari,

2. *Disclosures During Application*

Applicants must also make a series of disclosures during the application process. For example, section 8 of the Indian Act requires all applicants to inform the patent office of any application they (or a surrogate) have filed for a patent in another country with respect to “the same or substantially the same invention.”¹⁷² Applicants are also required, until the time of the patent’s grant, to keep the Controller General up to date, in writing, about the “detailed particulars of such application[s].”¹⁷³ The law does not specify exactly what must be reported, but a reasonable interpretation is that applicants must report any amendments to claims or any adverse office actions that affect parallel applications. The value of this information to the Indian Patent Office is substantial: it puts examiners on notice of potential problems with applications, which is particularly valuable in light of the office’s limited examining resources.¹⁷⁴

Applicants must also “disclose the source and geographical origin of [any] biological material in the specification, when used in an invention.”¹⁷⁵ This provision was added to the Act in 2005, and appears to derive from concerns about the misappropriation of biological materials (or “biopiracy”).¹⁷⁶ Again, the precise contours of the requirement are still unclear, but failure to accurately report under either section could be grounds for denial or revocation of a patent.¹⁷⁷

3. *Implications and Consistency with TRIPS*

The procedural lever in TRIPS is capable of three kinds of effects relevant here: it can (1) leverage the information of third parties to help patent offices identify important and suspect patents; (2) induce the applicant to give examiners information that may be relevant to patentability; and (3) increase compliance costs for applicants. Together, these effects can both increase the accuracy of determinations in the patent office and decrease the grant rate. This too is a powerful form of flexibility that countries can use to adapt TRIPS to their local context.

Partner, K&S Partners, in New Delhi, India (June 20, 2007) (notes on file with author); *see also* Mueller, *supra* note 12, at 567–68 (suggesting that a pre-grant opposition does not preclude a later court challenge); Pfizer Prods. Inc. v. Natco Pharma Ltd., Delhi Patent Office (2007), at 26, *available at* <http://www.i-mak.org/pharma-patent-decisions> (stating that the losing opponent could “if still aggrieved” proceed to post-grant opposition).

172. India Patents Act, *supra* note 101, § 8.

173. *Id.*

174. *See infra* Part III.A.

175. India Patents Act, *supra* note 101, § 10(4)(d)(ii)(D).

176. On the discourse of biopiracy, see Cynthia M. Ho, *Biopiracy and Beyond: A Consideration of Socio-Cultural Conflicts with Global Patent Policies*, 39 U. MICH. J.L. REFORM 433 (2006).

177. India Patents Act, *supra* note 101, §§ 64(1)(m), 64(1)(p).

Opposition proceedings with broad standing, for example, should decrease the cost of identifying and examining suspect claims. Scholars argue that it may be rational for a country like the United States to limit the resources it commits to patent examination, since few issued patents are ultimately licensed or litigated.¹⁷⁸ However, denying invalid patents is clearly preferable to paying the costs generated by bad patents (for example those associated with strategic behavior, licensing, and litigation), if patents that are likely invalid can be identified at low cost.

India's opposition proceedings help the patent offices achieve this. Before filing, potential competitor firms and public interest organizations review pending patents and determine which ones merit opposition, no doubt considering both the social or market value of the patent and its potential vulnerabilities. Their oppositions provide important signals to patent examiners, and bring to light additional arguments regarding patentability. Because public interest organizations have a different orientation than generic firms, their participation may be a particularly salient indicator of the social importance of a patent decision.¹⁷⁹ Section 8 of India's law provides another mechanism that helps examiners identify suspect patents and arguments relevant to patentability, and imposes the costs of providing the information on the applicant.

The procedural lever can also be used as an information-forcing mechanism.¹⁸⁰ For example, applicants must report the source of biological materials. They can likely provide this information most cheaply, justifying the placement of this burden upon them. The information garnered through this provision may be of use to governments, which enjoy certain sovereign rights over genetic resources under the Convention on Biological Diversity.¹⁸¹ It could also, if publicly accessible, elicit opponents to the patent that might bring important information and arguments to the examiner. Finally, it may help locals obtain compensation from patent-holders in jurisdictions where informed consent laws make that possible. Of course, such mechanisms will only

178. Mark A. Lemley, *Rational Ignorance at the Patent Office*, 95 Nw. U. L. REV. 1495, 1497 (2001).

179. For example, over time, larger generic firms may develop an interest in weakening certain aspects of India's law, such as the limitation on patenting of new dosages or formulations. Generic firms may also decline to bring oppositions altogether in certain cases, instead entering into licensing agreements. For a more general discussion of the potential role of public interest groups in improving regulatory outcomes and discouraging capture, see IAN AYRES & JOHN BRAITHWAITE, *RESPONSIVE REGULATION: TRANSCENDING THE DEREGULATION DEBATE* 54–100 (1992).

180. For an influential discussion of information-forcing default rules, see Ian Ayres & Robert Gertner, *Filling Gaps in Incomplete Contracts: An Economic Theory of Default Rules*, 99 YALE L.J. 87, 127–30 (1989). Ayres and Gertner call attention to how penalties can encourage private contracting around. I use the term “information forcing” here in a more basic sense, to designate that applicants are obliged to provide information directly to the patent office on pain of some penalty.

181. See United Nations Convention on Biological Diversity arts. 3, 15, June 5, 1992, 1760 U.N.T.S. 79, 31 I.L.M. 818, 823–24.

function if they are enforced with sanctions sufficient to induce compliance.

Finally, differences in patent application procedures from country to country clearly increase costs for applicants. These costs formed one of the primary justifications for the Patent Cooperation Treaty (PCT) and regional patent-granting systems such as the European Patent Office (EPO) and the African Regional Intellectual Property Organization (ARIPO).¹⁸² Those who advocate for increased global harmonization frequently cite the savings to applicants as one of the main justifications.¹⁸³ Conversely, increasing costs for applicants can benefit countries that want to limit the impact of the transition to TRIPS.

TRIPS minimally constrains the procedural lever. The Agreement specifically authorizes members to require patent applicants to make disclosures, including the “best mode for carrying out the invention,” as well as “information concerning the applicant’s corresponding foreign applications and grants.”¹⁸⁴ Countries can in addition impose all “reasonable procedures and formalities” on patent applicants.¹⁸⁵ The term “reasonable” is not defined, and commentators have shed little light on its meaning.¹⁸⁶ In the context of a minimum standards agreement, the most sensible interpretation would define a reasonable procedure according to its means-ends fit, such that members may “impose formalities that are adequate to their purpose, but on the other hand not overly restrictive on the applicant.”¹⁸⁷ Each of India’s procedural requirements has a clear and legitimate objective, such as improving patent quality and providing information relevant to patentability to the patent office. As further evidence of the reasonableness of at least some of its procedures, India can point to the availability of similar requirements in other countries. For example, post-grant opposition procedures exist at the EPO,¹⁸⁸ pre-grant and post-grant procedures exist in Australia,¹⁸⁹ and several other countries have laws requiring disclosure of geographic origin.¹⁹⁰

182. See, e.g., Anneliese M. Siefert, *Will the United States Take the Plunge into Global Patent Law Harmonization? A Discussion of the United States’ Past, Present, and Future Harmonization Efforts*, 6 MARQ. INTELL. PROP. L. REV. 173, 179–84 (2002).

183. See Hon. Q. Todd Dickinson, *The Long-Term International View of Patents and Trademarks*, in 4 INTERNATIONAL INTELLECTUAL PROPERTY LAW & POLICY 14-1–14-2 (Hugh C. Hansen, ed., 2000); Heinz Bardehle, *Patent Harmonization: Quo Vadis?*, 88 J. PAT. & TRADEMARK OFF. SOC’Y 644, 644 (2006).

184. TRIPS, *supra* note 1, art. 29.

185. *Id.* art. 62.1.

186. See, e.g., GERVAIS, *supra* note 144, at 495 (simply reiterating that “reasonable procedures and formalities” are required).

187. ICTSD & UNCTAD, *supra* note 111, at 622.

188. EPC, *supra* note 100, art. 99; see generally EUROPEAN PATENT OFFICE, GUIDELINES FOR EXAMINATION IN THE EPO pt. D.III.5, <http://www.epo.org/patents/law/legal-texts/html/guix/e/index.htm>.

189. See *supra* note 157.

190. See Carlos M. Correa, *The Politics and Practicalities of a Disclosure of Origin Obligation* (Quaker United Nations Office, Occasional Paper No. 16, 2005) (noting that the

Patent granting procedures must also permit patents to be granted “within a reasonable period of time so as to avoid unwarranted curtailment of the period of protection.”¹⁹¹ Again, the term “reasonable” is undefined. Reliable statistics about the time required for the resolution of applications in India are not yet available.¹⁹² Under the Act and its corresponding Rules it is possible, if the applicant seeks quick review of an application, for a patent to be granted in as little as six months.¹⁹³ Patents are granted regularly, and some pre-grant oppositions are resolved within two years. Notably, even in patent offices with far more resources, delays of several years from application to grant are not unusual, as table 2 shows.

Table 2: Average Pendencies in Months in EPO, JPO, & USPTO (2007)¹⁹⁴

	EPO	JPO	USPTO
Avg. pendency to first office action	22.8	26.7	24.9
Avg. pendency in examination (total)	45.3	32.4	32.0
Avg. pendency in opposition	18.6	n.a.	n.a.

The average patent examination process takes 3.8 years in the EPO, 2.7 years in the Japanese Patent Office (JPO), and 2.7 years in the United States Patent and Trademark Office (USPTO).¹⁹⁵ Statistics from patent offices with fewer resources are more difficult to obtain. Given the flexibility of the term “reasonable” and the special acknowledgement in TRIPS of the limitations

Andean Community, Brazil, and Costa Rica require disclosure of origin). Some have raised doubts about whether disclosure laws are justified under article 62.1, but noted that they might instead be conceived of as patent misuse provisions justifiable under article 8. See Nuno Pires de Carvalho, *Requiring Disclosure of the Origin of Genetic Resources and Prior Informed Consent in Patent Applications Without Infringing the TRIPS Agreement: The Problem and the Solution*, 2 WASH. U. J.L. & POL’Y 371 (2000).

191. TRIPS, *supra* note 1, art. 62.2.

192. PhRMA recently asserted that “the average pendency period [in India] is 2–3 years.” PHARMACEUTICAL RESEARCH & MFRS. OF AM., SPECIAL 301 SUBMISSION 2008, at 65 (2008). Mueller notes the absence of systematic data on pendencies, and cites reports suggesting pendency periods that range from three to six years. Mueller, *supra* note 12, at 627.

193. Interview with T.C. James (in his personal capacity), Dir., Dep’t of Indus. Policy & Promotion, Gov’t of India, in New Delhi, India (June 22, 2007) (notes on file with author); The Patent (Amendment) Rules (India), 2005, at R. 24B(2)-(3) (amending The Patent Rules, 2003), available at <http://ipindia.nic.in/ipr/patent/patents.htm>.

194. EUROPEAN PATENT OFFICE (EPO), JAPAN PATENT OFFICE (JPO), & THE U.S. PATENT & TRADEMARK OFFICE (USPTO), TRILATERAL STATISTICAL REPORT: 2007 EDITION 49 tbl.4 (2007), <http://www.trilateral.net/statistics/tsr/2007/TSR.pdf>. The EPO opposition procedures are post-grant, so they are not strictly comparable to pre-grant oppositions in terms of implications for patentees.

195. The Report does not make clear whether the EPO “time in examination” includes the period of post-grant opposition for those patents that are opposed.

faced by developing countries' legal systems,¹⁹⁶ developing countries should be accorded extra latitude with regard to pendencies. This is affirmed when article 62 is read in light of article 7: the time that it takes to evaluate patents in a way that protects the "mutual advantage of producers and users" and that is "conducive to social and economic welfare" may well be longer in contexts with fewer administrative resources.¹⁹⁷ Indian procedures thus should meet the requirement of reasonableness imposed by TRIPS.

Here too, in common law fashion, India has developed a mode of internalizing TRIPS that could be widely adopted by other developing countries, thus improving accuracy in patent offices and making it more difficult for applicants to secure patents.

C. Remedies

The TRIPS flexibility that has received the least attention in the existing literature also has the most expansive potential. The Indian example illustrates how courts could use standard equitable tests for injunctive relief to prevent exclusivity from hindering access to medicines. If developing countries follow the Indian model, patents on medicines could be subject to a liability rule rather than a property rule in all cases where this would enhance access to medicines. Perhaps surprisingly, nothing in TRIPS appears to prevent developing countries from taking this approach.

1. Remedies

The recent U.S. Supreme Court case *eBay v. MercExchange* has spurred renewed attention to the remedies lever in patent law.¹⁹⁸ In *eBay*, the Court rejected the notion that injunctions should issue as a matter of course in patent cases, and held that courts must apply a four-part equitable test before awarding injunctive relief.¹⁹⁹ The plaintiff must demonstrate (1) irreparable injury, (2) inadequacy of monetary damages, (3) that the balance of the hardships favors the plaintiff, and (4) that "the public interest would not be disserved."²⁰⁰ The long-term implications of the case are not yet clear, but it has led to a new willingness among district courts to deny permanent injunctions.²⁰¹ Similarly,

196. See TRIPS, *supra* note 1, art. 41.5 (TRIPS does not create "any obligation with respect to the distribution of resources as between enforcement of intellectual property rights and the enforcement of law in general").

197. See *id.* art. 7.

198. See, e.g., Benjamin H. Diessel, Note, *Trolling for Trolls: The Pitfalls of the Emerging Market Competition Requirement for Permanent Injunctions in Patent Cases Post-eBay*, 106 MICH. L. REV. 305 (2007); Benjamin Petersen, Note, *Injunctive Relief in the Post-eBay World*, 23 BERKELEY TECH. L.J. 193 (2008).

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

200. *Id.*

201. For a survey of the implementation of *eBay* in district courts, see Peterson, *supra* note 198.

under Indian law, a court “may” issue a permanent injunction after infringement is found, but is not obliged to.²⁰²

The potential scope of this lever is illustrated by the recent case, *Roche v. Cipla*,²⁰³ one of the first patent infringement suits regarding a medicine to come before an Indian court. Roche sued Cipla to prevent the Indian company from launching a generic version of a Roche drug covered by a patent in India.²⁰⁴ Cipla counterclaimed, seeking the patent’s revocation,²⁰⁵ and asserted that a preliminary injunction should not issue because of the “overwhelming interest of society” in access to affordable, life-saving medicines. In support of their position, Cipla cited the substantial price differential between the Cipla version (Rs. 1,600/month, or about \$36 at current exchange rates) and the Roche version (Rs. 4,880/month, or about \$110 at current exchange rates).²⁰⁶

Referencing *eBay*, the court concluded that it should apply the normal standards for injunctive relief,²⁰⁷ which in the preliminary injunction context in India includes consideration of likelihood of success on the merits, irreparable injury, and the balance of convenience.²⁰⁸ After finding that Cipla had a credible case on the merits, the court considered the price differential between the Cipla and Roche products and stated that it could not “be unmindful of the right of the general public to access life saving drugs which are available and for which such access would be denied if the injunction were granted.”²⁰⁹ “The degree of harm in such eventuality,” it continued, “is absolute; the chances of improvement of life expectancy; even chances of recovery in some cases would be snuffed out altogether, if [an] injunction were granted. Such injuries to third parties are un-compensatable.”²¹⁰ The court referred again to *eBay*, and to a nonprecedential Federal Circuit decision that cited public health concerns to affirm the denial of an injunction in a case involving a drug-eluting stent.²¹¹

202. India Patents Act, *supra* note 101, § 108. One statutory provision of Indian law denies injunctions in certain cases. Under section 11A of the Indian Act, holders of patents granted from the mailbox are only entitled to a “reasonable royalty” against defendants who have made “significant investment and [who] were producing and marketing the concerned product prior to [Jan. 1, 2005] and which continue to manufacture the product covered by the patent on the date of grant of the patent.” *Id.* § 11A(7). There appear to have been no requests for compensation made yet under section 11A. *See* Interview with Gopakumar Nair, *supra* note 56.

203. F. Hoffmann-La Roche Ltd. v. Cipla Ltd., (2008) 642 I.A [hereinafter *Roche v. Cipla*], available at <http://www.i-mak.org/storage/F%20Hoffmann%20La%20Roche%20v%20Cipla%20Ltd%202008.pdf>.

204. *Id.* ¶¶ 3–4.

205. *Id.* ¶¶ 9–12.

206. *Id.* ¶ 14.

207. *Id.* ¶ 63.

208. *See, e.g.,* Standipack Private Ltd. v. M/s. Oswal Trading Co., 2000 A.I.R. 23 (Del.) ¶ 20.

209. *Roche v. Cipla*, ¶ 78, ¶ 85.

210. *Id.* ¶ 85. It also indicated that such a result would conflict with the constitutional right to life. *Id.*; *see also* INDIA CONST. art. 21.

211. *Roche v. Cipla*, ¶ 85; *see also* Cordis v. Boston Scientific Co., 99 Fed. Appx. 928, 935 (Fed. Cir. 2004).

Concluding that the harm to third parties would be irreparable, the court denied the preliminary injunction.²¹²

This case is on appeal as of this writing, and the High Court's reasoning might not prevail.²¹³ But if it does, its logic would be easy to apply in the permanent injunction context. More importantly, the court, acting in common law fashion, has illustrated the enormous potential of the remedies lever to limit exclusive rights in the domain of medicines.

2. *Implications and Consistency with TRIPS*

If followed, the *Roche* precedent would render pharmaceutical patents subject to a liability rule in any case where a patent would inhibit access to medicines. This does not mean that courts would never grant injunctions. Courts might grant an injunction if, for example, the generic firm could not provide the product at lower cost, or if affordable alternatives were available in the market. If generic companies were confident that the *Roche* rule would be consistently applied, they would presumably enter the market and invite infringement suits or licenses wherever they could markedly undercut the originator's price. This would leave patent holders with damages in lieu of exclusive rights. The amount of damages awarded would of course be important to the effect of the rule. Lost profits would be one way to measure damages, and a hypothetical reasonable royalty another.²¹⁴ Where an injunction is denied because of the expected effects of profit-maximizing strategies on health, however, the reasonable royalty approach is clearly preferable. Depending on how they are calculated, reasonable royalties could substantially reduce the costs of medicines for patients.²¹⁵

Perhaps surprisingly, TRIPS does little to limit the remedial authority of judges. Article 44.1 states that “[t]he judicial authorities shall have the authority to order a party to desist from an infringement.”²¹⁶ As a panel recently emphasized in the *US—China Copyright* case, the phrase “have the authority” identifies an obligation “to ‘have’ authority not an obligation to ‘exercise’ authority.”²¹⁷ (While the panel was interpreting the term in the context of article 59, there is no obvious reason that its conclusion would not apply to the same term in article 44.1.) It also affirmed that the obligation to “have the

212. *Roche v. Cipla*, ¶¶ 86–87.

213. An appeal by Roche to the Delhi High Court for an interim injunction was recently rejected. See *F. Hoffmann-La Roche Ltd. v. Cipla Ltd.*, FAO (OS) 188/2008 (Apr. 24, 2009), available at <http://www.i-mak.org/pharma-patent-decisions/>.

214. See, e.g., 35 U.S.C. § 284 (2000).

215. For a list of the factors that U.S. courts consider in this analysis, see *Georgia-Pacific Corp. v. U.S. Plywood Corp.*, 318 F. Supp. 1116, 1120 (S.D.N.Y. 1970).

216. TRIPS, *supra* note 1, art. 44.1.

217. Panel Report, *China—Measures Affecting the Protection and Enforcement of Intellectual Property Rights*, ¶ 7.236, WT/DS362/R (Jan. 26, 2009) [hereinafter *China—Copyright*]; see also GERVAIS, *supra* note 144, at 447, 453.

authority” is not an obligation to “have the authority to order those remedies only,” or to “exercise that authority in a particular way, unless otherwise specified.”²¹⁸

The panel provided no clarity about the kinds of conditions that could legitimately be attached to the exercise of judicial authority to grant an injunction,²¹⁹ but did suggest that some degree of discretion might be required to meet the requirement to “have the authority.”²²⁰ There is room for debate about how much discretion article 44.1 gives to judges, but it is hard to see how a flexible equitable test such as the one employed in *Roche* or *eBay* would deny judges the “authority” to grant injunctions.²²¹ That is so even if they exercise that authority in predictable ways (as appears to be the case after *eBay* in the United States).²²² The exercise of judicial discretion is inevitably bounded in some fashion by precedent or statute—and perhaps must be, in light of other TRIPS requirements (such as the obligation in article 41.2, discussed below, that enforcement procedures be “fair”). Finally, article 44.2 suggests countries may be able to go still further and deny, as a matter of law, the application of injunctions altogether, although it is unclear how to reconcile this with article 44.1.²²³

218. *China—Copyright*, *supra* note 217, ¶¶ 7.238–239.

219. *Id.* ¶ 7.248.

220. *Id.* ¶ 7.252 (“Whilst authority to order a disposition method *not* required by Article 59 does not, in itself, lead to WTO-inconsistent action, to the extent that such authority mandates a disposition method in any given circumstance it may preclude authority that *is* required by Article 59. The preclusion of such authority may be WTO-inconsistent.”) (emphasis added). The panel also suggested that the existence of discretion alone does not shield a law from the requirements of article 59, but did not specify the terms under which such discretion would be problematic. *See id.* ¶ 7.253.

221. If the power in question was never used, an objection might be possible under another provision of TRIPS, such as the article 41 requirement “that enforcement procedures be ‘available . . . so as to permit effective action against any act of infringement. . . .’” *See* James Mendenhall, *WTO Panel Report on Consistency of Chinese Intellectual Property Standards*, ASIL INSIGHT, Apr. 3, 2009, <http://www.asil.org/insights090403.cfm> (citing TRIPS, *supra* note 1, art. 41.1). In the judicial remedies context, however, damages might well constitute “effective action” against infringement. The claim that a country member systematically refused to apply certain remedies would run up against the continued moratorium on nonviolation complaints under TRIPS. *See* World Trade Organization, Ministerial Declaration of 18 December 2005, ¶ 45, WT/MIN(05)/DEC (2005); GERVAIS, *supra* note 144, at 441.

222. On the aftermath of *eBay*, see Petersen, *supra* note 198, at 203 (concluding, for example, that courts are “much more likely” to grant an injunction if the patent holder practices the invention).

223. Article 44.2 states:

“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 [article 31(h)]. 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.”

TRIPS, *supra* note 1, art. 44.2. This rarely-noted provision appears to state that money judgments will be deemed sufficient in any case where a member’s own law does not permit injunctions. This reading gains some support from the preparatory history. It was not included in the initial

TRIPS does require enforcement proceedings to be effective and fair. Article 41.1 states that enforcement proceedings must “permit effective action against any act of infringement of intellectual property rights covered by the Agreement, including expeditious remedies to prevent infringements and remedies which constitute a deterrent to further infringements.”²²⁴ Article 41.2 states that “[p]rocedures concerning the enforcement of intellectual property rights shall be fair and equitable.”²²⁵ Again, commentators shed little light on the precise implications of these provisions. But they must be read to be consistent with article 44, which clearly contemplates that remedies other than injunctions will sometimes be imposed. Such remedies cannot, therefore, be categorically “unfair” or “ineffective.” If they were, *eBay* would be no less problematic than *Roche v. Cipla*. Articles 7 and 8 also ought to influence any reading of the remedies clauses in TRIPS. Read through the lens of these provisions, the nature of an “effective” remedy should be understood not solely from the perspective of a patent holder but also from the perspective of consumers. If injunctions are denied on the grounds that they conflict with the “balance of rights and obligations” or the “public interest,” then damages would seem the only “effective” remedy taking into account the perspective of both patentees and the public.

Finally, TRIPS requires that in a case of knowing infringement, judges “have the authority to order the infringer to pay the right holder damages adequate to compensate for the injury the right holder has suffered.”²²⁶ Again, the formulation “have the authority” makes clear that the obligation here is to provide courts with authority, not to require them to exercise it. No definition of “adequate compensation” is offered, leaving commentators to suggest that

1990 draft of the Agreement, which reflected provisions proposed by the European Community, the United States, Brazil, Argentina, Chile, China, Cuba, Columbia, Egypt, India, Peru, Nigeria, Tanzania, and Uruguay. GERVAIS, *supra* note 144, at 147 n.1. It was introduced in the Brussels draft, after broader negotiations. *Id.* at 449. Gervais notes that debates over the remedial provisions of TRIPS were difficult, in part because of the “differences amongst legal systems” present in the negotiations. *Id.* at 440. He cites in particular the fact that some Southeast Asian countries simply “did not provide for preventive injunctions.” *Id.* at 441. Some commentators have concluded that article 44.2 permits countries broad discretion to limit injunctions. Christopher A. Cotropia, *Compulsory Licensing Under TRIPS and the Supreme Court of the United States’ Decision in eBay v. MercExchange*, in PATENT LAW AND THEORY: A HANDBOOK OF CONTEMPORARY RESEARCH 557, 580 (Toshiko Takenaka ed., 2008) (suggesting that the *eBay* decision falls under the second sentence of article 44.2); Joshua D. Sarnoff, *Flexible Application of Injunctive Relief in Intellectual Property Enforcement (With Reference to Lessons from the Emerging US Jurisprudence)*, in INTELLECTUAL PROPERTY ENFORCEMENT (Xuan Li & Carlos M. Correa eds., forthcoming 2009). This interpretation puts article 44.2 in tension with article 44.1, leading some commentators to conclude that article 44.2 merely indicates that injunctions need not be permitted in cases challenging a decision to invoke the government use provisions of TRIPS. See ICTSD & UNCTAD, *supra* note 111, at 479. But that interpretation also strains the language of the provision, and seems less likely in light of the preparatory history.

224. TRIPS, *supra* note 1, art. 41.1.

225. *Id.* art. 41.2.

226. *Id.* art. 45.1.

“[m]embers have considerable leeway to determine when the compensation would be deemed adequate.”²²⁷

Were other developing countries to apply the logic of *Roche*, they would be able to eliminate exclusivity on medicines in every case where it would significantly threaten access to medicines. If courts acted consistently, this would create extensive scope for competition in the pharmaceutical sector while apparently fully complying with TRIPS.

D. Government Authorization

The patent levers that have received the most attention under TRIPS have been government use and compulsory licensing.²²⁸ Because they are well known in the literature, my review of their use in the Indian context will be brief.

1. Government Use and Compulsory Licensing

India's primary government use provision states that “the Central Government and any person authorised in writing by it, may use [an] invention” without the permission of the patent holder.²²⁹ In accordance with TRIPS requirements, the law provides for “adequate remuneration in the circumstances of each case, taking into account the economic value of the use of the patent,”²³⁰ and requires that the government notify patentees of the use as “soon as practicable,” except in cases of emergency.²³¹ Another provision of India's law predicates the grant of patents under the Act on the right of government use (for patented processes) and government importation and working (for patented machines, apparatuses, or products-by-process).²³² Finally, a provision specifically related to medicines permits the government to import patented drugs or medicines “for the purpose merely of its own use or for distribution in any dispensary, hospital or other medical institution” maintained by or for the government or designated under the Act.²³³

India's law also contains a very broad compulsory licensing provision. It may be invoked after three years from the grant of the patent,²³⁴ on three identified grounds: that (1) the “reasonable requirements of the public have not been satisfied”; (2) “the patented invention is not available to the public . . . at a reasonably affordable price”; and (3) “the patented invention is not worked in the territory of India.”²³⁵ If any of these criteria are met, the Controller General

227. ICTSD & UNCTAD, *supra* note 111, at 592.

228. *See supra* note 99.

229. India Patents Act, *supra* note 101, § 100(1).

230. *Id.* § 100(3); *cf.* TRIPS, *supra* note 1, art. 31(h).

231. India Patents Act, *supra* note 101, § 100(5); *cf.* TRIPS, *supra* note 1, art. 31(b).

232. India Patents Act, *supra* note 101, § 47(1)–(3).

233. *Id.* § 47(4).

234. *Id.* § 84(1).

235. *Id.* Section 84(7) also includes a list of circumstances where the reasonable

“may grant a license upon such terms as he may deem fit.”²³⁶

Private companies may apply for a compulsory license directly to the patent office that granted the patent.²³⁷ The controller who oversaw the grant of the patent in question will make the initial decision,²³⁸ taking into account factors, including “whether the applicant has made efforts to obtain a license from the patentee on reasonable terms and conditions and such efforts have not been successful within a reasonable period as the Controller may deem fit,” identified generally as a period not ordinarily exceeding six months.²³⁹

Another provision of the Indian Act permits export under compulsory license if the license is granted with the “predominant purpose of supply in the Indian market,” or if a compulsory license is issued to remedy anticompetitive practices.²⁴⁰ Special provision is made for compulsory license for export to countries with “insufficient or no manufacturing capacity.”²⁴¹ Where a compulsory license is sought for manufacture and export under this last provision, the controller apparently has no discretion to deny it.²⁴²

2. *Implications and Consistency with TRIPS*

The implications of government use and compulsory licensing provisions are straightforward: if employed, such provisions give the government the ability to set the terms of use for patents, converting a property rule to a liability rule. If widely used, these provisions would provide India and other developing countries with substantial freedom to permit competition in the area of medicines.

TRIPS permits both government use and compulsory licensing, as long as countries meet specified requirements.²⁴³ Decisions must be made on their “individual merits.”²⁴⁴ In cases of government use or emergency, there is no need for prior negotiation with the rights holder, but in other instances applicants must make “efforts to obtain authorization from the right holder on reasonable commercial terms and conditions” for a “reasonable period of time.”²⁴⁵ Patentees must be “paid adequate remuneration in the circumstances

requirements of the public shall be deemed to be unsatisfied, including where local demand is not satisfied, export markets are not satisfied, or the patent is licensed coercively or to prevent patent challenges. *Id.* § 84(7).

236. *Id.* § 84(4).

237. *Id.* § 84(1).

238. Interview with T.C. James (in his personal capacity), *supra* note 193.

239. India Patents Act, *supra* note 101, § 84(6)(ii), (iv).

240. *Id.* § 90(vii), (ix).

241. *Id.* § 92A.

242. *Id.* § 92A(2).

243. TRIPS, *supra* note 1, art. 31.

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

245. *Id.* art. 31(b). In cases of government use or emergency compulsory license, “the right holder shall be informed promptly.” *Id.*

of each case, taking into account the economic value of the authorization.”²⁴⁶ They must also be able to challenge the legal validity of the decision before a court or other independent body, except in cases of government use.²⁴⁷

Under TRIPS, countries are free to determine the circumstances in which compulsory licenses are appropriate.²⁴⁸ While some of India’s government-use provisions do not, by statute, require adequate compensation and notification to the rightsholder, these could be provided for by regulation. Alternatively, the government could rely on its main government-use provision in article 100, which appears to be fully TRIPS compliant. India’s export provisions, finally, should be fully consistent with article 31(f) and the recently negotiated waiver, assuming that the required notifications are made.²⁴⁹

In sum, pharmaceutical patents that survive the application of the other levers can be overridden via the government authorization lever, within the constraints of the TRIPS Agreement.

E. Patent Misuse

India’s law also includes robust prohibitions on patent misuse. If implemented strictly, these prohibitions could substantially constrain the terms of voluntary licenses between multinational and local firms, again consistent with the TRIPS Agreement.

1. Patent Misuse

In the United States, the common law doctrine of patent misuse evolved to restrain licensing or sale practices that violate antitrust laws or that “extend[]

246. *Id.* art. 31(h).

247. *See id.* arts. 31(i), 44.2.

248. *See* TRIPS, *supra* note 1, art. 31; *see also* Doha Declaration, *supra* note 7, ¶ 5(b) (affirming that signatories have “the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted”). Some have doubted whether local working is a legitimate ground for a compulsory license because article 27.1 states that “patents shall be available and patent rights enjoyable without discrimination as to . . . whether products are imported or locally produced.” TRIPS, *supra* note 1, art. 27.1. This arguably conflates rights and remedies, conflicts with the Doha Declaration, *supra* note 7, ¶ 5(b), and is in tension with the incorporation of article 5.2 of the Paris Convention into TRIPS. *See* TRIPS, *supra* note 1, art. 2 (incorporating arts. 1–12 and 19 of the Paris Convention); Paris Convention for the Protection of Industrial Property art. 5.2, Mar. 20, 1883, 21 U.S.T. 1583, 828 U.N.T.S. 305 (revised at Stockholm Revision Conference July 14, 1967) (“Each country of the Union shall have the right to take legislative measures providing for the grant of compulsory licenses . . . , for example, [for] failure to work.”).

249. Article 31(f) of TRIPS provides that use without the authorization of the patent holder “shall be authorized predominantly for the supply of the domestic market,” except in cases of anticompetitive practices. TRIPS, *supra* note 1, arts. 31(f), 31(k). A recent waiver permits countries to grant compulsory licenses for export to countries that attest that they have insufficient manufacturing capacity, provided that countries report, for example, the quantity of the goods exported. *See* Decision of the General Council, Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, WT/L/540 (Aug. 30, 2003).

the patent beyond its lawful scope.”²⁵⁰ It operates as an affirmative defense to an infringement proceeding,²⁵¹ and has been revised over the years to limit a fairly narrow set of practices.²⁵² It forbids, for example, “employing the patent beyond its . . . term,” and “using a patent which enjoys market power in the relevant market . . . to restrain competition in an unpatented product.”²⁵³ Tying arrangements (or restrictions on the sale of distinct articles) were once treated with great suspicion by U.S. courts, but are today only impermissible if the defendant demonstrates that the patentee has market power.²⁵⁴ Field of use restrictions are “generally upheld” and subject only to the rule of reason.²⁵⁵ Grant-back provisions are similarly treated with “lenien[cy],”²⁵⁶ although some analysts have suggested that exclusive grant-back provisions may be problematic and raise anti-competitive concerns.²⁵⁷

As in the United States, any party that can show patent misuse in India enjoys a complete defense to infringement.²⁵⁸ But India’s grounds for finding misuse are substantially broader than those in the United States. They cover any license, sale agreement, or lease that limits the recipient’s ability to acquire or use “any article other than the patented article,”²⁵⁹ or to use “any process other than the patented process.”²⁶⁰ Unlike in the United States, India’s restriction on tying appears to be absolute.

Also strictly prohibited are exclusive grant-back requirements,²⁶¹ prohibitions on “challenges to validity of [the covered] Patent,”²⁶² and “[c]oercive package licensing.”²⁶³ All three terms come directly from the

250. 6 CHISUM, *supra* note 126, § 19.04 (2000); *see also* Mallinckrodt, Inc. v. Medipart, Inc., 976 F.2d 700, 704 (Fed. Cir. 1992) (suggesting that the concept “arose to restrain practices that did not in themselves violate any law, but that drew anticompetitive strength from the patent right, and thus were deemed to be contrary to public policy”).

251. 6 CHISUM, *supra* note 126, § 19.04.

252. *See* Va. Panel Corp. v. MAC Panel Co., 133 F.3d 860, 869 (Fed. Cir. 1997) (setting forth a three-part test for evaluating patent misuse); *see also* Burk & Lemley, *supra* note 95, at 1663 (concluding that patent misuse claims “have been on the wane in patent law”).

253. B. Braun Med., Inc. v. Abbott Labs., 124 F.3d 1419, 1426 (Fed. Cir. 1997); *see also* Va. Panel Corp., 133 F.3d at 869.

254. 35 U.S.C. § 271(d)(5) (2000); *see also* Ill. Tool Works Inc. v. Indep. Ink, Inc., 547 U.S. 28, 45–46 (2006).

255. B. Braun Med., Inc., 124 F.3d at 1426.

256. ROBERT P. MERGES, PETER SETH MENELL & MARK A. LEMLEY, *INTELLECTUAL PROPERTY IN THE NEW TECHNOLOGICAL AGE* 340 (4th ed. 2007).

257. 1 HERBERT HOVENKAMP ET AL., *IP AND ANTITRUST: AN ANALYSIS OF ANTITRUST PRINCIPLES APPLIED TO INTELLECTUAL PROPERTY LAW* § 3.3b4 (Supp. 2003); U.S. DEP’T OF JUSTICE & FED. TRADE COMM’N, *ANTITRUST GUIDELINES FOR THE LICENSING OF INTELLECTUAL PROPERTY* § 5.6 (1995).

258. India Patents Act, *supra* note 101, § 140(3).

259. *Id.* § 140(iii)(a)–(b).

260. *Id.* § 140(iii)(c).

261. *Id.* § 140(iii)(d).

262. *Id.*

263. *Id.* § 140(iii)(c)–(d).

TRIPS Agreement.²⁶⁴ The first two requirements are fairly straightforward. The definition of the term “coercive package licensing” is more obscure. It goes undefined both in the statute and the Draft Patent Manual. The Act also requires that a copy of all “agreements, licenses and other documents affecting the title to any patent” be filed with the patent office.²⁶⁵ The provision does not appear to be in active use, perhaps because the penalty for failure to comply is unclear.²⁶⁶

2. *Implications and Consistency with TRIPS*

The narrow scope of patentability and multiple opportunities for challenging patents in India give patent-based firms an incentive to bargain around the law and strike voluntary licensing agreements with their local competitors. No systematic data about the practice is available, but a recent example will illustrate.

One of the most important AIDS drugs today is Tenofovir, a drug marketed by Gilead Inc. and subject to several patent applications in India. Several Indian NGOs filed an opposition to one of the patents in May 2006.²⁶⁷ The next day, Gilead announced that it had concluded voluntary licensing agreements covering Tenofovir with several Indian pharmaceutical companies.²⁶⁸ One company Gilead had approached was Cipla. According to Cipla CEO Yusuf Hamied, in their negotiations, Gilead sought to restrict export to countries where Gilead did not hold patents, insisted on the inclusion of know-how despite Cipla’s insistence that the company did not need it, demanded a grant-back of any improvements made by the licensee, and forbade any challenge to its patents.²⁶⁹ Hamied refused the agreement.²⁷⁰

Eleven other companies struck a deal with Gilead.²⁷¹ The terms of the licenses include limits on export (forbidding, for example, export to Brazil and

264. See TRIPS, *supra* note 1, art. 40(b).

265. India Patents Act, *supra* note 101, § 69(4).

266. See *id.* § 69(5); see also Posting of Shamnad Basheer to Spicy IP, <http://spicyipindia.blogspot.com/2008/08/roche-vs-cipla-is-roche-osipfizer.html> (Aug. 28, 2008, 22:54).

267. See Third World Network, *Indian Opposition to Drug Patents*, THIRD WORLD NETWORK INFO. SERVICE, May 23, 2006, <http://www.twinside.org.sg/title2/health.info/twninfohealth018.htm>.

268. Press Release, Gilead, Gilead Offers Voluntary Licenses for Manufacturing of Viread in Developing World (May 10, 2006), available at http://www.gilead.com/pr_1147371459.

269. Interview with Dr. Yusuf Hamied, Chairman & Managing Dir., Cipla Co., in Mumbai, India (May 30, 2007) (transcript on file with author).

270. *Id.*

271. See Press Release, Gilead, Gilead Announces Licensing Agreements with Three India-Based Companies for Manufacturing and Distribution of Generic Versions of Viread in the Developing World (Aug. 14, 2006), available at http://www.gilead.com/pr_895671; Press Release, Gilead, Gilead Announces Licensing Agreements with Eight India-Based Companies for Manufacturing and Distribution of Generic Versions of Viread in the Developing World (Sept. 22, 2006), available at http://www.gilead.com/pr_908393.

China), limits on the sale of APIs outside of India and the purchase of APIs from unapproved sources, and the transfer of know-how.²⁷² The last is notable, given the pending patent oppositions, because the inclusion of know-how could provide a basis for the continuing validity of the license even if the patents are denied. The license appears to exclude the requested restriction on opposing Gilead's patents, likely because it would contravene local patent misuse law.

If interpreted expansively, India's patent misuse provisions would forbid a series of terms that patent-based companies might otherwise seek to impose in licenses. If we were to presume costless transactions, the end result could be fewer voluntary licenses. Given the resource and informational asymmetries between patent-based companies and particularly the smaller local companies, it is equally plausible that the result will be less restrictive licensing agreements. Furthermore, if patent holders refuse to grant licenses, local competitors can avail themselves of some of India's other levers by, for example, seeking to invalidate the patents or to obtain compulsory licenses to override them.

India's patent misuse provisions appear to be fully consistent with TRIPS. Article 40.1 of the Agreement recognizes that "some licensing practices or conditions pertaining to intellectual property rights which restrain competition may have adverse effects on trade and may impede the transfer and dissemination of technology."²⁷³ Article 40.2 notes that TRIPS does not "prevent Members from specifying in their legislation licensing practices or conditions that may in particular cases constitute an abuse of intellectual property rights having an adverse effect on competition in the relevant market," and lists as examples "exclusive grantback conditions, conditions preventing challenges to validity and coercive package licensing."²⁷⁴ India's law simply mirrors TRIPS with regard to these latter three terms. India's restrictions on tying are clearly targeted at activities thought to "have an adverse effect on competition in the relevant market." India's model thus illustrates a final TRIPS lever that is rarely discussed, but that developing countries might adopt in order to constrain the terms of voluntary agreements and thus limit the leverage of patent holders.

F. Conclusion

There is now a significant resemblance between Indian law and U.S. law: both include the same key components of patentability (novelty, obviousness, and utility), and Indian law no longer categorically excludes patents on pharmaceutical compounds. This resemblance has important consequences, as the next Part will show. But it is also superficial. If implemented in their most

272. License Agreement between Gilead and Indian Licensees (on file with author) (provided by Brett Pletcher, Vice President, Corporate Legal Affairs at Gilead Sciences, Inc.).

273. TRIPS, *supra* note 1, art. 40.1.

274. *Id.* art. 40.2.

ambitious form, the nuances in India's law would permit it (and other developing countries) to produce results in the pharmaceutical domain dramatically different from those we see in the United States. Pharmaceutical patents would be largely limited to patents on new compounds, substantially reducing the number of patents related to medicines. This move alone would put a large number of medicines into the public domain, and significantly reduce the terms of exclusivity available for medicines subject to at least one valid patent. Some proportion of the remaining patents would be eliminated by a stringent obviousness requirement. Others would be invalidated because applicants failed to comply with procedural requirements or on the basis of information gathered through these requirements. Those patents still standing would provide exclusive rights, but only yield injunctive remedies in cases where there was no significant risk that poor patients would lose access to the medicine in question. In the rare case where these measures left in place exclusivity that caused concern from a public health standpoint, government use provisions and compulsory licenses could be deployed.

A substantial number of drug patents valid in the United States thus would be rendered invalid in India, and even valid medicine patents would provide very limited assurances of exclusivity. India would have made serious inroads into the ability of TRIPS to produce what its proponents desired, and yet almost certainly be in compliance with its TRIPS obligations.

III

LIMITATIONS ON TRIPS FLEXIBILITY

Under pressure from local industry and activists, the Indian government has creatively implemented TRIPS in a manner that leaves substantial scope for competition in the pharmaceutical sector. As a formal matter, this demonstrates that TRIPS cannot force developing countries to deeply harmonize their patent laws with those of developed countries. This Part demonstrates that TRIPS nonetheless sets up a strong harmonizing dynamic because it inserts developing countries into a transnational circuit that fills in gaps in the Agreement and works against the use of flexibilities.²⁷⁵ The effects of this can be observed in

275. Although many discussions of TRIPS flexibilities operate at the formal level, some scholars have done important work to show that contextual factors affect developing countries' ability to use TRIPS flexibilities. For discussions of the influence of unilateral pressure, see, for example, Fredrick M. Abbott & Jerome H. Reichman, *The Doha Round's Public Health Legacy: Strategies for the Production and Diffusion of Patented Medicines Under the Amended TRIPS Provisions*, 10 J. INT'L ECON. L. 921, 980–81 (2007), and MUSUNGU & OH, *supra* note 99, at 43–50. For accounts of the influence of technical assistance and resource limitations, see, for example, DEERE, *supra* note 12, and Peter Drahos, "Trust Me": *Patent Offices in Developing Countries*, 34 AM. J.L. & MED. 151 (2008). My contribution here is to offer a structured and detailed account of how such obstacles operate in the Indian context, to demonstrate that resource limitations and transnational culture are as important as the more commonly discussed obstacle of unilateral retaliation, and to show that all of these obstacles are not ancillary to, but shaped by, the transnational legalization of patent law.

India in three domains. The first relates to resources. As I will show, limitations on resources, particularly in the patent offices, interfere with consistent and independent interpretation of Indian law. These resource limitations are particularly acute because they are relative, and exist within a harmonized framework of patent law. Indian examiners face rising numbers of patent applications each year, facilitated in substantial part by the administrative harmonization imposed by the PCT and the changes in Indian patent law that render new subject matters open to protection.

These resource disparities are exacerbated by the influence of a second domain: transnational legal culture. Today, a robust network of transnational influences challenge India's ability to sustain its alternative vision of patent law over time, particularly in the context of limited resources. These influences are also conditioned by TRIPS. Although the Agreement does not require deep harmonization, it does produce formal similarity in the law of its members. This facilitates the provision of expertise from developed countries in the form of both training and doctrine—expertise that is keyed to the broad similarities rather than the differences between local law and the law of the country providing the assistance.

Third, exploitation of the more politically salient policy levers, and particularly of compulsory licensing, may be influenced by extralegal pressures from countries whose trade policies are responsive to the patent-based pharmaceutical industry. These pressures are in some ways constrained by TRIPS (at least in theory), but they also work in conjunction with it, by discouraging developing countries from adopting expansive interpretations of the Agreement's flexibilities.

A. *Resource Limitations*

The recent amendments inaugurated dramatic changes in Indian patent law. India's judiciary and patent offices are thus approaching for the first time the many complex questions associated with these developments. There is substantial worry among those following the implementation of the new law that it will not be interpreted accurately, and that provisions such as section 3(d), with its undefined reference to "efficacy," leave too much discretion in the hands of individuals with little exposure to the issues.²⁷⁶ My interviews in three of India's four patent offices indicate that different offices, and even different examiners in the same office, took substantially different views on questions such as the meaning of the term "efficacy" or the proper approach to the inventive step inquiry. According to some observers, by simply perusing the titles of granted patents one can tell that patents are being granted on clearly unpatentable subject matter.²⁷⁷ This is not unusual in resource-poor settings. As

276. See, e.g., Interview with Dr. B.K. Keayla, *supra* note 29, at 7–8.

277. Interview with K.M. Gopakumar, *supra* note 83.

others have noted, “the task of determining whether the criteria of novelty, inventive step, and industrial applicability [are] met [is] often beyond the technical, legal, or scientific competence of national IP officials” in developing countries.²⁷⁸ As a result, “the practice of rubber-stamping patents already issued elsewhere . . . , whether or not consistent with national IP laws, [has] continued widely across Africa and the developing world.”²⁷⁹

Some of these issues may be transitional. However, administering a patent system is a resource-intensive business, requiring substantial financial input and skilled examiners. Resource-poor countries simply lack the ability to marshal the kinds of resources allocated to patent examinations in, for example, the United States. Officials in Indian patent offices note that there are too few examiners in India and that examiners are lured away by higher salaries in the private sector.²⁸⁰ Although the same complaints can be heard at the USPTO,²⁸¹ the following data show that Indian examiners must do nearly twice the work with just 3 percent of the funding per patent of U.S. examiners (or, if funding is adjusted using purchasing power exchange rates, with less than half the resources).²⁸²

278. DEERE, *supra* note 12, at 202.

279. *Id.*

280. *See, e.g.*, Interview with Controller #1 (notes on file with author). Some interviewees in the patent offices requested that I not use their names and refer to them only as, for example, a patent examiner, or a patent examiner from a particular office. In order to protect the confidentiality of those who sought it, and for the sake of consistency, I refer to all of those who I interviewed in the patent offices by title alone. I also give each interviewee or group of interviewees a number, so that readers can identify statements made by the same interviewee(s). I conducted the interviews in person at three of India’s four patent offices (all except Kolkata) in June 2007.

281. *See, e.g.*, U.S. GOV’T ACCOUNTABILITY OFFICE, U.S. PATENT AND TRADEMARK OFFICE: HIRING EFFORTS ARE NOT SUFFICIENT TO REDUCE THE PATENT APPLICATION BACKLOG 13–17 (2007) (reporting problems with attrition and excessive workloads).

282. A rupee in India buys much more than it would in the United States. Comparing costs across countries is thus notoriously difficult. A rough comparison can be generated using the World Bank’s “purchasing power parity” (PPP) exchange rates, which estimate the amount of money required in different countries to purchase a set basket of goods. *See* World Bank, International Comparison Program—Overview, <http://go.worldbank.org/X3R0INN80> (last visited Nov. 11, 2009). The latest (2007) conversion rate for India is 16.537 rupees to the dollar. *See* United Nations, Millennium Development Goals Indicators, <http://mdgs.un.org/unsd/mdg/SeriesDetail.aspx?srid=699> (last visited Nov. 11, 2009). The PPP method has been sharply criticized, and likely underestimates the actual degree of inequality between countries, particularly when considering the very poor. *See* Sanjay G. Reddy & Thomas W. Pogge, *How Not to Count the Poor*, SOCIALANALYSIS.ORG, Oct. 29, 2005, <http://www.socialanalysis.org/>. PPP figures thus should be treated very cautiously.

Table 3: Average Workload & Resources, Indian vs. U.S. Examiners (2005–08)

	Avg. Number of Examiners, 2005–08 ²⁸³	Avg. Annual Requests for Examination / Applications, 2005–08 ²⁸⁴	Avg. Annual Applications per Examiner, 2005–08 ²⁸⁵
India	137	20,930	153
United States	5168	454,643	88

	Estimated Avg. Annual Patent Budget, 2005–08 ²⁸⁶	Avg. Annual Requests for Examination / Applications, 2005–08 ²⁸⁷	Avg. Annual Budget per Application	PPP comparison
India	\$1.89 million	20,930	\$90	\$1425
United States	\$1.4 billion	454,643	\$3232	\$3232

283. Indian data from IPO ANNUAL REPORT 2008, *supra* note 155, app. A; OFFICE OF THE CONTROLLER GEN. OF PATENT DESIGNS & TRADEMARKS, GOV'T OF INDIA, ANNUAL REPORT 2006–2007 app. A (2007), *available at* <http://www.patentoffice.nic.in/>; OFFICE OF THE CONTROLLER GEN. OF PATENT DESIGNS & TRADEMARKS, GOV'T OF INDIA, ANNUAL REPORT 2005–2006 app. A (2006), *available at* <http://www.patentoffice.nic.in/>; OFFICE OF THE CONTROLLER GEN. OF PATENT DESIGNS & TRADEMARKS, GOV'T OF INDIA, ANNUAL REPORT 2004–2005 app. A (2005), *available at* <http://www.patentoffice.nic.in/>. U.S. data from U.S. PATENT & TRADEMARK OFFICE, PERFORMANCE AND ACCOUNTABILITY REPORT 143 (2008) [hereinafter PTO ANNUAL REPORT].

284. Data from IPO ANNUAL REPORT 2008, *supra* note 155, at App. D; PTO ANNUAL REPORT, *supra* note 283, at 62. The U.S. system requires examination of every patent while the Indian system requires examination only upon the request of the patent holder. The figures thus compare numbers of requests for examination in India with numbers of applications in the United States. If the Indian system of requests for examination weeds out a substantial number of patents that would be easy to resolve, the workload for Indian examiners would be yet more disproportionate, because each application would be on average more difficult to resolve.

285. The Indian estimate is consistent with reported quotas, which are between ten and fifteen applications per month (for a total of 120 to 180 applications per year). Interview with Controller #1, *supra* note 280.

286. This is the average expenditure from the years 2005 to 2008. For the Indian figures by year, *see* IPO ANNUAL REPORT 2008, *supra* note 155, at 12; OFFICE OF THE CONTROLLER GEN. OF PATENT DESIGNS & TRADEMARKS, GOV'T OF INDIA, ANNUAL REPORT 2006–2007, at 6 [hereinafter IPO ANNUAL REPORT 2007]; OFFICE OF THE CONTROLLER GEN. OF PATENT DESIGNS & TRADEMARKS, GOV'T OF INDIA, ANNUAL REPORT 2005–2006, at 7; OFFICE OF THE CONTROLLER GEN. OF PATENT DESIGNS & TRADEMARKS, GOV'T OF INDIA, ANNUAL REPORT 2004–2005, at 4. The Indian average was converted to dollars using prevailing exchange rates at the time of writing. The USPTO does not report estimates of the costs of examining a patent. But because funding for the USPTO budget comes almost entirely from fees collected from users of the system, we can get a rough estimate of the amount available for patent examination. *See* PTO ANNUAL REPORT, *supra* note 283, at 74–75. The average revenues from patent filing fees from 2005 to 2008 were about \$1.4 billion per year. *Id.* at 56. This compares favorably to Merges's estimate, derived in the same way, from the mid-1990s. *See* Robert P. Merges, *As Many as Six Impossible Patents Before Breakfast: Property Rights for Business Concepts and Patent System Reform*, 14 BERKELEY TECH. L.J. 577, 692 (1999) (citing available revenues of about \$3000 per patent).

287. *See supra* note 284.

The funding limitations might be alleviated in part by allocating more of the revenues that the Indian patent offices generate directly back to their activities. The patent office took in about \$35.3 million last year, most of which went to the central government.²⁸⁸ If more of that funding were allocated instead to the patent offices, parity in terms of purchasing power estimates (although not absolute parity) could be produced. Of course it is not clear that this budgetary allocation would be superior, given the competing demands on India's budget.

The true disparities, however, are more substantial than these comparisons reveal. Indian offices are only beginning to digitize, meaning that they benefit from very few of the efficiency gains that may be associated with information and communication technologies.²⁸⁹ Examiners recently gained access to a serious prior art database, but some report that the access is insufficient because of the limited funds allocated to pay for searches.²⁹⁰ Others report that it is still difficult to gain access to basic prior art materials such as journals and books.²⁹¹ Shortages of examiners and difficulty predicting the type of examiners that will be needed mean that examiners are sometimes assigned outside of their area.²⁹² With so many fewer examiners, it is of course also impossible for the Indian office to specialize to the degree possible at the USPTO. This means that examiners in India must inevitably evaluate a broader range of technologies than examiners in the United States. Alongside these challenges come substantial time pressures: Indian examiners are expected to produce a preliminary examination report in just three months.²⁹³ That report is reviewed by a controller, with a time limit of six months from the date of requested examination to the first response to the applicant.²⁹⁴

288. IPO ANNUAL REPORT 2008, *supra* note 155, at 4.

289. All applications filed after January 1, 2005 have reportedly been digitized, but it is unclear whether the resulting database includes the full text of the applications or is readily searchable. *See* IPO ANNUAL REPORT 2007, *supra* note 286, at 10. As of the summer of 2007, examiners did not have access to a full text-searchable database. *See* Interview with Patent Examiner #1 (notes on file with author).

290. Interview with Patent Examiner #1, *supra* note 289.

291. Interview with Patent Examiners #2 (notes on file with author); Interview with Patent Examiner #1, *supra* note 289.

292. Interview with T.C. James (in his personal capacity), *supra* note 193; Interview with Patent Examiner #1, *supra* note 289 (noting that assignments are made according to very broad subject areas such as "chemistry," and that examiners from one field, such as electronics, may be assigned to another field, such as biotechnology, if the office has too few examiners in an area); *see also* Mueller, *supra* note 12, at 618 (noting the need for more examiners in the "chemical arts").

293. The Patent (Amendment) Rules (India), 2005, at R. 24B(2)(ii), (amending The Patent Rules, 2003), *available at* <http://ipindia.nic.in/ipr/patent/patents.htm>.

294. *Id.* at R. 24B(3). Because of the requirement of a request for examination, this is hard to compare to the U.S. process. For what it's worth, the average period for a first action in the USPTO in 2008 was 25.6 months, with a target time of 26.9 months. PTO ANNUAL REPORT, *supra* note 283, at 16.

If recent trends continue, the future is likely to bring substantially more applications. Driven by PCT applications and the new subject matter introduced in 2005, the Indian offices have recently seen significant increases in applications.²⁹⁵ In the past three years, for example, patent applications increased by 38 percent from 2003–2004 to 2004–2005, 40 percent from 2004–2005 to 2005–2006, 18 percent from 2005–2006 to 2006–2007, and 22 percent from 2006–2007 to 2007–2008.²⁹⁶ These increases are substantially larger than the comparable figures in the United States, which are 8.1 percent, 8.8 percent, 5.1 percent, and 5.7 percent.²⁹⁷ If applications continue to rise in similar ways, this will compound the resource disparities.

Hiring a substantial number of new examiners in India is a challenge because of limits on infrastructure and space, and because hiring formalities can take up to two or three years.²⁹⁸ Moreover, examiners are often lured into the private sector once they have been trained, because the private sector offers substantially higher salaries.²⁹⁹ Attrition is a problem in many patent offices, but it is particularly acute in a country where there is such an explosive demand for patent expertise, and where examiners must learn a great deal on the job.

Substantial disparities between the U.S. and Indian offices exist with respect to training. Examiners in India and the United States are subject to similar minimum educational requirements, typically a Bachelor of Arts degree in a specified field of science or engineering.³⁰⁰ Once hired, Indian examiners are required to attend a two-week training institute and one week of in-house training, with occasional short trainings by a program funded by the EU or

295. See Mueller, *supra* note 12, at 624–25 (reporting data showing a steady increase in patent applications after India joined the PCT, and showing that “37 percent of . . . FY 2004–05 filings claimed chemical-, drug-, or food-related inventions”); see also *id.* at 626 (reporting that PCT applications made up 60 to 61 percent of patents filed from 2002 to 2005).

296. IPO ANNUAL REPORT 2008, *supra* note 155, at 4.

297. PTO ANNUAL REPORT, *supra* note 283, at 62. These figures are for financial years 2005, 2006, 2007, and 2008, respectively.

298. Interview with Controller #1, *supra* note 280.

299. *Id.* (noting that the government salaries are about Rs. 22,000 to 23,000 per month for examiners while private sector jobs may offer twice as much). As an executive in one of India’s leading drug companies put it, “the Government of India is going to find it very hard to hold on to patent examiners because the moment they learn something about patents they will be snapped up by our industry.” Interview with Raghu Cidambi, *supra* note 25. The revolving door between the Patent Office and private firms also raises concerns of influence on examiners who hope to make the move to the private sector, and by those now seeking patents before the Office. See Interview with K.M. Gopakumar, *supra* note 83. Although there is speculation about serious corruption regarding certain individuals or cases, most of those I interviewed expressed the view that any influence would be felt in a minor, “greasing-the-wheels” fashion. See, e.g., Interview with K.M. Gopakumar, *supra* note 83; Interview with Biswajit Dhar, *supra* note 36. One patent examiner whom I interviewed did, however, state that some examiners and controllers took money from applicants. Interview with Patent Examiner #1, *supra* note 289.

300. See USPTO, PATENT EXAMINER POSITIONS (Nov. 16, 2003), <http://www.uspto.gov/web/offices/pac/exam.htm#req>; Interview with Controller #1, *supra* note 280.

conducted by the EPO.³⁰¹ Examiners in the United States, in comparison, attend eight months of full-time study, which includes “extensive lecture and lab training, . . . the examination of real patent applications in a setting that provides immediate assistance when needed,” and “classes in more than a dozen specialized applications used in patent examination, multiple search systems, databases, and commonly used office applications.”³⁰² For the first two years of employment, U.S. examiners are also subject to an ongoing program of mentoring and training.³⁰³

Providing comparable training in India would require substantial resource investments, and would be difficult to achieve in the context of India’s heightened demand for examiners and high attrition rates. In the meantime, examiners get supplemental training through the EPO and, to a much smaller degree, the USPTO—a phenomenon that raises its own concerns.

B. *Transnational Legal Culture*

The second influence on India’s ability to make use of the policy levers identified above is the increasingly transnationalized legal culture in which the Indian patent offices and courts operate. This transnational culture has been cultivated by the United States and Europe not only through efforts to harmonize substantive law (such as TRIPS), but also through much more mundane-seeming efforts to harmonize procedural aspects of transnational patent law and provide technical assistance to patent offices around the world.³⁰⁴ The Indian example thus offers a detailed and nuanced example of the dynamics of structural “isomorphism” that can lead organizations to become increasingly alike.³⁰⁵

Transnationalized legal culture, as I intend the term, is generated in part (but only in part) by the “transnational regulatory networks” discussed by scholars of international relations and international law.³⁰⁶ Such regulatory

301. See Interview with Patent Examiner #3 (notes on file with author); see also Interview with M. Sahasranaman, European Union Trade & Inv. Dev. Program, in New Delhi (May 29, 2007) (notes on file with author) (describing trainings provided by the EU-funded “Trade and Investment Development Program”).

302. PTO ANNUAL REPORT, *supra* note 283, at 105.

303. *Id.*

304. See Marney L. Cheek, *The Limits of Informal Regulatory Cooperation in International Affairs: A Review of the Global Intellectual Property Regime*, 33 GEO. WASH. INT’L L. REV. 277, 306–09 (2001); Drahos, *supra* note 275, at 152–54; Christopher May, *Capacity Building and the (Re)production of Intellectual Property Rights*, 25 THIRD WORLD Q. 821 (2004).

305. See Ryan Goodman & Derek Jinks, *Toward an Institutional Theory of Sovereignty*, 55 STAN. L. REV. 1749, 1755 (2003).

306. See, e.g., ANNE-MARIE SLAUGHTER, *A NEW WORLD ORDER* (2004); cf. Sol Picciotto, *Networks in International Economic Integration: Fragmented States and the Dilemmas of Neo-Liberalism*, 17 NW. J. INT’L L. & BUS. 1014, 1035–36 (1996–1997); Kal Raustiala, *The Architecture of International Cooperation: Transgovernmental Networks and the Future of International Law*, 43 VA. J. INT’L L. 1 (2002); Pierre-Hugues Verdier, *Transnational Regulatory Networks and Their Limits*, 34 YALE J. INT’L L. 113 (2009).

networks are “informal multilateral forums that bring together representatives from national regulatory agencies or departments to facilitate multilateral cooperation on issues of mutual interest within the authority of the participants.”³⁰⁷ The term tends to be used to refer to relatively formalized interactions among regulators, and to exclude both treaty-based organizations and strictly bilateral arrangements.³⁰⁸ Some of the relationships that shape the transnational culture of patent law can be described as transnational regulatory networks of this sort, networks that are of course also shaped by laws and legal institutions. But the influence of transnational legal culture is not limited to the influence of such networks. It can also be found in the dynamic of cross-referencing and citations that favor jurisdictions with readily accessible laws. It is also present in the exchange of policy and scholarly papers. Each of these components of transnational legal culture is disproportionately influenced by high-protection jurisdictions, which have a comparative advantage in generating, legitimating, and disseminating their writings.³⁰⁹

Consider first the transnational regulatory network that has grown up in the patent domain over the past two or three decades. Since the 1980s, patent offices in Europe, the United States, and Japan have actively cooperated around a host of issues related to patent filing and administration.³¹⁰ This “trilateral hub” has increased its degree of cooperation over time, and linked to other patents offices “via ‘spokes’ of bilateral or multilateral co-operation.”³¹¹ The trilateral hub has committed increasing resources to “technical assistance” for developing countries’ patent offices, and in at least some instances, has come to significantly influence their day-to-day operations.³¹² One analysis reports that

307. Verdier, *supra* note 306, at 118.

308. *Id.* at 118–19.

309. Similarly, the concept of transnational legal culture overlaps with, but is distinct from, the concept of epistemic communities, as articulated by Peter Haas and others. “An epistemic community is a network of professionals with recognized expertise and competence in a particular domain and an authoritative claim to policy-relevant knowledge within that domain or issue-area.” Peter M. Haas, *Introduction: Epistemic Communities and International Policy Coordination*, 46 INT’L ORG. 1, 3 (1992). Such epistemic communities may include experts from a variety of disciplines, united by a shared set of beliefs and a common policy enterprise. *Id.* A transnational legal culture, in contrast, is centered on law as a central medium of exchange, and may be more diffuse than the networks of policy experts that make up an epistemic community. It encompasses not only patent officials coordinating policy across borders, but also, for example, judicial officials engaged in transnational legal cross-references in their opinions, and patent examiners who are targets of patent law trainings. But like the discourse of epistemic communities, a focus on transnational legal culture highlights the role that ideas or “epistemes” play in, for example, “fram[ing] the issues for collective debate” and “identifying specific policies for national and collective adoption.” *Id.* at 5, 26.

310. Drahos, *supra* note 275, at 155; Cheek, *supra* note 304, at 308.

311. Drahos, *supra* note 275, at 155–56.

312. *Id.* at 157–58 (noting that “after co-operation projects with the EPO, [patent offices in] Argentina, Mexico, Malaysia, the Philippines and Thailand decide[d] to use the EPO’s search results to speed up their granting procedures”); *id.* at 158 (“[T]he steady drip-drip of technical assistance over a period of years has led to the formation of trust between the EPO and developing country offices”).

“every U.S. official in the international affairs division at the USPTO and the Copyright Office is involved in direct assistance to several countries,” with the most common task being “the review of draft legislation” to assist countries in complying with TRIPS.³¹³ WIPO also engages in extensive “technical assistance” for developing countries, in the form of, for example, conferences, trainings, and the provision of draft laws.³¹⁴ Because of the broad flexibilities in TRIPS, influence on the drafting and implementation of laws can have substantial effects.

The influence of this transnational network on Indian examiners is most direct in the domain of training. Indian examiners are regularly trained in programs organized predominantly by the EPO, and to a lesser extent by the JPO and the USPTO.³¹⁵ Some of these trainings occur in India, but others involve trips to Europe or the United States.³¹⁶ Such trips tend to be highly desirable.³¹⁷ According to D.G. Shah, they also

ha[ve] a potential for abuse. Today the officials here are smart. They want only assistance, so they are sending people, examiners from here to [the] U.S. patent office for six months to study and understand how they operate. They are not letting [the] U.S. patent office touch India’s patent manual or guidelines for patent examination. . . . I am not personally happy with it because there is a potential for abuse. But at the moment it is not going against India’s interest.³¹⁸

The Director of the Department of Industrial Policy and Promotion, which oversees India’s patent offices, similarly indicated that such trainings were intended to provide “exposure,” and would not lead examiners to confuse Indian law with, for example, the law of the EPO.³¹⁹

There is room for doubt, however. As Peter Drahos has argued, drawing on fieldwork in several developing-country patent offices, “Technical assistance of the long-term kind practised by the EPO creates in those receiving the assistance assumptions of reliability about the operation of systems (technocratic trust) and these in turn help to integrate the recipients of this assistance into the broader technocratic community that the EPO represents.”³²⁰ Others have also noted that “[t]he high degree to which [developing country] IP offices have relied on external support [has] rendered them vulnerable to financial influence from donors” and contributed to “a compliance-plus

313. See Cheek, *supra* note 304, at 306.

314. See *id.* at 305–06; May, *supra* note 304, at 825–26.

315. See Interview with Controller #1, *supra* note 280. Several examiners volunteered in interviews that they had been extensively trained by the EPO. Interview with Patent Examiners #2, *supra* note 291.

316. Interview with Controller #1, *supra* note 280.

317. Interview with Patent Examiner #1, *supra* note 289.

318. Interview with Dilip G. Shah, *supra* note 28.

319. Interview with T.C. James (in his personal capacity), *supra* note 193.

320. Drahos, *supra* note 275, at 160.

approach to TRIPS implementation.”³²¹

Evidence of this dynamic can be discerned in India. As discussed in Part II, for example, India’s law incorporates what appears to be an “obviousness-plus” standard, requiring not only that an invention be non-obvious to a person skilled in the art, but *also* that it embody a technical advance or have an economic effect. In my interviews with examiners and controllers in the patent offices, however, many insisted that Indian standards for inventive step are identical to those of the EPO and the United States.³²² The lead IP official in the Indian government acknowledged that examiners took this view, and gave some a personal briefing emphasizing that the standards were not the same.³²³ A lawyer in a prominent local law firm that deals regularly with patent issues noted that examiners seemed to rely especially on the EPO’s inventive step standard, and explained this as the result of the fact that examiners from the EPO regularly train local examiners.³²⁴

The PCT preliminary search report system generates a similar form of influence. The PCT establishes a streamlined system for international patent applications with implications for both preservation of priority dates and for patent examination procedures. When applicants choose to use the PCT system, a preliminary opinion on patentability is completed by a designated search office (almost all in developed countries) and provided to national offices that receive the application.³²⁵ An applicant may also request an international “preliminary examination,” typically on an amended version of the application.³²⁶

According to WIPO, any preliminary search report “should be considered by the [national] Offices but is not binding on them.”³²⁷ In resource-poor

321. DEERE, *supra* note 12, at 200 (also contending that “[c]ountries with the lowest technical capacity on IP, such as those in Africa, were particularly vulnerable to pro-IP capacity-building”).

322. Interview with Patent Examiners #2, *supra* note 291; Interview with Controller #2 (notes on file with author); Interview with Controller #1, *supra* note 280.

323. Interview with T.C. James (in his personal capacity), *supra* note 193.

324. Interview with H. Rajeshwari, *supra* note 171.

325. WORLD INTELLECTUAL PROP. ORG., PROTECTING YOUR INVENTIONS ABROAD: FREQUENTLY ASKED QUESTIONS ABOUT THE PATENT COOPERATION TREATY 8–11 (2006). The PCT and its rules establish broad standards to guide the inquiry of the international searching authorities. *See, e.g.*, Patent Cooperation Treaty art. 33.3, June 19, 1970, 28 U.S.T. 7645, 1160 U.N.T.S. 231 [hereinafter PCT] (“a claimed invention shall be considered to involve an inventive step if, having regard to the prior art as defined in the Regulations, it is not, at the prescribed relevant date, obvious to a person skilled in the art”); Regulations Under the Patent Cooperation Treaty, rule 65.1, June 19, 1970 (as in force from July 1, 2009), 28 U.S.T. 7645, 1160 U.N.T.S. 231 (“[T]he international preliminary examination shall take into consideration the relation of any particular claim to the prior art as a whole.”). Because these standards are quite vague, examiners appear to follow their own national law on matters such as inventive step, which of course may not match the law of receiving countries. *See* CONCISE EUROPEAN PATENT LAW 487 (Richard Hacon & Jochen Pagenberg eds., 2007).

326. WORLD INTELLECTUAL PROP. ORG., *supra* note 325, at 4.

327. *Id.* at 12.

settings, however, it is easy to see how these preliminary results can play a decisive role. One Indian controller indicated that if the PCT report included a favorable determination on obviousness and novelty, this would decide the matter, because India had the same standards.³²⁸ Another indicated that examiners almost always followed the PCT determination, and that only in very rare cases would they disagree.³²⁹ One examiner reported that the Controller General had issued a confidential office order at one point indicating that if a patent had issued in other countries, no examination would be conducted in India.³³⁰

One controller indicated that the PCT conclusion was not binding, but that examiners would only sometimes do their own search for a PCT application.³³¹ But he also noted that examiners sometimes came to a different conclusion than the PCT report, pointing to the Novartis Gleevec patent as an example.³³² He suggested that these divergent results would probably be more likely in pharmaceuticals than in other areas, because oppositions were more common in this domain.³³³ Oppositions apparently operate here as an important signaling device, drawing attention to particular applications and offering arguments that differ from those found in a PCT report, oriented specifically to India's law.³³⁴

The influence of patent law's transnational legal culture is not only felt in India through trainings and the PCT system. Examiners and controllers also seek out and rely on U.S. and particularly European patent law doctrines and precedents, because they have few of their own to rely upon. A patent litigator explained, for example, that it is very common to cite EPO and UK precedents in arguments to courts because they may be influential and are readily accessible.³³⁵ (This in turn points to the important role that the cohort of patent attorneys may have in influencing national patent offices.³³⁶) Examiners rely more heavily on EPO precedents than on U.S. precedents, and some rely on

328. Interview with Controller #1, *supra* note 280.

329. Interview with Controller #2, *supra* note 322.

330. Interview with Patent Examiner #1, *supra* note 289. According to the same examiner, some examiners understood themselves to be there to grant patents and thus did not undertake any examination at all. *Id.* Some controllers apparently take the same view, and overrule examiners who raise objections without reference to the substance of the concern. *Id.*

331. Interview with Controller #3 (notes on file with author). Others stated that they invariably conducted their own searches in PCT cases. *See* Interview with Patent Examiners #2, *supra* note 291.

332. Interview with Controller #3, *supra* note 331.

333. *Id.*

334. Interview with Patent Examiner #1, *supra* note 289 (noting that examiners were more diligent in cases where oppositions were filed).

335. Interview with Ms. H. Rajeshwari, *supra* note 171. Alan Watson cites "accessibility" as the central criterion for the source of rules that are legally transplanted. ALAN WATSON, *LEGAL TRANSPLANTS: AN APPROACH TO COMPARATIVE LAW* 113 (2d. ed. 1993). Watson also notes the "retention of, and even increased borrowing from, the law of a colonial power by a former dependency." *Id.* at 120 n.23.

336. *See* DEERE, *supra* note 12, at 168; *see also* Helfer, Alter, & Guertzovich, *supra* note 150, at 39.

reports from EPO examinations rather than conduct their own examinations.³³⁷

India's Draft Patent Manual also draws very substantially on UK patent precedents.³³⁸ When preparing the draft, examiners and controllers in the Indian patent offices were instructed to go section by section to elaborate on the case law. In order of preference, they were to cite decisions by controllers in the patent offices, then Indian courts, and then foreign precedents, with UK precedents coming first because Indian law has been most influenced by British law.³³⁹

Where there are few local precedents to rely on, the Draft Patent Manual refers to UK law. The requirement of inventive step was introduced into Indian law only in 2002, so it is unsurprising to find that the section of the Draft Patent Manual on inventive step relies almost exclusively on UK law.³⁴⁰ A recent decision of the Intellectual Property Appeal Board similarly follows the practice of high-protection jurisdictions and deems India's inventive step requirement to be met upon a showing of "surprising" and beneficial effects.³⁴¹ The unique aspects of India's inventive step standard, in the process, effectively disappear.

C. Unilateral Retaliation

The deployment of TRIPS levers may also be met with unilateral retaliation, or threats thereof. Such retaliation can come from a number of countries and on a number of fronts, but the most salient threats tend to emanate from the Special 301 process in the United States.³⁴² Enacted by Congress in 1988, the Special 301 provisions of the Trade Act of 1974 oblige the Office of the United States Trade Representative (USTR) each year to identify a list of "priority countries" within thirty days after the publication of the National Trade Estimate report.³⁴³ Priority countries are defined as those who "have the most onerous or egregious acts, policies, or practices" that "deny

337. Interview with Patent Examiner #1, *supra* note 289; *cf. supra* note 312.

338. See PATENT OFFICE (INDIA), *supra* note 122, at 356–68.

339. Interview with T.C. James (in his personal capacity), *supra* note 193.

340. See PATENT OFFICE (INDIA), *supra* note 122, at 33–51. Groups such as the National Working Group on Patent Law and the drug company lobbying organization IDMA strongly objected to this practice in their submitted comments on the Draft Patent Manual. See Letter from Nat'l Working Group on Patent Laws to V. Ravi, Controller Gen. of Patents, Designs, and Trade Marks (Apr. 16, 2008), available at http://ipindia.nic.in/ipr/patent/Patent_Manual_Feedback/national_working_group_on_patent_laws_new_delhi.pdf; Letter from the Indian Drug Mfrs.' Ass'n to the Office of the Controller Gen. of Patents, Designs, and Trade Marks (Apr. 24, 2008), available at http://ipindia.nic.in/ipr/patent/Patent_Manual_Feedback/INDIAN_DRUG_MANUFACTURERS_ASSOCIATION_MUMBAI.pdf.

341. Novartis AG v. Union of India, Order No. 100/2009 (Intellectual Prop. Appellate Board, June 29, 2009) at 184, available at <http://www.i-mak.org/pharma-patent-decisions>.

342. See 19 U.S.C. §§ 2242, 2411–16 (2006) (outlining Special 301 procedures).

343. Under 19 U.S.C. § 2241(b)(2), this report must be compiled each year by the USTR, to identify "any act, policy, or practice" of foreign nations, including those related to IP, that create significant barriers to trade.

adequate and effective intellectual property rights,” or “deny fair and equitable market access to United States persons that rely upon intellectual property protection.”³⁴⁴ To be designated as a priority country, the USTR must also find that a nation is not “entering into good faith negotiations” or “making significant progress in bilateral or multilateral negotiations to provide adequate and effective protection of intellectual property rights.”³⁴⁵

If a country is designated a priority country, the USTR must undertake an investigation, to be completed according to a timeline that depends upon whether the USTR finds that TRIPS is involved.³⁴⁶ Upon the investigation’s completion, the USTR is permitted, but not required, to retaliate.³⁴⁷ Additionally, the law provides that a finding by a WTO dispute settlement proceeding that the provision in question is consistent with TRIPS would provide a permissive, but not mandatory, reason for the USTR not to retaliate.³⁴⁸

The USTR has the authority to retaliate by imposing tariffs or import restrictions, or by withdrawing concessions granted under preferential trade agreements such as the Caribbean Basin Economic Recovery Act³⁴⁹ and the Andean Trade Preference Act.³⁵⁰ The President may also direct the Trade Representative to retaliate in any area of trade or foreign relations that is within the President’s power.³⁵¹ Although not provided for by statute, the USTR has created additional components to the Special 301 scheme, creating a “watch list” and a “priority watch list,” designations that “indicate[] that particular problems exist in that country with respect to IPR protection, enforcement, or market access for persons relying on intellectual property.”³⁵² The watch lists thus serve as a warning to countries that they may face “priority country” listing in the future.

The consistency of the Special 301 process with WTO law is a matter of some dispute. If the United States were to impose unilateral sanctions in violation of its WTO commitments—for example, enforcing a tariff greater than permitted in General Agreement on Tariffs and Trade (GATT) schedules—it would clearly be violating its WTO obligations.³⁵³ However, the

344. *Id.* § 2242(b)(1)(A).

345. *Id.* § 2242(b)(1)(C).

346. If TRIPS is implicated, the investigation must be completed within thirty days of the completion of a dispute settlement procedure; if not, it must be completed within six months of the investigation’s initiation. *Id.* § 2414(a)(3)(A). In the latter case, an extension of three months is possible in complicated cases. *See id.* § 2414(a)(3)(B).

347. *Id.* § 2411(a).

348. *Id.* § 2411(a)(2)(A).

349. *Id.* § 2702(b)–(c).

350. *Id.* § 3202(c)–(d).

351. *Id.* § 2411(a)(1)(B)(ii).

352. OFFICE OF THE U.S. TRADE REPRESENTATIVE, 2008 SPECIAL 301 REPORT 18 (2008); *see also id.* (“Countries placed on the Priority Watch List are the focus of increased bilateral attention concerning the problem areas.”).

353. *See* General Agreement on Tariffs and Trade art. II, Oct. 30, 1947, 61 Stat. A-11, 55 U.N.T.S. 194.

United States has many alternative options for sanctions, particularly with respect to developing countries. These alternatives include withdrawal of GSP preferences, military aid, humanitarian assistance, development assistance, and political support.³⁵⁴

The WTO's dispute resolution agreement also, however, requires members to seek redress for purported violations through the dispute settlement process,³⁵⁵ and forbids members seeking redress from "mak[ing] a determination to the effect that a violation has occurred . . . or that the attainment of any objective of the covered agreements has been impeded, except through recourse to dispute settlement."³⁵⁶ In 2000, a WTO panel concluded that the United States would violate the dispute settlement agreement if it were to determine, before the completion of a dispute, that a country was in violation of its WTO obligations.³⁵⁷ The same logic would prevent the United States from determining that a country was acting in violation of TRIPS and retaliating in domains not regulated by the WTO, such as military or humanitarian aid.³⁵⁸ The dispute settlement agreement, however, does not explicitly prohibit any unilateral retaliation not designed to "redress . . . a violation of obligations or other nullification or impairment of benefits under the covered agreements."³⁵⁹ This creates difficult questions about when retaliation on the basis of IP concerns constitutes retaliation "under the covered agreements," and also of how that might be determined.

354. Cf. Chad P. Bown & Bernard M. Hoekman, *WTO Dispute Settlement and the Missing Developing Country Cases: Engaging the Private Sector*, 8 J. INT'L ECON. L. 861, 866 (2005). The U.S. "Generalized System of Preferences" extends special trade benefits to developing countries. See 19 U.S.C. §§ 2461–66.

355. According to article 23.1 of the DSU, "[w]hen Members seek the redress of a violation of obligations or other nullification or impairment of benefits under the covered agreements . . . they shall have recourse to, and abide by, the rules and procedures of this Understanding." Understanding on Rules and Procedures Governing the Settlement of Disputes art. 23.1, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 2, Legal Instruments—Results of the Uruguay Round, 33 I.L.M. 1125 (1994) [hereinafter DSU].

356. *Id.* art. 23.2(a).

357. See Panel Report, *United States—Sections 301–310 of the Trade Act of 1974*, ¶ 7.96, WT/DS152/R (Dec. 22, 1999) ("[T]he statutory language of Section 304—by mandating a determination *before* the adoption of DSB findings and statutorily reserving the right for this determination to be one of inconsistency—must be considered presumptively to be inconsistent with the obligations in Article 23.2(a)."); *id.* ¶ 7.126 (also accepting U.S. guarantees that it would not exercise the statutory discretion in this fashion); see also Appellate Body Report, *United States—Import Measures on Certain Products from the European Communities*, ¶ 111, WT/DS165/AB/R (Dec. 11, 2000); Panel Report, *European Communities—Measures Affecting Trade in Commercial Vessels*, ¶ 7.207, WT/DS301/R (Apr. 22, 2005). The Panel in the 301 case presumably understood such determinations as problematic where they were linked to efforts to obtain "redress," as is suggested by the language of article 23. See DSU, *supra* note 355, art. 23 (forbidding unilateral determination of a violation "in such cases," apparently referring to cases where "Members seek the redress of a violation of obligations").

358. See MICHAEL J. TREBILCOCK & ROBERT HOWSE, *THE REGULATION OF INTERNATIONAL TRADE* 434 (3d ed. 2005).

359. DSU, *supra* note 355, art. 23.1.

The implications of WTO obligations for the “watch list” element of 301 are also unclear. A country listed on the watch list or priority watch list is not subject to sanctions (this occurs only after a “priority country” designation), but is identified as a subject of U.S. concern, and as a possible future target of retaliation or dispute settlement. The United States has made frequent use of the watch list system to press developing countries on its IP priorities in recent years.³⁶⁰ There are several notable and recent examples of the use of 301 against countries contemplating compulsory licensing, for example. In 1998, South Africa was placed on the Special 301 watch list because of a law that permitted compulsory licensing.³⁶¹ In 1999, Thailand was threatened with “sanctions on core Thai exports” when it was considering compulsorily licensing an AIDS drug.³⁶² In 2007, the Thai government issued several compulsory licenses, a fact cited in its priority watch list listing a year later.³⁶³ PhRMA has urged that the USTR designate Thailand a priority country on the basis of these licenses, a step that the United States has so far declined to take.³⁶⁴

If past is prologue, countries that engage in compulsory licensing may face threats of U.S. retaliation through the 301 process and otherwise.³⁶⁵ Some interviewees in civil society groups expressed concern that such threats will discourage the Indian government from using levers like compulsory licensing.³⁶⁶ Others were not convinced, and doubted that the United States will engage in substantial threats or retaliation against India, particularly in light of the current terms of trade.³⁶⁷ D.G. Shah suggested that “[t]he question is of political will—of implementation, whether government will invoke compulsory license[s] in such situations,” and that this “would ultimately depend at that point of time [on] the incumbent government and what message it wants to give to the rest of the world.”³⁶⁸ It is clear, however, that the possibility of unilateral retaliation will be a factor in the exercise of TRIPS policy levers, although one that will be modulated by the overall relationship between the relevant governments and the local agendas of national leaders.³⁶⁹

360. See DEERE, *supra* note 12, at 341–42 (charting 301 pressure on developing countries from 1995–2007); see also Brook K. Baker, *Ending Drug Registration Apartheid: Taming Data Exclusivity and Patent/Registration Linkage*, 34 AM. J. L. & MED. 303, 324–26 (2008) (cataloguing examples).

361. Susan K. Sell, *Post-TRIPS Developments: The Tension Between Commercial and Social Agendas in the Context of Intellectual Property*, 14 FLA. J. INT’L L. 193, 209 (2002).

362. *Id.* at 210.

363. See OFFICE OF THE U.S. TRADE REPRESENTATIVE, *supra* note 352, at 37.

364. USTR *Not Preparing a Case Against Thailand for Compulsory Licenses*, INSIDE U.S. TRADE (Feb. 29, 2008); Phusadee Arunmas, *Thailand Could Face Sanctions After Lobbying by Drug Firms*, BANGKOK POST, Jan. 31, 2008.

365. See DEERE, *supra* note 12, at 231 (also noting that such pressures are particularly acute for middle-income countries).

366. Interview with K.M. Gopakumar, *supra* note 83.

367. Interview with Dilip G. Shah, *supra* note 28.

368. *Id.*

369. *Cf.* DEERE, *supra* note 12, at 165–66 (documenting a number of developing countries,

D. Conclusion

Although TRIPS leaves developing countries substantial flexibility as a formal matter, the constraints imposed by resource disparities, transnational legal culture, and the persistent threat of unilateral retaliation mean that such countries have far less flexibility *in practice* than they do in theory. As the Article's Conclusion will discuss in more detail, these limitations gain a substantial portion of their force from the increasingly transnational circuit of legality in which India finds itself. For example, the limited resources available to Indian patent offices are *particularly* problematic in light of the fact that TRIPS and the PCT facilitate transnational patent applications, by standardizing the application process and helping applicants secure rents to spend on seeking patents in new jurisdictions. Transnational legal culture and threats of unilateral retaliation also gain some of their purchase through the transnationalization of law, which facilitates these pressures as well as channels them.

Analyzing the various constraints on the use of TRIPS flexibilities also demonstrates that the most important avenues of such flexibility may be different than one might expect from the literature's characteristic focus on compulsory licensing. The subject matter lever, for example, may be less susceptible to the threat of unilateral retaliation than the government authorization lever. While PhRMA urged the USTR to designate India a "priority country" in 2008 (which would make sanctions possible), citing pre-grant oppositions and section 3(d) in particular, India remained on the "priority watch list" in 2008 and the USTR did not identify any specific aspect of India's patent law as a concern.³⁷⁰ As noted above, Thailand's recent compulsory licenses, in contrast, were cited in the elevation of the country to the U.S. priority watch list in 2008. Although scope of patentability issues have been cited in 301 reports in some instances, they may be less likely to be the focus of extensive public criticism or WTO disputes.³⁷¹ A government decision to override a patent can easily be framed as expropriation or "stealing."³⁷² A government decision adopting strict standards for patentability cannot so readily be cast in the same terms, and has the positive connotation of seeking to promote genuine rather than trivial innovation. The architectural framing effects of law might also play

including India, that appear not to have yielded to the pressures exerted via the Special 301 process).

370. See PHARMACEUTICAL RESEARCH & MFRS. OF AM., *supra* note 192, at 64–68; OFFICE OF THE U.S. TRADE REPRESENTATIVE, *supra* note 352, at 35–36.

371. The difficulty pharmaceutical companies had in obtaining patents on "methods of treatment or diagnosis" in China was cited in the 2007 301 Report. OFFICE OF THE U.S. TRADE REPRESENTATIVE, 2007 SPECIAL 301 REPORT 22 (2007). In that report, China remained on the priority watch list, though it is difficult to determine the role played by patent issues and those played by the more prominently discussed copyright and trademark issues (which the United States pursued in a dispute settlement negotiation that year). *Id.* at 2.

372. For a discussion of the relationship between law and framing, see Kapczynski, *supra* note 8.

a role:³⁷³ the United States can more readily criticize a country for issuing compulsory licenses to reduce prices for drugs than for seeking to tailor its patent law to restrict trivial patents. This is because the United States commits itself to the latter practice but not the former. Developed countries also may be reluctant to invite a WTO panel to constrain a country's standards of patentability because a ruling could call into question policy space that developed countries themselves wish to retain.³⁷⁴

Resource limitations and the influence of transnational legal culture may make the subject matter lever more useful in developing countries than the inventive step lever. Patent examiners are likely to find it easier to apply an exclusion on salt patents than to apply an obviousness test such as the one that sometimes invalidates salt patents in the United States.³⁷⁵ Patent applicants may be able to avoid subject matter restrictions with artful drafting,³⁷⁶ but firms may not find it worthwhile to tailor their applications to small markets. The subject matter lever also can route around the influence of transnational legal culture, when subject matter restrictions have no developed country analogues.

The procedural lever similarly appears comparatively more important in the context of limited administrative resources and transnational legal culture. Oppositions with broad standing allow a resource-poor administrative agency to harness the power of third-party participants to identify suspect patents and cheaply mine arguments against them. Disclosures can also substantially decrease administrative burdens, particularly if policed with the sanction of patent rejection or invalidation. Both levers construct procedural firewalls against the pull of transnational legal culture, because they focus attention on patents that may be problematic under local standards. These strategies also may be less susceptible than the government authorization lever to unilateral threats, for the reasons noted above.

The most effective strategy to limit the influence of exclusive rights in the pharmaceutical context in developing countries may involve the remedies lever. The lever could be as influential as the government authorization lever, but is less amenable to unilateral retaliation. It may be politically more difficult to attack the decisions of judges than to attack decisions made by those in the executive branch, particularly if the judges in question are applying a legal

373. For a description of architectural framing effects, see *id.* at 864.

374. For example, the obviousness standard in the United States has varied over time. See, e.g., ADAM B. JAFFE & JOSH LERNER, INNOVATION AND ITS DISCONTENTS 35 (2004). See also Reichman & Dreyfuss, *supra* note 141, at 103–06 (discussing the uncertainty in policy circles in Europe and the United States regarding the need for reforms to their patent systems).

375. *Pfizer v. Apotex, Inc.*, 480 F.3d 1348, 1372 (Fed. Cir. 2007). India's requirement that the salt patent be granted if an applicant can show "increased efficacy" adds complexity to what would be an otherwise straightforward analysis. For countries with still fewer administrative resources, a categorical ban on such patents might be necessary to achieve the central objective.

376. See, e.g., Brief of Amicus Curiae of 22 Law and Business Professors in Support of Appellants at 9–11, 21–25, *In re Bilski*, 545 F.3d 943 (Fed. Cir. 2008) (No. 2007-1130).

standard used around the world. Nonetheless, this lever is not without difficulties. The most important of these is the challenge of guiding the exercise of judicial discretion. Resource constraints will likely affect the consistency and predictability of court decisions, and judges also participate in the transnationalized culture of patent law.³⁷⁷ There are questions about the degree to which governments can, consistent with article 44.1 of TRIPS, guide the discretion of judges through a statutory framework.³⁷⁸ If the remedies lever becomes increasingly guided by statute, the insulation provided from unilateral retaliation will also likely diminish.

Considering constraints imposed by resource limitations, the increasingly transnationalized legal culture surrounding patent law, and the potential for unilateral retaliation, countries may find the government authorization lever less attractive than commonly assumed, and levers such as subject matter limitations, oppositions and disclosures, and remedial limitations relatively more attractive. A more precise articulation of the suitability of each lever, of course, requires more attention to the context of the country in question. For example, government authorization requires far fewer technical resources than the application of most other levers. It is thus likely to be comparatively more useful in settings with more extreme limitations on technical and administrative resources.

This does not mean that any of these levers are trivial to implement—all face obstacles. Barriers exist even in a country like India, which has exceptionally strong and engaged health advocates and generic industry actors, has more administrative resources than many other developing countries, and is somewhat more insulated than many others from the influence of transnational legal culture and unilateral threats of retaliation.

IV

FRAGMENTATION, MIMICRY, AND COUNTER-HARMONIZATION

Given these obstacles, can developing countries make TRIPS flexibilities real? To understand the dynamics of TRIPS implementation, we must explore the strategies that countries have at their disposal to address the aforementioned constraints. For example, countries might increase the resources they allocate to patent examinations, refuse offers of technical assistance from high-protection jurisdictions, and simply decide to ignore the threat posed by the U.S. Special 301 process. Such national-level measures would do little, however, to counter

377. For example, George Washington University Law School has an “India Project” designed to raise “awareness in India of the benefits of a strong IP law regime.” George Washington School of Law, India Project, http://www.law.gwu.edu/Academics/research_centers/india/Pages/Overview.aspx (last visited June 16, 2009). The project trains Indian High Court and Supreme Court judges on patent law. *GW Law School in India: Building Bridges & Strengthening Capacity*, GW MAGAZINE, Sept. 2006, http://www.gwu.edu/~magazine/archive/2006_sept/docs/feature_lawindia.html.

378. See *supra* text accompanying notes 219–22.

the transnational dynamics that give these dynamics much of their force. TRIPS implementation refers countries like India to a transnational context that makes it difficult for them to implement an autonomous patent law. Are there a series of compensating strategies that can act upon the same transnational circuits that condition the problem?

The following Part describes three strategies evident in the Indian context that can help to slow or rewrite circuits of transnational influence, strategies that I call fragmentation, mimicry, and counter-harmonization. Such strategies, and particularly counter-harmonization, will be critical to the ability of developing countries to utilize TRIPS flexibilities effectively, in light of the obstacles identified above.

A. *Fragmentation*

What did India do by adopting section 3(d) into its law? Viewed from a domestic perspective, it simply established a high standard for patentability. But section 3(d) has had another effect, which must be understood in a transnational context: because it was new to patent law when introduced in India, Indian patent officials cannot look to other jurisdictions to elaborate its meaning. Several controllers, for example, who asserted that U.S. and EPO law were the same as Indian law with respect to obviousness also stated that Indian law was different with respect to patentability, citing section 3(d).³⁷⁹ With respect to section 3(d), then, examiners cannot simply follow the EPO or the PCT recommendation. Indian courts must instead rely on local legislative history and their own interpretation of the meaning of terms like “efficacy” in section 3(d), because no other precedents are available. Specific and unique local provisions such as this offer administrative officials and judges some insulation from the influence of transnational legal culture.

Similarly, India’s law, unlike patent laws in the United States and European Union, requires disclosure of the “source and geographical origin of biological material” in a patent specification,³⁸⁰ and states that patents may not be granted on inventions that are, “in effect, . . . traditional knowledge [or an] aggregation of traditionally known component or components.”³⁸¹ Local officials and judges will be unable to rely upon PCT opinions, UK or U.S. precedent, or trainings from foreign patent offices in interpreting these provisions. If other developing countries have similar clauses, Indian officials and judges could draw on those interpretations. But such interpretations are likely to be relatively less accessible, suggesting that there will be a margin of freedom in the adoption of legal requirements unknown in the jurisdictions that

379. Interview with Controller #2, *supra* note 322; Interview with Controller #1, *supra* note 280.

380. India Patents Act, *supra* note 101, § 10(4)(d)(ii)(D).

381. *Id.* § 3(p).

largely constitute the transnational legal culture of patent law.³⁸²

Both examples are instances of a strategy that I call fragmentation, which involves the adoption of unique or semi-unique national variations in law that create legal “friction,” impeding the flow of the transnational circuits that challenge countries’ abilities to implement autonomous local law. Such friction clearly diminishes the effects of transnational legal culture, but it also counters the transnational pressures on administrative resources. Fragmented provisions counteract one of the central aims of recent international IP law-making endeavors: the reduction of transaction costs for multinational companies seeking exclusive rights around the world. Both section 3(d) and the geographic origin and traditional knowledge requirements generate specialized requirements that oblige applicants to tailor their applications to the jurisdiction in question, increasing the costs of applying, and potentially decreasing the cost of local implementation.

A major benefit purportedly provided by the PCT system is a single application form that all PCT members must accept.³⁸³ Applicants can amend their claims after filing that application in national offices, and must do so to comply with specialized local law.³⁸⁴ This entails costs. If the requirements of Indian applications are treated as obligatory and if failure to comply with them provides grounds for rejection or invalidation of a patent, the applicant must bear the cost of tailoring his application or run the risk that it will be rejected. This relative increase in costs for multinationals is likely an unintended side-effect of fragmented patent provisions, but one that might ameliorate some of the impact of the disparities in administrative resources. Applicants will either provide more information to local offices or decide that tailoring their applications to the local requirements is not worth the costs, thus reducing the number of applications.

Fragmentation is a way of making a country less locatable to the transnationalized dynamics of patent law today—of introducing friction into the transnational circuits of influence discussed above. It can generate a small amount of protection from the flood of applications associated with joining the PCT, but only if protection in the jurisdiction is not worth the additional cost to applicants of tailoring their applications. It can also permit local patent officers to interpret their law more autonomously, but only if local officials are sophisticated and motivated enough to use this margin of freedom to do so. It

382. Alternatively, if the interpretations of other developing country jurisdictions were available, India could take advantage of some of the benefits of counter-harmonization. *See infra* Part IV.C.

383. WORLD INTELLECTUAL PROP. ORG., PCT APPLICANT’S GUIDE—INTERNATIONAL PHASE 5 (2009). Nearly 70 percent of patent applications in India today are filed through the PCT, presumably in part because of this advantage. *See* IPO ANNUAL REPORT 2008, *supra* note 155, at app. C.

384. The PCT guarantees that applicants through the PCT system must have at least one opportunity to amend their claim. PCT, *supra* note 325, art. 28(1).

may be difficult, especially in the most resource-constrained settings, to generate the distance from transnational legal culture needed to implement a strategy of fragmentation. It is common for a developing country's laws to fail to make use of even the most basic TRIPS flexibilities, in part because of the role of "technical assistance" from organizations like WIPO.³⁸⁵ Fragmentation is thus likely to be a strategy of fairly limited scope.

B. Mimicry

Might countries also use the transnational nature of patent law discourse to their advantage, to undermine some of the effects of unilateral pressure, for example? One such strategy illustrated in the Indian context can be called mimicry, which I define as a strategy of transformative copying.³⁸⁶ Here, "recipient" countries model and legitimate their local law with reference to the law of "dominant" countries. But rather than adopt wholesale the meanings of these provisions, these texts are revised or reinscribed. Mimicry is legal transplantation with a difference.³⁸⁷ Transplantation designates the simple "moving of a rule of law or a system of law from one country to another."³⁸⁸ It identifies a kind of mindless borrowing; "transplanted" rules are typically not transformed when adopted, though they may evolve once implemented.³⁸⁹ Mimicry, in contrast, is a dynamic reworking cast as a sharing or borrowing.

The Indian context offers an illuminating example of the practice. Recall *Roche v. Cipla*. There, the Delhi High Court denied a preliminary injunction against an alleged patent infringer, concluding that the disparity in price between the generic and patented version of the drug would work irreparable harm for patients who could no longer afford the medicine. In defending this interpretation, the court in two prominent places cited the U.S. case of *eBay v. MercExchange*.³⁹⁰ In the first reference, the court articulated the general

385. On the limited use of flexibilities in developing countries, see SISULE F. MUSUNGU, UNITED NATIONS DEV. PROGRAMME (UNDP) REG'L SERV. CENTRE FOR E. AND S. AFR., ACCESS TO ART AND OTHER ESSENTIAL MEDICINES IN SUB-SAHARAN AFRICA: INTELLECTUAL PROPERTY AND RELEVANT LEGISLATIONS (Sept. 2007), available at http://www.soros.org/initiatives/health/focus/access/articles_publications/publications/artafrica_20090313. On concerns about the nature and influence of WIPO technical assistance, see WORLD INTELLECTUAL PROP. ORG., PROPOSAL TO ESTABLISH A DEVELOPMENT AGENDA FOR WIPO: AN ELABORATION OF ISSUES RAISED IN DOCUMENT WO/GA/31/II, Apr. 6, 2005, available at http://www.wipo.int/meetings/en/doc_details.jsp?doc_id=42376.

386. My use of the term here shares something with Homi Bhabha's influential articulation of the concept. Bhabha uses it to refer to "a sign of a double articulation; a complex strategy of reform, regulation and discipline, which 'appropriates' the Other as it visualizes power." HOMI BHABHA, THE LOCATION OF CULTURE 122 (2004). Mimicry designates a form of "almost the same, *but not quite*," that is "at once resemblance and menace." *Id.* at 123.

387. For the classic work on legal borrowing, see WATSON, *supra* note 107, at 21.

388. *Id.*

389. *Id.* at 27, 95–96.

390. 547 U.S. 388 (2006).

principle that “courts should examine the claim for interlocutory injunction with some degree of circumspection,” defending this by noting that

[t]his view accords with the trend in the United States, where in *eBay v. MercExchange*, the Supreme Court of United States rendered a significant judgment relevant in the present context The Supreme Court . . . held that courts should consider the traditional four-factor test for issuance of an injunction, (i.e. existence of prima facie case, balance of convenience, irreparable injury and public interest) and should not issue injunctions automatically. Such an approach has been also favoured by two decisions of this court. . . . The Calcutta High Court too has endorsed this view.³⁹¹

The court invokes *eBay* again in its discussion of the central holding of the case. After declaring that “the Court cannot be unmindful of the right of the general public to access life saving drugs which are available and for which such access would be denied if the injunction were granted,” it says “[e]ven the United States Supreme Court was not unmindful of such considerations when recently it disavowed the liberal practice of granting injunctions, and underlining [*sic*] the necessity of weighing relevant factors, including public interest, in *eBay*.”³⁹²

Why the pointed references to *eBay*? There is of course a resemblance between the standard invoked by the *Roche* court and that invoked in *eBay*,³⁹³ but it is at best skin deep. The Indian cases cited by the court in the first reference reflect skepticism towards injunctions not found in contemporary U.S. cases, and that renders preliminary injunctions in patent cases very difficult to obtain.³⁹⁴ And while one could fit the reasoning of the *Roche* court under the “public interest” prong of the *eBay* test, it will surprise no one

391. *Roche v. Cipla*, ¶ 63, I.A 642/2008 IN CS (OS) 89/2008 (Delhi H.C., Mar. 19, 2008), available at <http://www.i-mak.org/storage/F%20Hoffmann%20La%20Roche%20v%20Cipla%20Ltd%202008.pdf> (internal citations omitted).

392. *Id.* ¶ 85.

393. For example, the cases the *Roche* court refers to do hold that to obtain a preliminary injunction “the plaintiff in a patent case must show a prima facie case of an infringement, and further that the balance of convenience or an inconvenience is in his favour.” *Standipack Private Ltd. v. Oswal Trading Co.*, 2000 A.I.R. 23 (Del.) ¶ 20. See also *Hindustan Lever Ltd. v. Godrej Soaps Ltd.*, 1996 A.I.R. 367 (Cal.) ¶ 59 (reflecting the same standard). It is not surprising that Indian and U.S. courts invoke similar terms when evaluating injunctions in equity, given the influence of UK law in both jurisdictions.

394. One case states, for example, that injunctions will be denied in India “when the patent in question is a new one the validity of which has not been established in any legal proceedings and the validity whereof is under serious dispute or challenge.” *Hindustan Lever Ltd.*, A.I.R. ¶ 12. Another case declares that “in a patent case the onus of showing a prima facie case justifying the grant of an injunction is a heavy one and it’s comparatively easy for the respondent to establish a defence sufficient to prevent the grant of such an injunction.” *Standipack Private Ltd.*, A.I.R. ¶ 20. The third indicates that “[s]tultification of defendant’s investment, loss of employment, public interest in the product (such a life saving drug), product quality coupled with price, or the defendant being smaller in size, may go against the plaintiff.” *Franz Xaver Huemer v. New Yash Engineers*, 1997 A.I.R. 79 (Del.) ¶ 33.

familiar with the Federal Circuit to learn that the court has not done so. Rather, it has upheld injunctions issued by district courts over arguments that these injunctions would impede access to affordable medicines,³⁹⁵ noting, for example, that “the public interest includes consideration of whether, by shifting market benefits to the infringer while litigation is pending for patents that are likely to withstand the attack, the incentive for discovery and development of new products is adversely affected.”³⁹⁶

It is to be expected that courts applying broad equitable standards will come to different conclusions in different contexts. Indeed, the “balance of convenience” may in fact tilt more decisively towards patent holders in the United States than in India.³⁹⁷ But given the differences in their approaches, the *Roche* court’s insistent references to *eBay* is notable. It could be seen as a symptom of the effects of transnational legal culture on courts. On that theory, the difference would be unintended, and perhaps an example of the kind of wandering that those associated with the concept of legal borrowing have suggested occurs.³⁹⁸ But a close reading of the case suggests instead that the references to *eBay* represent not a borrowing, but something more complex—a kind of mimicry, where the *Roche* court cites *eBay* precisely *because* it knows the difference.

Roche, as described above, has expansive implications that work against the interests of patent holders. To cast the decision as the simple application of standards adopted in the United States and the United Kingdom may lend some legitimacy to the court’s decision, in domestic as well as international circles. If India’s courts are viewed as applying the same standards as U.S. courts, it may be more difficult for the United States to object to the outcome of those cases. TRIPS itself may be difficult to apply to differential applications of the same formal standards.³⁹⁹ By framing India’s standards as being the same as those of the United States, Indian courts may also make it more difficult for countries like the United States and for multinational firms to publicly criticize their decisions.

Adopting similar language and laws but interpreting them differently and strategically casting local laws as analogous to those of high-protection jurisdictions may be appealing strategies that diminish some of the effects of

395. See, e.g., *Abbott Labs. v. Sandoz, Inc.*, 544 F.3d 1341, 1362–63 (Fed. Cir. 2008); *Sanofi-Synthelabo v. Apotex, Inc.*, 470 F.3d 1368, 1383–84 (Fed. Cir. 2006).

396. *Abbott Labs.*, 544 F.3d at 1362–63.

397. Courts in India might be responding, for example, to concerns about the lack of an effective antitrust framework, or out of different priorities associated with development. See, e.g., *Hindusthan Lever Ltd.*, A.I.R. ¶ 13–14. The impact that patents have on access to medicines in a context largely without health insurance is also of course quite different than in a context where health insurance is common.

398. See *supra* note 389.

399. See Yoshifumi Fukunaga, *Enforcing TRIPS: Challenges of Adjudicating Minimum Standards Agreements*, 23 BERKELEY TECH. L.J. 867, 903–06 (2008).

unilateral pressure. But these strategies also have limitations, such as their susceptibility to the pull of transnational legal discourse. The court in *Roche* may be engaged in mimicry, but a later court may take the references to *eBay* more literally and move the doctrine toward subsequent U.S. decisions implementing *eBay*. Strategic citation of legal precedents from other jurisdictions may evolve into a more general adoption of foreign rules of law as the effects of transnational legal networks make themselves felt. Thus, it may thus be difficult to sustain mimicked interpretations over time.

C. Counter-Harmonization

If countries with similar aims in TRIPS implementation coordinate their legal frameworks, they can reduce the collective administrative costs of adopting an alternative patent regime, create a transnational “counter-culture,” and increase the costs to their opponents of extralegal retaliation. I call this process “counter-harmonization.”⁴⁰⁰ It is a strategy that works less by resisting the transnational circuit of patent law than by rewriting it.

Counter-harmonization allows countries to pool their resources to lower administrative costs. The costs of identifying patents that fail provisions like section 3(d), for example, is high in India and relatively higher in countries with fewer administrative resources. But if multiple developing countries adopted such provisions, they could share the expense of identifying invalid patents, with wealthier developing countries effectively cross-subsidizing the examination efforts of poorer ones. Because firms file the same patents in multiple jurisdictions, oppositions drafted for one jurisdiction could be deployed in others, further expanding the pool of potential opponents and helping compensate for resource limitations in patent offices.

Courts and patent officials in counter-harmonizing countries could also look to one another for guidance and assistance. Counter-harmonization thus takes advantage of the same mechanisms as the influence of transnational legal culture, but in the opposite direction. More precisely, counter-harmonization facilitates the creation of a transnational counter-culture that shares the costs of implementing patent laws tailored to the needs of developing countries. Counter-harmonization might also provide a measure of protection against political retaliation from more developed countries, if it enhances the legitimacy of alternative interpretations of TRIPS and increases the overall costs of retaliating for developed nations.⁴⁰¹

400. One might instead use the term to mark efforts by developing countries to impose their preferred form of harmonization on developed countries (for example, by seeking universal protection for traditional knowledge). I thank Peter Yu for this point. Because my interest here is in TRIPS implementation, I define counter-harmonization rather as a process whereby developing countries collectively adopt and implement an alternative regime of patent law keyed to their needs.

401. See ANDREW T. GUZMÁN, *HOW INTERNATIONAL LAW WORKS: A RATIONAL CHOICE THEORY* 46–48 (2008) (discussing the role that the overall cost of retaliation plays in discouraging

Resource limitations, though, create an entry barrier to a system of coordination. The gravitational pull of the transnational legal culture dominated by developed countries, which will continue to have greater resources to conduct trainings and make their legal regimes accessible as models, also works against this strategy. While counter-harmonization can make political retaliation more expensive for developed countries, it can also make it more worthwhile. A set of unusual flexibilities adopted in one developing country may not be worth the effort of a concerted response. A set of coordinated flexibilities deployed in several countries is a more compelling target. Notably, high-protection jurisdictions are already targeting some of the flexibilities discussed in Part II. Some bilateral preferential trade agreements negotiated by the United States include obligations to issue second-use patents, restrictions on patent oppositions and compulsory licensing, and obligations to introduce forms of data exclusivity that might be susceptible to far fewer flexibilities than are patents.⁴⁰² High-protection jurisdictions have also for many years sought to negotiate a Substantive Patent Law Treaty that would “adopt identical rules concerning what constitutes a novel and useful invention, when a technical advance meets the requirement for an ‘inventive step’ (nonobviousness), and how much information must be revealed by the patent disclosure.”⁴⁰³ The recent Anti-Counterfeiting Trade Agreement negotiations launched by Japan and the United States could restrict countries’ flexibilities with respect to remedies and introduce new requirements for customs’ seizures of disputed medicines.⁴⁰⁴

Counter-harmonizing efforts thus cannot be expected to succeed in every case. Nonetheless, there are several reasons to see the counter-harmonization strategy as the most promising of the three. A more compelling target is also a more costly target, from the perspective of a retaliating country. Developing

retaliation in the international context). Helfer, Alter, and Guerzovich offer an intriguing example of the potential benefits of counter-harmonization that is also judicialized. They discuss several rulings of the regional Andean Tribunal of Justice that have enforced Andean Community patent law to reject local patent reforms that increased the strength of patents. *See* Helfer, Alter, & Guerzovich, *supra* note 150, at 26–30. These rulings, they conclude, have “helped Andean countries to resist pressure from the United States to expand IP protection for foreign corporations.” *Id.* at 46.

402. *See* Richard D. Smith, Carlos Correa, & Cecilia Oh, *Trade, TRIPS, and Pharmaceuticals*, 373 *LANCET* 684, 687 (2009).

403. *See* Reichman & Dreyfuss, *supra* note 3, at 90.

404. *See* U.S. TRADE REPRESENTATIVE, THE ANTI-COUNTERFEITING TRADE AGREEMENT—SUMMARY OF KEY ELEMENTS UNDER DISCUSSION 1, 3 (2009), available at http://www.ustr.gov/sites/default/files/uploads/factsheets/2009/asset_upload_file917_15546.pdf. The negotiations do not currently include developing countries, but signatories would likely press other countries to join any agreement concluded. The recent push to define “counterfeit” medicines as those that violate patent rights (rather than as medicines that are substandard or violate a trademark) may also have important implications for generic producers. *See, e.g.*, Kevin Outtersson, *Import Safety Rules and Generic Drug Markets*, in *IMPORT SAFETY: REGULATORY GOVERNANCE IN THE GLOBAL ECONOMY* (Cary Coglianese, Adam Finkel, & David Zaring, eds., forthcoming 2009).

countries that coordinate their flexibilities must forego some of the benefits of fragmentation, because it will be easier for transnational companies to identify and meet the requirements of their laws. But such laws also have independent purpose. Counter-harmonizing the requirement of reporting the source of genetic material, for example, could increase the likelihood that such reporting is done, and that failure to disclose is detected. That in turn would make it feasible to enforce limitations on patents obtained in violation of local rules on informed consent. If coordination is possible, developing countries likely have more to gain than to lose from the potential for increased adherence to such requirements.

India is well positioned to lead a new counter-harmonizing trend. It has developed innovative tools such as section 3(d) and its active pre-grant opposition system, and has sketched out others, such as limitations on injunction remedies. India has more technical capacity, resources, and political and economic power than many other developing countries, yet would itself benefit from sharing the burden of articulating and legitimating an alternative vision of patent law. Several national and transnational NGOs, as well as international agencies such as the WHO, lobbied for many of the pertinent provisions in Indian law, and therefore may be conduits to the introduction of elements of that law in other jurisdictions.⁴⁰⁵

Notably, there are already some signs that India could provide a new pole for counter-harmonization. The Philippines recently adopted a new exception to their patent law modeled on section 3(d) of the Indian Act. The law was explicitly modeled on India's law, which the WHO, among others, recommended.⁴⁰⁶ More recently still, Zanzibar also adopted a similar provision.⁴⁰⁷

Oppositions are another emerging locus of coordination. In July 2008, the Brazilian Interdisciplinary HIV/AIDS Association announced that it had filed two oppositions to patents on Gilead's important anti-HIV drug Tenofovir—one in Brazil, and another in India in conjunction with Indian NGOs.⁴⁰⁸ The Indian application has yet to be resolved, but the Brazilian opposition was granted in September 2008.⁴⁰⁹ This was the first time a patent on an

405. See the Philippines example, *infra* note 406.

406. Senate of the Philippines, Comms. on Trade and Commerce & Health, Demography and Finance, Comm. Rep. No. 6, at 9 (Oct. 1, 2007) (on file with author). For the text of the new law, see An Act Providing for Cheaper and Quality Medicines, Amending for the Purpose Republic Act No. 8293 or the Intellectual Property Code, Republic Act No. 6675 or the Generics Act of 1988, and Republic Act No. 5921 or the Pharmacy Law, and for Other Purposes, Rep. Act No. 9502, §§ 5–6 (June 6, 2008) (Phil.), available at http://www.senate.gov.ph/republic_acts/ra%209502.pdf.

407. Intellectual Property Act, 2008, § 3(v) (Zanzibar) (excluding from patentability “new uses or forms of known product or process”) (on file with author).

408. *Brazil & India Are Increasingly Challenging Prices by Opposing Patents*, ECONOMIST INTELLIGENCE UNIT, July 2, 2008, http://viewswire.eiu.com/index.asp?layout=ib3Article&article_id=793514664&pubtypeid=1152462500&rf=0.

409. Médecins Sans Frontières, Press Release, Brazil Rejects Patent on an Essential AIDS

antiretroviral drug had been denied in Brazil because of a pre-grant opposition.⁴¹⁰ NGOs have also begun to explore the possibility of oppositions in other countries⁴¹¹ and to publicize opposition decisions to facilitate their use in other developing countries.⁴¹²

Others have noted the value that cooperation might have for developing countries seeking to implement TRIPS to their advantage.⁴¹³ But most of the discussion of collective action in the literature has focused on the domain of trade negotiations, and has assumed that “countries usually stand alone when it comes to translating WTO law into national policy.”⁴¹⁴ The concept of counter-harmonization identifies the potential benefits of coordination in the realm of implementation, and helps us identify the broad range of benefits that such coordination may provide. Developing countries that counter-harmonize may benefit not only from protection in numbers against threats of unilateral retaliation, but also from the ballast that such counter-harmonization can create against the effects of transnational legal culture and the cost savings it can provide to their administrative agencies. While strategies of fragmentation and mimicry can address some of the obstacles to the implementation of TRIPS flexibilities articulated above, counter-harmonization appears to have the greatest scope of the three strategies identified here.

CONCLUSION

To date, the academic conversation about the dynamics of TRIPS implementation has been largely theoretical. The primary aim of this Article has been to use an empirical case study approach to enrich our understanding of the nature and utility of TRIPS flexibilities, and of the potential for TRIPS to serve as a harmonizing force.

The Indian example shows that that TRIPS leaves developing countries a more diverse and wide-ranging set of flexibilities at the formal level than the existing literature typically suggests. If India implemented its adopted

Medicine (Sept. 3, 2008), *available at* http://www.msf.org/msfinternational/invoke.cfm?objectid=28630EB3-15C5-F00A-251F391A2B46443A&component=toolkit.pressrelease&method=full_html.

410. *Id.*

411. *See, e.g.*, TAHIR AMIN, I-MAK, PRE-GRANT PATENT OPINIONS IN VIETNAM AND THEIR ROLE IN ACCESS TO MEDICINES: A BRIEF PRACTICAL GUIDE (2006), *available at* <http://www.law.fsu.edu/gpc2007/materials/Pre-grantPatentObservationsinVietnam.pdf>.

412. *See, e.g.*, I-MAK, Pharmaceutical Patent Case Law, <http://www.i-mak.org/pharmapatient-decisions/> (last visited Nov. 11, 2009).

413. *See, e.g.*, Abbott & Reichman, *supra* note 275, at 985; Peter Drahos, *Four Lessons for Developing Countries from the Trade Negotiations over Access to Medicines*, 28 LIVERPOOL L. REV. 11, 24 (2007); Reichman, *supra* note 11, at 458; *see also* SISULE F. MUSUNGU, SUSAN VILLANUEVA & ROXANA BLASETTI, S. CENTRE, UTILIZING TRIPS FLEXIBILITIES FOR PUBLIC HEALTH PROTECTION THROUGH SOUTH-SOUTH REGIONAL FRAMEWORKS (2004), <http://apps.who.int/medicinedocs/en/d/Js4968e/>; Peter K. Yu, *Access to Medicines, BRICS Alliances, and Collective Action*, 34 AM. J.L. & MED. 345, 394 (2008).

414. DEERE, *supra* note 12, at 21.

flexibilities to their full potential, it could generate significant scope for competition in the pharmaceutical sector without ever issuing a compulsory license. TRIPS cannot force deep harmonization between countries because its formal standards permit countries to take materially different approaches to IP, deploying the substantive and procedural flexibilities that the Agreement permits. Nonetheless, TRIPS channels a strong harmonizing force. Resource limitations, the influence of a highly transnationalized legal culture dominated by high-protection jurisdictions, and the persistent threat of unilateral pressure all make it difficult for a country like India to effectively implement a relatively autonomous vision of patent law. Nonetheless, countries have recourse to compensating strategies of fragmentation, mimicry, and counter-harmonization that can counteract the transnational dynamics that militate against the use of flexibilities. While no silver bullet, the last strategy shows the most promise for countries seeking to take maximum advantage of TRIPS flexibilities. Because of India's leading role as a generic supplier in the world pharmaceutical market, and given the novelty and expansiveness of the implementation approach it has taken, the flexibilities adopted in the Indian patent context may well become central to new interpretive conflicts over TRIPS.

The case study offered here suggests that as we enter into the era of TRIPS implementation, we should expect a new period of political polarization—not over whether developing countries will adhere to TRIPS, but over what it *means* to adhere to TRIPS. In previous work, I have discussed the role of international agreements in constituting transnational “publics,” by recruiting social actors into the terms of law as these groups compete for the instrumental and symbolic power of law.⁴¹⁵ This dynamic is also evidenced in the Indian context, as Part I shows: Indian firms and health activists were drawn into the terms of IP law through their encounter with TRIPS, and played an important role in recasting the terms of TRIPS as they pressed India to adopt the substantial flexibilities that it chose. Here I extend this perspective to include state actors. Rather than reject TRIPS, Indian government actors have engaged in creative acts of legal interpretation that take extensive advantage of known TRIPS flexibilities, and that have also generated new ones.⁴¹⁶ In the process, India has paved the way for new interpretive disagreements over the meaning of TRIPS. The dynamic has clearly operated beyond India as well. The process of TRIPS implementation has more generally led developing countries to make new demands with regard to TRIPS reform, and to become “more active participants in global IP debates.”⁴¹⁷

Those who lobbied in favor of TRIPS have often spoken as if the primary question about the Agreement were whether or not developing countries would

415. See Kapczynski, *supra* note 8, 880–81.

416. On the role of TRIPS in Parliamentary debates in India, see *supra* note 91.

417. DEERE, *supra* note 12, at 119.

comply with it.⁴¹⁸ Notably, leading voices in that group have begun to reassess that view, recognizing that they crafted a *legal* agreement, and thus entered into an interpretive struggle with their opponents (understood here to be developing country governments). Perhaps the single most important figure behind the TRIPS Agreement, Jacques Gorlin, recently had this to say:

The biggest problem [for] those of us who were involved in the take off of TRIPS is that, after the TRIPS agreement went into effect, the lawyers took over. Most of us who have a background, not in intellectual property, but in trade, looked at the TRIPS agreement not so much as a legal instrument but as more of a political document that included minimum standards of intellectual property protection.⁴¹⁹

Another key advocate of TRIPS, Charles Levy, came to a similar conclusion: “Those of us involved in the negotiations thought that, for the most part, we had a clear idea of what the provisions meant. Now, even what should be the most straightforward provisions are being challenged.”⁴²⁰ He concluded: “we underestimated the ability of countries to reinterpret the commitments in TRIPS to respond to domestic political and economic pressures.”⁴²¹

According to these accounts, key proponents of the Agreement misunderstood the potential of the legalization of their political victory to provide flexibility to their opponents. Or, they failed to realize that countries like India did not need to cheat; they could lawyer instead. This view supports the long tradition within trade law scholarship that argues that legalization of the world trade regime will benefit countries with relatively less economic power.⁴²² But as this Article shows, the implications of legalization in the Indian context have been far more complex than the statements of Gorlin and Levy, or a simple identification between legalization and the leveling of power differences, suggest. It is true that TRIPS leaves developing countries substantial flexibility, and that India has been able to craft a creative new patent

418. See *supra* note 10.

419. Jacques J. Gorlin, *U.S. Industries, Trade Associations, and Intellectual Property Lawmaking*, 10 *CARDOZO J. INT'L & COMP. L.* 5, 5 (2002). Gorlin acted as the chair of the Intellectual Property Committee, the chief lobbying force behind TRIPS. See *SELL*, *supra* note 37, at 1–2.

420. Levy, *supra* note 10, at 791. Levy was counsel to the Intellectual Property Committee.

421. *Id.* A further example of the dynamic Levy speaks of comes from China, and a recent dispute brought by the United States over copyright piracy. Industry representatives regularly complain of what they characterize as rampant disregard in China for international copyright law. But it turns out that those obligations are not as clear as industry, or the United States, have insisted. The recent dispute generated a substantial loss for the United States, and a victory for China, which argued that TRIPS did not oblige it to criminalize copyright piracy below a certain value threshold. See Panel Report, *China—Copyright*, *supra* note 217.

422. See, e.g., JOHN H. JACKSON, *WORLD TRADE AND THE LAW OF GATT* 763–65 (1969); James McCall Smith, *The Politics of Dispute Settlement Design: Explaining Legalism in Regional Trade Pacts*, 54 *INT'L ORG.* 137, 148 (2000); see also Kenneth W. Abbott & Duncan Snidal, *Hard and Soft Law in International Governance*, 54 *INT'L ORG.* 421, 447 (2000) (“[T]raditional legal scholars generally agree that legalization aids weak states.”).

law that could produce dramatically more competition in the pharmaceutical sector than other TRIPS-compliant countries enjoy. But it is equally clear that it is quite difficult for developing countries—even those as comparatively well-resourced and powerful as India—to make practical use of the legal flexibilities that the Agreement permits. (Recall too that many other developing countries have implemented IP laws that are more restrictive than TRIPS requires, in part because of the same resource limitations, transnational cultural circuits, and extralegal pressures that influence the implementation of India’s law.)⁴²³ Even a highly flexible agreement such as TRIPS sets up a strong harmonizing dynamic, because it inserts countries into a transnational circuit that fills in the gaps in the Agreement.

Such pressures are not independent of the dynamic of legalization, but are shaped by it. The standardization of patent laws makes resource disparities more acute, because developing country offices face a rapidly growing field of transnational applicants who can spend substantial sums on patenting and take advantage of economies of scale through systems like the PCT. Technical assistance such as that provided to India by the EPO is predicated on the general similarity of the laws in question. (It is difficult, for example, to imagine that the kind of technical assistance offered in the patent context could be offered or received with respect to India’s personal law.)⁴²⁴ The pressure that may be exerted by developed countries outside of the realm of TRIPS, though it may in fact be somewhat constrained by the Agreement, also can work in tandem with the Agreement, pressing countries away from more ambitious interpretations of the Agreement’s provisions. Countries can, as I have shown, slow or rewrite these circuits of transnational influence, using strategies like fragmentation, mimicry, and counter-harmonization. While the last strategy is the most promising, none offer a simple solution to the dilemmas produced by the attempt to comply with TRIPS while creatively adapting its requirements to local needs.

The notion that TRIPS implementation can be expected to lead to a new period of political polarization about what it means to adhere to TRIPS also brings a new perspective to the debates about the “constitutionalization” of the WTO. Such debates have today become “the centre of academic writing” in the field of trade law.⁴²⁵ From the beginning of the transition from the GATT to the more formal, institutionalized WTO, “the idea that the WTO might be constitutionalizing began to take hold.”⁴²⁶ Notably, the term has come into use

423. See DEERE, *supra* note 12, at 13, 159–61, 203–04.

424. Under India’s system of “personal law,” many aspects of family law turn on the religion of the parties involved. See, e.g., Seval Yildirim, *Expanding Secularism’s Scope: An Indian Case Study*, 52 AM. J. COMP. L. 901, 913 (2004).

425. Jeffrey L. Dunoff, *Constitutional Conceits: The WTO’s ‘Constitution’ and the Discipline of International Law*, 17 EUR. J. INT’L L. 647, 650 (2006).

426. DEBORAH Z. CASS, *THE CONSTITUTIONALIZATION OF THE WORLD TRADE ORGANIZATION* 16 (2005).

without any agreement about what it means, and despite considerable unease about its suitability and implications.⁴²⁷ Constitutions are, of course, identified with national-level governance. In the United States in particular they are identified with a unitary written text that serves as a broad national charter, establishing not only basic structures of government but also normative principles that define the aspirations of a national community. If this is the model, there are clearly many reasons that the term “constitutional” is a poor fit for the WTO. Those who find value in the use of the term note, however, that it is “difficult to say what is the core meaning of ‘constitution’, and what is a trope,” and charge those who reject the term outright with a “false rigidity” that prevents us from identifying and talking about aspects of the world trading order that may have features associated with constitutions.⁴²⁸

Deborah Cass has usefully identified the three dominant visions of the constitutionalization of the WTO.⁴²⁹ The first, “institutional managerialism,” is associated most prominently with the influential trade law scholar John Jackson. Jackson identifies the term with the process of institutionalization, which he in turn associates with greater predictability and rule-orientation.⁴³⁰ He presents the constitutionalization of trade law as both desirable and inevitable. As he puts it, “To a large degree, the history of civilization may be described as a gradual evolution from a power oriented approach, in the state of nature, towards a rule oriented approach,” and he asserts that “to a certain extent this same evolution must occur” in international law.⁴³¹ The trend is also to be welcomed, particularly in trade law, because it promises “less reliance on raw power,” “a fairer break for the smaller countries, or at least a perception of greater fairness,” and structure that is both reasonably predictable and reasonably open to the influence of engaged citizens.⁴³²

A second vision, that of “rights-based constitutionalism,” is most prominently associated with Ernst-Ulrich Petersmann.⁴³³ This theory equates constitutionalism with the defense of the “equal rights of the citizens against” abuses of government power.⁴³⁴ More controversially, it asserts that economic

427. *Id.* at 16–18.

428. Joel P. Trachtman, *The Constitutions of the WTO*, 17 EUR. J. INT’L L. 623, 623, 626 (2006).

429. Cass, *supra* note 426, at 21–22; *see also* Dunoff, *supra* note 425, at 651 (offering the same typology).

430. JOHN H. JACKSON, *THE WORLD TRADE ORGANIZATION: CONSTITUTION AND JURISPRUDENCE* 6 (1998) (identifying the constitution of the WTO as its “institutional structure,” including its treaties and dispute-settlement processes); JOHN H. JACKSON, *RESTRUCTURING THE GATT SYSTEM* 51 (1990) (identifying constitutionalism with a shift from a “power-oriented” system to a “rule-oriented” system) [hereinafter JACKSON, *RESTRUCTURING GATT*]; *see also* CASS, *supra* note 426, at 100–01, 103.

431. JACKSON, *RESTRUCTURING GATT*, *supra* note 430, at 52–53.

432. *Id.* at 53–54.

433. CASS, *supra* note 426, at 145.

434. Ernst-Ulrich Petersmann, *How to Constitutionalize International Law and Foreign Policy for the Benefit of Civil Society?*, 20 MICH. J. INT’L L. 1, 1 (1998).

freedoms such as the security of property and the right to trade are fundamental human rights, and that the WTO is constitutionalized because it protects individuals' economic freedoms and prevents economic discrimination.⁴³⁵

A third vision has been promoted by Cass herself, and equates constitutionalization with "judicial norm-generation."⁴³⁶ It suggests that the WTO dispute-resolution system acts as a constitutionalizing force because it is developing doctrines common in constitutional systems (e.g., of jurisdiction), creating "system making" rules (e.g., regarding the relationship between the WTO and other domains of law), and taking on traditionally domestic subject matters such as the environment and health.⁴³⁷

In a recent article, Jeffrey Dunoff points out that despite their differences, the three dominant accounts incorporate a similar conception of the purpose and effects of constitutionalism. Constitutionalism is identified with the "principled and authoritative settlement of divisive issues."⁴³⁸ It occurs "through reference to a meta-agreement . . . [that] can then be used to resolve and pre-empt debate over what would otherwise be controversial issues."⁴³⁹ The "turn to constitutionalism" in trade law thus represents, according to Dunoff, both a desire for and an attempt to build "a mechanism for withdrawing controversial and potentially destabilizing issues from the parry and thrust of ordinary politics."⁴⁴⁰ For Jackson, this occurs through institutions that bind power to rules.⁴⁴¹ For Petersmann, it occurs by promoting economic freedoms over other basic rights.⁴⁴² For Cass, it occurs through the judicial development of basic norms and rules for the world trading order.⁴⁴³ Dunoff objects to the anti-political characterization of constitutionalism offered in these accounts, and argues that "the turn to constitutionalism is self-defeating because constitutionalism does not and cannot generate finality on highly contested issues."⁴⁴⁴

The present study suggests an alternative way of understanding the constitutional nature of the WTO, one that identifies constitutionalism not with the suppression of politics, but rather with new theories of "democratic constitutionalism" that emphasize "the deep and inevitable interdependence of

435. See, e.g., Ernst-Ulrich Petersmann, *The WTO Constitution and Human Rights*, 3 J. INT'L ECON. L. 19, 19–21 (2000).

436. Cass, *supra* note 426, at 177.

437. *Id.* at 178.

438. Dunoff, *supra* note 425, at 662.

439. *Id.*

440. *Id.* at 649.

441. *Id.* at 663.

442. *Id.*

443. *Id.* Cass has tempered her claims about the constitutionalizing force of the judicial norm generation approach, concluding that her earlier work did not give due weight to questions of legitimacy, or to "the role of politics in the constitutionalization process." Cass, *supra* note 426, at 178.

444. Dunoff, *supra* note 425, at 665.

constitutional law and politics.”⁴⁴⁵ Democratic constitutionalists argue that constitutionalism does not, and cannot, render issues “off-limits to politics.”⁴⁴⁶ Rather, it provides a means of “negotiat[ing] the tension between the rule of law and self-governance.”⁴⁴⁷ This uneasy and always incomplete reconciliation occurs not through the suppression of dissent, but through a process of dialogic engagement between mobilized social actors and legal institutions (most typically, courts). The “open-ended” nature of certain constitutional commitments, and their claim to “express[] national ideals,” invite and channel contestation over the meaning of these ideals, producing conflict over constitutional meaning but also helping to ensure that constitutional law retains democratic legitimacy.⁴⁴⁸

The theory of democratic constitutionalism provides an alternative way to understand the constitutional capacities of the WTO. It suggests that if the WTO does have a “constitutional” nature, it lies in the institution’s capacity not to suppress or authoritatively end disputes, but rather to constitute and channel transnational disagreement. The Indian example illustrates this: the TRIPS Agreement has helped bring not only the Indian government but also its drug industry and health activists into a transnational debate about the proper scope and meaning of IP law, anchored in the legal obligations that WTO members must comply with under TRIPS. It is likewise doing so in the dozens of other countries around the world that have recently had to bring their law into conformity with the Agreement. This in turn may have the effect of legitimating the TRIPS Agreement, as it both creates new possibilities for the implementation of TRIPS that are more palatable for developing countries, and leads such countries to seek to comply with rather than reject the Agreement. On this account, the new interpretive conflicts that TRIPS is generating signal not the failure of the constitutional nature of the WTO, but its success. Such contestation may provide a means to negotiate the tension between law and legitimacy that pervades this increasingly legalized institution.

A full account of the implications of a theory of democratic constitutionalism at the WTO cannot be provided here. Such an account would provoke, and would therefore have to address, many important questions. The first of these is the value and appropriateness of “constitutional” language in this context. What is special about a constitution in the theory of democratic constitutionalism, and does the WTO have that something? If the processes of democratic constitutionalism turn on the identification between “We the People” and a given text

445. Robert Post & Reva Siegel, *Roe Rage: Democratic Constitutionalism and Backlash*, 42 HARV. C.R.-C.L. REV. 373, 433 (2007).

446. *Id.* at 403 (internal quotation marks omitted).

447. *Id.* at 376.

448. *Id.* at 378–79; see also Reva B. Siegel, *Constitutional Culture, Social Movement Conflict, and Constitutional Change: The Case of the De Facto ERA*, 94 CALIF. L. REV. 1323 (2006).

or normative order, for example,⁴⁴⁹ the WTO clearly falls short. If it is instead a product of legal texts that are at once open-ended, highly consequential, and extremely difficult to amend,⁴⁵⁰ then the WTO looks exceptionally susceptible to the dynamics of democratic constitutionalism. Could a theory of democratic constitutionalism at the WTO help us theorize how the WTO might reconcile demands for the kind of stability sought by Jackson with the “sociological legitimacy” sought by Dunoff?⁴⁵¹ Perhaps. By considering the traditions of constitutionalism that permit the successful alchemy of politics and law under this theory, we might gain insights into practices that would permit a better reconciliation of the two at the WTO. Alternatively, we might come to better understand why the WTO may be unable, over time, to successfully mediate between the two.

449. See Post & Siegel, *supra* note 445, at 374.

450. *Id.* at 378, 380.

451. Dunoff, *supra* note 425, at 674.

