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# An Exploration of Compulsory Licensing as an Effective Policy Tool for Antiretroviral Drugs in India

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# AN EXPLORATION OF COMPULSORY LICENSING AS AN EFFECTIVE POLICY TOOL FOR ANTIRETROVIRAL DRUGS IN INDIA<sup>\*</sup>

*Dipika Jain<sup>†</sup> & Jonathan J. Darrow<sup>††</sup>*

## ABSTRACT

Access to affordable drugs for the treatment of HIV/AIDS and other diseases is increasingly challenging in many developing countries such as Brazil, South Africa, and India. These challenges are in part the result of strengthened patent laws mandated by the 1994 Trade-Related Aspects of Intellectual Property Rights (TRIPS) treaty. However, there are underutilized instruments within TRIPS that governments can use to limit the adverse effects of patent protection and thereby ensure a supply of affordable generic drugs to their people. One such instrument is compulsory licensing, which allows generic manufacturers to produce pharmaceutical products that are currently subject to patent protection. Compulsory licensing has been used by a number of countries in the last few years, including the United States, Canada, Indonesia, Malaysia, Brazil, and Thailand, and is particularly significant for countries such as India, where large numbers of people are infected with HIV. This Article explores the feasibility of compulsory licensing as a tool to facilitate access to essential medicines within the current patent regime in India, drawing on the experiences of other countries.

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## INTRODUCTION

Antiretroviral (ARV) treatment remains the only proven treatment to extend the lives of individuals living with HIV/AIDS.<sup>1</sup> Nevertheless, access to affordable ARV drugs is increasingly challenging in many developing countries including Brazil, South Africa, and India. According to a 2007 joint report of the World Health Organization and the United Nations Program on HIV/AIDS, 2.5 million people in India are infected with the disease.<sup>2</sup> The infection is manageable in these developing countries only because of the emergence of ARV drug treatment, also known as antiretroviral therapy, highly active antiretroviral therapy, or potent combination antiretroviral therapy.<sup>3</sup>

The US Food and Drug Administration approved the first antiretroviral HIV drug, zidovudine (AZT, sold under the brand names Retrovir and Retrovis) in 1986.<sup>4</sup> The discovery that AZT, a drug originally intended to treat cancer, could effectively reduce HIV in the body, represented hope for a better life for the tens of thousands of HIV-positive people around the world. As one of the most expensive drugs

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1. *See generally Patent Situation of HIV/AIDS-Related Drugs in 80 Countries*, UNAIDS & WORLD HEALTH ORG. 13–15 (2000), <http://apps.who.int/medicinedocs/pdf/whozip17e/whozip17e.pdf> (providing a list of patents protecting HIV/AIDS-related drugs throughout the world).
  2. UNAIDS & WORLD HEALTH ORG., AIDS EPIDEMIC UPDATE: REGIONAL SUMMARY 5 (2008), *available at* [http://data.unaids.org/pub/Report/2008/jc1527\\_epibriefs\\_asia\\_en.pdf](http://data.unaids.org/pub/Report/2008/jc1527_epibriefs_asia_en.pdf).
  3. NAT'L CTR. HIV/AIDS, VIRAL HEPATITIS, STD, & TB PREVENTION, CDC, BACKGROUND BRIEF ON THE PREVENTION BENEFITS OF HIV TREATMENT 1–2 (2013), *available at* [http://www.cdc.gov/hiv/topics/treatment/resources/factsheets/pdf/Prevention\\_Benefits\\_of\\_HIV\\_Treatment.pdf](http://www.cdc.gov/hiv/topics/treatment/resources/factsheets/pdf/Prevention_Benefits_of_HIV_Treatment.pdf).
  4. Michael Shernoff & Raymond A. Smith, *HIV Treatments: A History of Scientific Advance*, THE BODY (July 2001), <http://www.thebody.com/content/art30909.html>.

ever to reach the market,<sup>5</sup> AZT also represented the beginning of a struggle for affordable treatment that continues today. The drug was prohibitively expensive for the vast majority of HIV-infected persons in developing countries.

The emergence of generic ARV drugs from India brought some relief beginning in 1991, selling for one-quarter of the price of the original AZT.<sup>6</sup> India soon emerged as a world leader in the generic manufacture of AIDS drugs, bringing prices within reach of not only those in India, but also many more around the world. India remains the supplier of choice for medications in most developing countries, producing medicines of respected quality that meet international standards at the lowest cost.<sup>7</sup> A study comparing the prices in India and other countries where patent protection exists found that drugs are up to forty-one times more expensive in countries with patent protection than in those countries without it.<sup>8</sup> A 1990 study by an economist from the International Monetary Fund reported that drug prices in Malaysia, where drug product patent protection already existed, were from 20 to 760 percent higher than in India,<sup>9</sup> which did not have drug product patent protection at the time. The Indian pharmaceutical industry has been an important supplier of generic ARVs both domestically and to the less-regulated markets of Africa, Asia, and Latin America. Today, India continues to be a major supplier of finished products, including vaccines and ARVs, to buyers around the world.

At the same time, certain international developments over the past two decades have threatened access to essential medications. In 1995, the establishment of the World Trade Organization (WTO) and its Agreement on Trade-Related Aspects of Intellectual Property Rights

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5. Brian O'Reilly & Nora E. Field, *The Inside Story of the AIDS Drug*, FORTUNE, Nov. 5, 1990, at 113 (noting a year's worth of AZT cost \$10,000 in 1990).
  6. Carin Håkansta, *The Battle on Patents and AIDS Treatment*, 34 BIOTECH. & DEV. MONITOR 16 (1998); see also Eloan Pinheiro et al., *Examining the Production Costs of Antiretroviral Drugs*, 20 AIDS 1745, 1746 (2006) (noting "a significant decrease" in the price of ARVs between 2001 and 2006).
  7. Caroline Berman et al., *India's Pharmaceutical Industry: A Shift in Strategy*, in WINNING STRATEGIES FOR THE INDIAN MARKET 176 (Anuradha Dayal-Gulati & Dipak Jain eds., 2010); Brenda Waning et al., *A Lifeline to Treatment: The Role of Indian Generic Manufacturers in Supplying Antiretroviral Medicines to Developing Countries*, 13 J. INT'L AIDS SOC'Y 1, 2 (2010).
  8. K. Balasubramaniam, *Access to Medicines and Public Policy Safeguards under TRIPS*, in TRADING IN KNOWLEDGE: DEVELOPMENT PERSPECTIVES ON TRIPS, TRADE AND SUSTAINABILITY 13 (Christophe Bellmannet et al. eds., 2003).
  9. *Id.* at 137.

(TRIPS)<sup>10</sup> committed most nations to implementing or strengthening patent legislation that would require pharmaceutical products (in addition to processes) to be eligible for patent protection. A patent is a right granted by a government to an inventor that allows that inventor, for a limited period of time, to exclude others from making, using, selling, or importing an invention. This Article examines the exclusionary function of patents that allows brand-name drug companies to temporarily exclude generic drug manufacturers from producing life-sustaining medications.

Patent protection is often cited as one of the primary reasons for the limited availability and affordability of medication for HIV/AIDS.<sup>11</sup> Although patents are generally available for inventions related to any type of drug, the effects on HIV/AIDS drugs is particularly pointed because HIV/AIDS emerged quite recently in medical history and so the drugs that treat it are relatively new. Although patent rights are temporary and will eventually expire, not enough time has yet elapsed for most HIV/AIDS drugs to come off patent. Thus, there are often few effective options for patients who cannot afford newer, patented medications.

Historically, many developing countries lacked strong protection of intellectual property rights,<sup>12</sup> and even many developed countries did not allow patents to issue on pharmaceutical products until recently. Italy, for example, extended patent protection to pharmaceutical products only in 1978 as the result of a decision of its supreme court.<sup>13</sup> Similarly, France began to recognize pharmaceutical product patents only in 1960; Japan in 1976; Germany in 1968, Denmark in 1983; Norway in 1992; and Finland in 1995.<sup>14</sup> The TRIPS Agreement thus reinforced an existing trend toward extending patent coverage to include pharmaceutical products. Although the processes used to make pharmaceutical products were already patentable in many countries, there are often many

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10. See Agreement on Trade-Related Aspects of Intellectual Property Rights art. 28, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299 [hereinafter TRIPS].
  11. See Waning et al., *supra* note 7, at 2.
  12. See, e.g., JAYASHREE WATAL, INTELLECTUAL PROPERTY RIGHTS IN THE WTO AND DEVELOPING COUNTRIES 13 (2001).
  13. See F.M. Scherer & Sandy Weisburst, *Economic Effects of Strengthening Pharmaceutical Patent Protection in Italy*, 26 INT'L REV. OF INDUS. PROP. & COPYRIGHT L. 1009, 1009 (1995).
  14. Daniel J. Gifford, *Government Policy Towards Innovation in the United States, Canada, and the European Union as Manifested in Patent, Copyright, and Competition Laws*, 57 SMU L. REV. 1339, 1350 (2004); Alan S. Gutterman, *The North-South Debate Regarding the Protection of Intellectual Property Rights*, 28 WAKE FOREST L. REV. 89, 126 n.258 (1993).

different ways to synthesize a particular drug.<sup>15</sup> As a result, it can be relatively easy to “invent-around” a process patent, weakening the effect of the patent holder’s right. In contrast, it is often difficult or impossible to “invent around” a product patent. The extension of patent protection to drug products (as distinct from the processes used to make them) therefore greatly strengthened the ability of pharmaceutical companies to exclude others from making those products.

Developing countries such as India, China, and Brazil were permitted to delay implementation of their obligations under the TRIPS Agreement until 2005.<sup>16</sup> This negotiated delay allowed those countries time to readjust and plan for the eventual phase-in of stricter intellectual property laws. Eventually it was realized that even this ten-year phase-in period was insufficient for the least-developed countries, and in 2002, the TRIPS Council (the WTO body that oversees the TRIPS Agreement) issued a decision extending until January 1, 2016, the date by which least-developed country members had to institute pharmaceutical patent protection.<sup>17</sup> A list of least-developed countries is maintained by the United Nations Office of the High Representative for Least Developed Countries.<sup>18</sup> India is not a least-developed country (neither are China or Brazil) and so it does not benefit from the extended deadline.

Consistent with its TRIPS obligation, the Indian government passed a new Indian Patents (Amendment) Act in 2005 (2005 IPA), extending patent protection to cover pharmaceutical products for the first time since the elimination of colonial-era drug patents in 1970.<sup>19</sup> The 2005 IPA protected generic drugs already on the market as of January 1, 2005, from the institution of infringement proceedings, allowing companies to continue to sell these inexpensive generic products upon the payment of a

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15. See Linfong Tzeng, *Follow-On Biologics, Data Exclusivity, and the FDA*, 25 BERKELEY TECH. L.J. 135, 154–55 (2010).
  16. See TRIPS art. 66; see also Laura Chung, *Use of Paragraph 6 System for Access to Medicine*, 36 N.C. J. INT’L L. & COM. REG. 137, 174 (2010).
  17. The Council for TRIPS, *Extension of the Transition Period Under Article 66.1 of the TRIPS Agreement for Least-Developed Country Members for Certain Obligations with Respect to Pharmaceutical Products*, WORLD TRADE ORG. (July 1, 2002), [http://www.wto.org/english/tratop\\_e/trips\\_e/art66\\_1\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/art66_1_e.htm).
  18. *About LDCs*, UN-OHRLLS, <http://www.unohrlls.org/en/ldc/25/> (last visited May 25, 2013).
  19. Philippe Cullet, *The Patents Amendment Act and Access to Medicine*, INT’L ENV’T L. RESEARCH CTR. (May 27, 2002), <http://www.ielrc.org/content/n0204.htm>. The United Kingdom had extended patent protection to drug products in 1949. Gutterman, *supra* note 14, at 126 n.258. India, as a British colony, had similar protection. Linda L. Lee, *Trials and TRIPS-ulations: Indian Patent Law and Novartis AG v. Union of India*, 23 BERKELEY TECH. L.J. 281, 290–91 (2008).

reasonable royalty.<sup>20</sup> However, many new AIDS therapies continued to be developed.<sup>21</sup> Significantly, some of these new therapies help to combat the virus once it develops resistance to existing combinations of antiretroviral drugs.<sup>22</sup> These newer drugs are therefore known as “second-line” ARV therapies,<sup>23</sup> and contingency “third-line” ARV treatments also exist.<sup>24</sup>

While many first-line ARVs were produced and marketed in India prior to 1995 and therefore escape the 2005 legislation, the availability and affordability of any drugs introduced in India after that date remain in question. Branded products may be priced out of reach, while generic versions introduced to the Indian market on or after January 1, 2005, are generally illegal and therefore not allowed in the Indian market unless authorized by the patent holder.<sup>25</sup> As a result, the 2005 IPA precludes the generic production of newer, more expensive second-line treatments that are needed for people living with resistant strains of HIV/AIDS until the patents on those newer drugs expire. Though patent-protected ARV drugs are relatively few in number, their high cost means that they nevertheless represent a very large percentage of health and treatment budgets. For example, of fourteen ARV drugs in the Brazilian National AIDS Program, three accounted for 63 percent of total program costs.<sup>26</sup> With new waves of ARV drugs being produced to combat resistance, access to the newest treatments will only worsen

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20. The Patents (Amendment) Act, 2005, No. 15, Acts of Parliament, 2005, § 10(c) (amending section 11A of the 1970 Indian Patent Act) [hereinafter Indian Patent Act (2005)].
  21. *Antiretroviral Drugs Used in the Treatment of HIV Infection*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/ForConsumers/byAudience/ForPatientAdvocates/HIVandAIDSactivities/ucm118915.htm> (last visited June 3, 2013) (listing a number of HIV drugs approved after January 1, 2005, including Edurant, extended-release Viramune XR, and combination drug Stribild).
  22. See Maxwell R. Morgan, *Medicines for the Developing World: Promoting Access and Innovation in the Post-TRIPS Environment*, 64 U. TORONTO FAC. L. REV. 45, 72 n.139 (2006).
  23. *Id.*
  24. UNAIDS, FAST FACTS ABOUT HIV TREATMENT 3 (2009), [http://www.unaids.org/en/media/unaids/contentassets/dataimport/pub/factsheet/2009/20090903\\_fastfacts\\_treatment\\_en.pdf](http://www.unaids.org/en/media/unaids/contentassets/dataimport/pub/factsheet/2009/20090903_fastfacts_treatment_en.pdf).
  25. 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, 575–76 (2007) (noting that the 2005 Indian Patent Act makes an exception for products already being sold prior to January 1, 2005, which may continue to be lawfully sold after that date, although the patent holder will be entitled to receive a reasonable royalty following the issuance of the patent in India).
  26. Eric Goemaere et al., Letter to the Editor, *Patent Status Matters*, 23 HEALTH AFF. 279, 279 (2004), available at <http://content.healthaffairs.org/cgi/content/full/23/5/279-a>.

because these new drugs will generally be subject to patent protection and priced accordingly.

Because membership in the WTO meant conforming to its patent policies, country representatives repeatedly voiced concerns regarding access to medicines.<sup>27</sup> In 2001, these concerns culminated in the issuance of the Doha Declaration, a statement by the WTO Ministerial Conference recognizing both the importance of intellectual property to the development of new medicines, as well as “the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.”<sup>28</sup> As a result of the Doha Declaration and its related deliberations, the developing country members, led by Brazil and India, effectively negotiated for flexibilities within the TRIPS regime beyond those that it already contained.<sup>29</sup> For example, there were already instruments within TRIPS that national governments could utilize to ensure a supply of affordable medication, including most notably the compulsory licensing provisions of TRIPS Article 31.<sup>30</sup> The 2003 Doha Implementation Decision addressed the inability of compulsory licenses to serve the needs of developing countries that did not themselves have sufficient manufacturing capacity by allowing third countries (such as India) to issue compulsory licenses to export to these countries.<sup>31</sup>

The compulsory license is an important tool that can protect the public from patent holders who refuse to license or sell their products on reasonable terms.<sup>32</sup> Under the terms of the TRIPS Agreement as modified by the 2003 Doha Implementation Decision, governments may issue compulsory licenses to permit government or third-party manufacture of a patented invention without the patent holder’s permission, so long as certain conditions are met.<sup>33</sup> Governments may choose to issue them, for

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27. Jayashree Watal, *Access to Essential Medicines in Developing Countries: Does the WTO TRIPS Agreement Hinder It?* 2 (Harvard Univ. Ctr. for Int’l Dev., Discussion Paper No. 8, 2000), available at <http://www.cid.harvard.edu/archive/biotech/papers/discussion8.pdf>.
  28. World Trade Organization, Ministerial Declaration of 20 Nov. 2001, WT/MN(01)/DEC/2 [hereinafter 2001 Doha Declaration].
  29. See Decision of the General Council, *Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, WT/L/540 (Sept. 1, 2003) [hereinafter 2003 Doha Implementation]; see also Watal, *supra* note 27, at 3.
  30. TRIPS art. 31 (“Other Use Without Authorization of Rights Holder”); see also TRIPS art. 30 (“Exceptions to Rights Conferred”).
  31. 2003 Doha Implementation.
  32. Stephen Barnes, Note, *Pharmaceutical Patents and TRIPS: A Comparison of India and South Africa*, 91 KY. L.J. 911, 922 (2003).
  33. TRIPS art. 31; see generally Roger Kampf & Hannu Wager, *The Role of the TRIPS Agreement in Global Health Policy*, STAN. J.L. SCI. & POL’Y 17, 22 (2011).



example, if patent owners offer their inventions at a price too high for potential buyers to afford,<sup>34</sup> so long as the proposed user has made efforts to obtain a voluntary license, the license is issued for public non-commercial use, or there is a national emergency.<sup>35</sup> Generic companies can then produce the patented product and offer it to the public at affordable cost.<sup>36</sup>

Even under a compulsory license, however, the patent holder must be paid a reasonable royalty under the terms of the TRIPS Agreement.<sup>37</sup> In this sense, government-issued compulsory licenses are not altogether different from the government-imposed price controls on drugs that prevail in most of the world's developed countries.<sup>38</sup> Both serve to substantially limit the profit a patent holder can earn. Thus, attention-grabbing references to compulsory licenses as the “nuclear option”<sup>39</sup> are significantly overstated.

Well-known commentators on access to essential medicines issues, such as Jamie Love and Carlos Correa, consider compulsory licenses to be effective tools that place reasonable limits on patent rights,<sup>40</sup> and developing-country governments have demonstrated their potency in practice. For example, Brazil effectively and consistently manages to control the costs of ARV drugs by threatening to issue compulsory licenses under the terms of the TRIPS Agreement.<sup>41</sup> As a result of such maneuvering, the average cost per individual per day of ARV treatment decreased by 65 percent for one drug and 59 percent for another—a

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34. Cf. Jessica J. Fayerman, *The Spirit of TRIPS and the Importation of Medicines Made Under Compulsory License After the August 2003 TRIPS Council Agreement*, 25 NW. J. INT'L L. & BUS. 257, 260 (2005).

35. TRIPS art. 31(b).

36. See *id.*

37. TRIPS art. 31(h).

38. U.S. DEP'T OF COMMERCE: INT'L TRADE ADMIN., PHARMACEUTICAL PRICE CONTROLS IN OECD COUNTRIES: IMPLICATIONS FOR U.S. CONSUMERS, PRICING, RESEARCH AND DEVELOPMENT, AND INNOVATION viii (2004), <http://www.ita.doc.gov/td/chemicals/drugpricingstudy.pdf> (noting that all eleven OECD countries studied imposed some form of price control).

39. See, e.g., *Corrupted: Brazil's Corruption Scandal May Deal a Blow to Intellectual-Property Rights*, ECONOMIST, July 22, 2005, at 61.

40. See generally Carlos Correa, *Intellectual Property Rights and the Use of Compulsory Licenses: Options for Developing Countries* (South Centre, Working Paper No. 5, 1999), available at [http://southcentre.org/index.php?option=com\\_docman&task=doc\\_download&gid=15](http://southcentre.org/index.php?option=com_docman&task=doc_download&gid=15); JAMES LOVE, REMUNERATION GUIDELINES FOR NON-VOLUNTARY USE OF A PATENT ON MEDICAL TECHNOLOGIES 17-18 (2005), available at [http://apps.who.int/iris/bitstream/10665/69199/1/WHO\\_TCM\\_2005.1\\_eng.pdf](http://apps.who.int/iris/bitstream/10665/69199/1/WHO_TCM_2005.1_eng.pdf).

41. See Brent Savoie, Note, *Thailand's Test: Compulsory Licensing in an Era of Epidemicologic Transition*, 48 VA. J. INT'L L. 211, 237-38 (2007).

testament to the effectiveness of the mere availability of compulsory licensing, even if no compulsory license is actually issued.<sup>42</sup>

The main objective of this Article is to critically explore the feasibility of compulsory licensing as a policy tool to facilitate access to essential medicines within the current Indian patent regime in the context of the global political climate. Part I is an examination of both the historical discourse regarding patent law and the implications of the TRIPS regime in India. Part II looks at flexibilities provided within the TRIPS regime vis-à-vis access to drugs. Part III examines the compulsory licensing provision within the 2005 IPA. It evaluates the political dimensions of the issue, discusses proposed amendments to Indian patent law, explores bilateral pressures exerted by developed countries on developing countries with respect to TRIPS flexibilities, and considers Thailand's use of compulsory licensing in 2007. Part IV critically explores the compulsory licensing provision implemented in Canada and the benefit that accrued to that nation's generic drug industry. Part V concludes by discussing the political environment in which the pharmaceutical industry operates.

## I. TRIPS AND ITS IMPLICATIONS FOR INDIAN LAW

To clearly understand the implications of the TRIPS regime on Indian patent law and thus on access to drugs, the nature and history of the Indian patent system must be explored. The Indian Patent Act of 1856, implemented while India was under British rule, remained in effect even after India achieved independence in 1947.<sup>43</sup> The Act provided for patents lasting fourteen years for both processes and products, with extensions as permitted by the Governor General.<sup>44</sup> Even after independence, foreign interests controlled eight of the ten pharmaceutical companies with the largest retail sales in India and possessed 80–90 percent of the patents.<sup>45</sup> To evaluate the impact of the Indian Patent Act of 1856 on the cost of medicines, the Indian government convened two committees in 1970.<sup>46</sup> The committees' recommendations led to a landmark new law—the Indian Patent Act of 1970 (the 1970 IPA).

The 1970 IPA reduced patent rights in a number of ways. It shortened the duration of pharmaceutical process patents to seven years,

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42. *Brazil Wins Fights Over Prices of Merck AIDs Drugs*, N.Y. TIMES, Mar. 29, 2001.

43. Santanu Mukherjee, *The New Indian Patent Law: A Challenge for India*, 1 INT'L J. INTELL. PROP. MGT. 131, 131 (2006).

44. *Id.*

45. PAUL WILSON & AARTHI RAO, INDIA'S ROLE IN GLOBAL HEALTH R&D 47 (2012), available at <http://healthresearchpolicy.org/sites/healthresearchpolicy.org/files/assessments/files/R4D%20-%20Indias%20Role%20in%20Global%20Health%20RD%20Final.pdf>.

46. N.R. AYYANGAR, REPORT ON THE REVISION OF THE PATENTS LAW (1959).

eliminated pharmaceutical product patents, and established automatic compulsory licensing.<sup>47</sup> The 1970 IPA also prohibited patent protection on food and agrochemical products.<sup>48</sup> As a result of these changes, India became one of the most prolific countries in the world with respect to the production of low-cost drugs.<sup>49</sup> The passage of the 1970 IPA made it clear that the Indian government was focused on public health and the expansion of the Indian generic manufacturing industry. By 2004, “India supplie[d] 22 percent of the world’s generic drugs and a significant proportion of the vaccines made for the developing world.”<sup>50</sup>

In 1995, India joined the WTO and, as a condition of its membership, became a signatory to the TRIPS Agreement.<sup>51</sup> As required by TRIPS, India amended its Patent Act on January 1, 2005.<sup>52</sup> The amendments resulted in the extension of patents to microorganisms and pharmaceutical products, the lengthening of the term of patent protection for both products and processes to twenty years, and the introduction of TRIPS-compliant compulsory license provisions that were less generous than the previous law had been.<sup>53</sup>

The changes resulting from the implementation of TRIPS obligations have been criticized as exacerbating difficulties in supplying ARV drugs to people in poor countries<sup>54</sup> and contributing to the prioritization of phar-

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47. See Laura Chung, *Use of Paragraph 6 System for Access to Medicine*, 36 N.C. J. INT’L L. & COM. REG. 137, 144–45 (2010).
  48. The Patents Act, 1970, No. 39, 27 India A.I.R. Manual 450, § 5 [hereinafter Indian Patent Act (1970)].
  49. See Mueller, *supra* note 25, at 514.
  50. CHERI GRACE, A BRIEFING PAPER FOR DFID: UPDATE ON CHINA AND INDIA AND ACCESS TO MEDICINES 8 (2005), available at <http://www.heart-resources.org/wp-content/uploads/2012/09/Update-on-China-an-India-and-Access-to-Medicines.pdf>.
  51. See *Members and Observers*, WORLD TRADE ORG., [http://www.wto.org/english/thewto\\_e/whatis\\_e/tif\\_e/org6\\_e.htm](http://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm) (last visited June 2, 2013) (noting India’s date of membership as “1 January 1995”); Marrakesh Agreement Establishing the World Trade Organization, Apr. 15, 1994, 1867 U.N.T.S. 154, 155, art. II(2) (“The agreements and associated legal instruments included in Annexes 1, 2 and 3 . . . are integral parts of this Agreement, binding on all Members”). Annex 1C contains the TRIPS Agreement. See Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299.
  52. Indian Patent Act (2005), § 1(2).
  53. *Id.* §§ 2(a), 38(a), 55.
  54. SORCHA O’CARROLL, IMPORTING INDIAN GENERIC DRUGS FOLLOWING TRIPS: CASE STUDIES FROM ZAMBIA AND KENYA 1 (2005), available at [http://www.mcmillan.ca/Files/SOCarroll\\_ImportingIndianGenericDrugs.pdf](http://www.mcmillan.ca/Files/SOCarroll_ImportingIndianGenericDrugs.pdf).

maceutical company profits above the legitimate needs of public health.<sup>55</sup> Although not without merit, such criticism of the TRIPS Agreement is overstated. In fact, TRIPS provides significant flexibilities that allow countries to mitigate the potentially harsh effects of pharmaceutical patents.

## II. TRIPS FLEXIBILITIES

A 2001 WTO Ministerial Declaration contemporaneous with the Doha Declaration affirms that “under WTO rules [including TRIPS] no country should be prevented from taking measures for the protection of human . . . health” provided that those measures “are otherwise in accordance with the provisions of the WTO Agreements.”<sup>56</sup> The Doha Declaration itself proclaims that each member has the right to grant compulsory licenses and may freely determine the grounds upon which a compulsory license might be granted.<sup>57</sup> Similarly, each member may determine what constitutes national emergencies and other circumstances of extreme urgency.<sup>58</sup>

The Doha Declaration also notes that, in applying TRIPS, each of its provisions must be read in light of the objectives and purposes of the TRIPS Agreement as reflected in Articles 7 and 8.<sup>59</sup> Article 7 notes that intellectual property rights should be protected and enforced in a manner “conducive to social and economic welfare” and “to a balance of rights and obligations.”<sup>60</sup> Article 8 states that, in formulating or amending national patent legislation, members “may . . . adopt measures necessary to protect public health and nutrition and to promote the public interest in sectors of vital importance . . . .”<sup>61</sup>

The Doha Declaration therefore emphasizes the right—already contained within the TRIPS Agreement<sup>62</sup>—to issue a compulsory license on pharmaceutical products. Although often misunderstood, the issuance of compulsory licenses under the TRIPS Agreement is *not* limited to

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55. See, e.g., Cecilia Oh, *TRIPS and Pharmaceuticals: A Case of Corporate Profits over Public Health*, THIRD WORLD NETWORK, <http://www.twinside.org.sg/title/twr120a.htm> (last visited June 1, 2013).
56. World Trade Organization, Ministerial Declaration of 14 Nov. 2001, WT/MIN(01)/DEC/1 [hereinafter Ministerial Declaration].
57. 2001 Doha Declaration, ¶ 5(b); see also Alberto do Amaral Junior, *Compulsory Licensing and Access to Medicine in Developing Countries*, YALE L. SCH. 7 (2005), [http://www.law.yale.edu/documents/pdf/Compulsory\\_Licensing.pdf](http://www.law.yale.edu/documents/pdf/Compulsory_Licensing.pdf).
58. 2001 Doha Declaration, ¶ 5(c).
59. Ministerial Declaration, ¶ 19.
60. TRIPS art. 7.
61. *Id.* art. 8.
62. *Id.* art. 31.

cases of national emergency, nor was it so limited prior to the Doha Declaration. Under the TRIPS Agreement, interested parties must normally first request a license from the patent holder.<sup>63</sup> TRIPS merely provides that this obligation to first negotiate in good faith with the patent holder is inapplicable in the case of national emergency.<sup>64</sup> Stated differently, members are free to issue compulsory licenses even if there is no national emergency, so long as they first make efforts to obtain a voluntary license from the patent holder. In addition, the TRIPS Agreement allows members to issue compulsory licenses for public non-commercial use (e.g., government-funded health care programs) where there is no national emergency even if they have not previously negotiated with the patent holder.<sup>65</sup> Despite the attention that has been cast upon it, the Doha Declaration merely adds that “[e]ach member has the right to determine what constitutes a national emergency.”<sup>66</sup> This clarification is of modest importance, however, given that a national emergency is not a prerequisite to the grant of a compulsory license. In short, Article 31 of TRIPS details a number of grounds for the grant of compulsory licenses (not all mentioned here) but provides WTO members with substantial freedom to determine when and to whom compulsory licenses can be issued.<sup>67</sup>

Interestingly, TRIPS does not use the term “compulsory licensing.” Instead, Article 31 refers broadly to “use without authorization of the right holder” and includes use both by third parties and by the government.<sup>68</sup> In specifying the conditions for the grant of compulsory licenses, Article 31 refers to five possible grounds for granting them: (1) cases of refusal to deal; (2) situations of national emergency and extreme urgency; (3) as a remedy for anti-competitive practices; (4) public non-commercial use; and (5) to facilitate use of dependent patents.<sup>69</sup> In addition, Article 5(2) of the Paris Convention, a separate treaty negotiated in 1883, provides that “[e]ach country of the Union shall have the right to take legislative measures providing for the grant of compulsory licenses to prevent the abuses which might result from the exercise of the exclusive

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

64. *Id.*

65. *Id.*

66. World Trade Organization, Declaration on the TRIPS Agreement and Public Health, WT/MIN(01)/DEC/2 (2001).

67. *Id.*

68. Sumana Chatterjee, Flexibilities Under Trips [Compulsory Licensing]: The Pharmaceutical Industry in India and Canada 6 (June 14, 2007) (unpublished manuscript), available at <http://ssrn.com/abstract=1025386>.

69. TRIPS art. 31. “Dependent” patents are those that build from, and potentially infringe on, an underlying patent; the underlying patent is known as a “blocking patent” because, absent a compulsory license, it may block use of the dependent patent.

rights conferred by the patent, for example, failure to work.”<sup>70</sup> Much of the Paris Convention, including Article 5(2), is incorporated by reference into the TRIPS Agreement, making its provisions binding on WTO member countries.<sup>71</sup>

Unfortunately, while provisions exist for national governments to use tools such as compulsory licensing, it may not be politically or economically feasible to exercise such options. The United Nations Development Program’s 2001 Human Development Report found that “pressure from Europe and the United States makes many developing countries fear that they will lose foreign direct investment if they legislate for or use compulsory licences.”<sup>72</sup> Given the importance of bilateral and international trade relationships in today’s globalized world, countries like India are pressured politically and economically to limit the use of compulsory licensing outside of national emergencies. This helps to explain the emphasis placed on the Doha Declaration’s reference to national emergencies despite the literal meaning of the text.

### III. COMPULSORY LICENSING UNDER THE INDIAN PATENTS (AMENDMENT) ACT OF 2005

Chapter XVI of the 2005 Indian Patents (Amendment) Act (2005 IPA) discusses compulsory licenses.<sup>73</sup> Section 84 of the 2005 IPA provides for compulsory licenses to make way for access to drugs.<sup>74</sup> Under both the 1970 and 2005 IPAs, any person can make an application for a grant of a compulsory license for a patent three years after grant of that patent.<sup>75</sup> Among the grounds on which an application for compulsory license may be made include: (a) if the public deems the patented invention to be unsatisfactory; (b) if the public cannot access patented inventions at a reasonable price; and (c) if the patented invention is being worked outside

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70. Paris Convention for the Protection of Industrial Property, art. 5(A)(2), Mar. 20, 1883, *last revised* July 14, 1967, 21 U.S.T. 1583, 828 U.N.T.S. 305.

71. TRIPS art. 2(1).

72. CHERI GRACE, THE EFFECT OF CHANGING INTELLECTUAL PROPERTY ON PHARMACEUTICAL INDUSTRY PROSPECTS IN INDIA AND CHINA: CONSIDERATIONS FOR ACCESS TO MEDICINES 35 (2004), *available at* <http://www.who.int/hiv/amds/Grace2China.pdf> (quoting SAKIKO FUKUDA-PARR ET AL., UNITED NATIONS DEVELOPMENT PROGRAMME, HUMAN DEVELOPMENT REPORT 2001: MAKING NEW TECHNOLOGIES WORK FOR HUMAN DEVELOPMENT 107 (Bruce Ross-Larson & Justin Leites eds., 2001)).

73. FERAZ ALI KHADER, THE LAW OF PATENTS WITH A SPECIAL FOCUS ON PHARMACEUTICALS IN INDIA 717 (2007).

74. *Id.*

75. Indian Patent Act (1970), § 84; *see also* Indian Patent Act (2005), § 52 (retaining the three-year period).

the territory of India.<sup>76</sup> Subsection 6 of Section 84 provides that the Controller, an official appointed by the Ministry of Commerce, shall consider a number of factors when evaluating an application under Section 84.<sup>77</sup> These include the nature of the invention, the ability of the applicant to work the invention to the public advantage, the capacity of the applicant to undertake the risk in providing capital and working the invention if the application were granted, and whether the applicant has made efforts to obtain a license from the patentee on reasonable terms and conditions.<sup>78</sup> Notably, Section 90 of the 2005 IPA also empowers the Controller to set the terms and conditions for compulsory licenses.<sup>79</sup> As is evident from these provisions, the grant of compulsory licenses is perforated with technical indulgences and is administratively cumbersome.

Under Section 84 of the Patent Act, an individual may submit an application for a compulsory license to the Controller of Patents only after the expiration of three years from the date the patent was granted.<sup>80</sup> If the reasonable expectations of the public with respect to access to the patented medication remain unfulfilled or the medication is not fairly priced, anyone may apply to the Controller for a compulsory license following the three-year period.<sup>81</sup>

Concerns regarding this three-year lock-in period were raised by a number of stakeholders during interviews conducted by one of this Article's authors to assess different perspectives on the use of compulsory licensing. The semi-structured interviews were conducted between 2008 and 2010 in New Delhi, India, with experts from three sections: academia, civil society groups, and government policy makers. Interviewees from non-governmental organizations (NGOs) and academia were especially concerned. For example, Mr. Gopakumar of the Center for Trade and Development, an Indian NGO working on the issue of access to essential medicines, argued that Indian patent law needs substantial amendments so that it is easier to administer.<sup>82</sup> Another expert, Mr. P. Chan, in the Lawyers Collective, another Indian NGO concerned with human rights issues such as access to drugs, stated that although Indian patent law remains the best law among the developing countries, the three-year

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76. KHADER, *supra* note 73, at 717.

77. *Id.*

78. SHAIL JAIN & R.K. JAIN, PATENTS: PROCEDURES AND PRACTICES 96 (2011).

79. KHADER, *supra* note 73, at 722.

80. *Id.*

81. *Id.*

82. Interview with K. M. Gopakumar, Research Officer, Ctr. for Trade & Dev., in New Delhi, India (July 2008).

lock-in period is a cause for concern, and there is an urgent need for legislative reforms.<sup>83</sup>

People living with HIV/AIDS are increasingly developing resistance to first-generation ARV drugs. They will therefore need to start taking second- and third-generation drugs, most of which will still be patented. An exclusive right to these drugs for three years can result in a prolonged lack of access to proper medication.

In addition to the automatic three-year delay, Section 84 also requires that the person applying for a compulsory license set out the nature of that person's interest,<sup>84</sup> and a separate provision provides an opportunity for the patent holder to oppose the application.<sup>85</sup> Applications for compulsory licenses can be significantly delayed during these opposition proceedings, thereby limiting the effectiveness of this provision. In considering the merits of an application, the Controller takes into account factors such as the nature of invention, the time elapsed, the applicant's efforts in obtaining a voluntary license, the rate of royalty, etc.<sup>86</sup> These factors may further complicate and delay the process.<sup>87</sup> When disputes occur, litigation during the compulsory licensing process may further delay the accessibility of drugs. For example, in the 1978 case of *Imperial Chemical Industries Ltd. v. Controller General of Patents, Designs and Trade Marks*,<sup>88</sup> the delay was so extreme that the case was closed because the patent expired before the dispute could be resolved.<sup>89</sup> Similar delays could occur under the current patent provisions.

To ensure an effective, speedy solution to the problem of access to essential medicines, the Indian Government should consider amending the current compulsory licensing provisions. First, it should eliminate the three-year waiting period before an application can be made for any ARV drug. Under the current regime, patients with serious diseases may die before an application for a compulsory license is even filed. Second, with regard to essential medicines, a priority review process should be made available to speed along the processing of applications once they have been filed. Third, a specific protocol and time period should be established with respect to negotiations for voluntary licenses. The TRIPS Agreement requires that (except in certain cases such as "national emergency" or "public non-commercial use") a compulsory license cannot

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83. Interview with Mr. P. Chan, Lawyers Collective, in New Delhi, India (July 2008).

84. Indian Patent Act (1970), § 84(3).

85. *Id.* § 92(2).

86. JAIN & JAIN, *supra* note 78, at 96.

87. See Shamnad Basheer, *India's Tryst with TRIPS*, 1 INDIAN J.L. & TECH. 15, 27 (2005).

88. See generally A.I.R. 1978 Cal. 77 (India).

89. *Id.* ¶ 14.



be issued until negotiations for voluntary licenses have proven unsuccessful for more than “a reasonable period of time.”<sup>90</sup> The uncertainty created by this vague requirement was reduced by the 2005 IPA, which specifies that six months “shall be construed” as a reasonable period of time.<sup>91</sup> A shorter provision, however, would be preferable, such as the thirty-day period provided in Canadian patent legislation.<sup>92</sup>

Many proponents of patenting argue that patents represent one of the most important incentives for commercial enterprises to undertake research and development by allowing them to enjoy financial returns based on the patent’s teachings.<sup>93</sup> Thus, the three-year period allows the inventor at least some minimal amount of time to commercialize the invention, recover the investment, and make a profit. Proponents may further point out that in some cases it can take three years or more following the grant of a patent to obtain regulatory approval in a country such as India. During that time, the patent holder would not be able to profit from its invention. The three-year waiting period would thus make no difference even if a compulsory license was issued because the drug could still not be sold until approved by the health authorities. However, in those cases where a drug is approved prior to end of the three-year waiting period, it may be inappropriate to make desperate patients wait.

HIV/AIDS is somewhat unusual in that it remains one of the few diseases common to both the developed and the developing world. Therefore, it is not inconceivable that pharmaceutical companies that produce ARV drugs can recoup their investment via sales to the developed world and accept smaller profits from sales to the developing world, such as those generated by the remuneration required by TRIPS in the case of compulsory licenses. A compulsory license does not negate all profits for the patent holder. Although royalty rates may be set at low levels, these rates may apply to vast quantities purchased by governments as part of public health programs. This can result in sizeable profits for the patent holder, even if those profits would be less than the patent holder might obtain by charging a very high price but only serving the wealthiest fraction of the population. Without affordable prices, the vast majority of the population in India will be unable to buy these drugs, suggesting that profits in developing countries such as India will be relatively small whether or not patents are used to restrict output. According to Harvard University Professor F.M. Scherer, if developing countries do not offer patent protection and allow generic

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90. TRIPS art. 31(b).

91. Indian Patent Act (2005), § 52(b).

92. Patent Act, R.S.C., 1985, c. P-4, § 21.04(3)(c) (Can.).

93. See, e.g., Jorge A. Goldstein & Elina Golod, *Human Gene Patents*, 77 ACAD. MED. 1315, 1323–24 (2002).

competition on pharmaceutical products, the aggregate gain to consumers living in the poor countries is likely to be much more than the loss to pharmaceutical companies.<sup>94</sup>

The various conditions imposed for the issuance of a compulsory license by the Controller should also be simplified or clarified. For example, the term “reasonable royalty” should be defined and not merely left to the unfettered discretion of the Controller General. Negotiations that take place in the absence of a clear framework for determining a royalty rate can unnecessarily delay the grant of a compulsory license. To combat needless delay, the law should provide for a shorter time period for the Controller to make a decision, including resolution of matters such as the nature of the invention and efforts to obtain the license. A reasonable period might be borrowed from Canadian patent law, which requires issuance of a compulsory license if negotiations do not lead to a voluntary license within thirty days.<sup>95</sup> Furthermore, the royalty rate could be fixed at a reasonable percentage as was done in Canada during legislative reforms, where the royalty rate was fixed at 4 percent.<sup>96</sup>

Due to the ambiguities and administrative irregularities just discussed, the compulsory licensing provisions of the Indian Patent Act lack efficacy. It is therefore no surprise that India did not issue its first compulsory license to a generic drug manufacturer until 2012,<sup>97</sup> seven years after the 2005 IPA was enacted. The drug, Nexavar (sorafenib tosylate), is widely used to treat kidney and liver cancer.<sup>98</sup> It was developed and patented by Bayer and received FDA approval in 2005<sup>99</sup> with Bayer receiving rights to market the drug in India in 2007.<sup>100</sup>

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94. See F.M. Scherer, *A Note on Global Welfare in Pharmaceutical Patenting*, 27 WORLD ECON. 1127, 1141 (2004).
  95. See Ashley Weber & Lisa Mills, *A One-Time Only Combination: Emergency Medicine Exports Under Canada's Access to Medicines Regime*, 12 HEALTH & HUM. RTS. IN PRAC. 109, 115 (2010).
  96. Paul K. Gorecki & Ida Henderson, *Compulsory Patent Licensing of Drugs in Canada: A Comment on the Debate*, 7 CAN. PUB. POL'Y—ANALYSE DE POLITIQUES 559, 560 (1981).
  97. *Access to Medicines: India Offers First Compulsory License*, MEDECINS SANS FRONTIERES (Mar. 12, 2012), <http://www.doctorswithoutborders.org/press/release.cfm?id=5816&cat=press-release>.
  98. Maricel Estavillo, *India Grants First Compulsory Licence, For Bayer Cancer Drug*, INTELL. PROP. WATCH (Mar. 12, 2012), <http://www.ip-watch.org/2012/03/12/india-grants-first-compulsory-licence-for-bayer-cancer-drug/>.
  99. *Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations*, FDA, [http://www.accessdata.fda.gov/scripts/cder/ob/docs/obdetail.cfm?Appl\\_No=021923&TABLE1=OB\\_Rx](http://www.accessdata.fda.gov/scripts/cder/ob/docs/obdetail.cfm?Appl_No=021923&TABLE1=OB_Rx) (last visited May 25, 2013).
  100. Estavillo, *supra* note 98.

However, despite obtaining exclusive rights over the Indian market, Bayer did not import the drug to India at all in 2008 and imported only very small quantities in the following two years.<sup>101</sup> As a result, the Indian generic drug manufacturing corporation Natco Pharma Ltd. applied to the Controller for a compulsory license.<sup>102</sup> The justification for application fell within Section 84(1) of the IPA—that the reasonable needs of the public with respect to the patented invention had not been met.

In a March 2012 decision, the Controller for the first time granted a compulsory license to a third party (Natco) to manufacture and sell a patented drug (Nexavar) within the Indian market.<sup>103</sup> As a result of this compulsory license, the same drug can now be sold at one-tenth of the original price in the Indian market.<sup>104</sup>

Bayer appealed the decision of the Controller on grounds that the corporation should have been given more time to “work” the patent in India even though the three-year period during which a compulsory license cannot be issued had already passed.<sup>105</sup> Bayer received rights to market the drug in India in 2007, and Natco did not apply for a compulsory license until July 2011.<sup>106</sup> Bayer is now appealing the decision in the Intellectual Property Appellate Board in Chennai, India, and hearings began on January 23, 2013.<sup>107</sup> In March 2013, the Intellectual Property Appellate Board allowed the generic version to be on the market.<sup>108</sup> Bayer lost the appeal.<sup>109</sup>

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101. Bayer explained its inaction by pointing to the allegedly infringing activities of Cipla, another Indian generic, which Bayer accused of illegally marketing a similar drug in India without authorization. *Id.*

102. *Id.*

103. *See Client Briefing: Patent Law Series—Compulsory License—A Growing Threat to Patent Holders?*, CLIFFORD CHANCE (May 2012), [http://www.cliffordchance.com/publicationviews/publications/2012/05/client\\_briefing\\_patentlawseriescompulsor.html](http://www.cliffordchance.com/publicationviews/publications/2012/05/client_briefing_patentlawseriescompulsor.html).

104. C.H. Unnikrishnan, *Compulsory Licences May Spur More Voluntary Licensing Deals*, LIVEMINT (Jan. 24, 2013, 11:01 PM), <http://www.livemint.com/Home-Page/f0R9060osU7bENFNwlnx5O/Compulsory-licences-may-spur-more-voluntary-licensing-deals.html>.

105. Ramesh Shankar, *Final Hearings in Bayer’s Appeal Against India’s First-Ever CL on Nexavar to Begin at IPAB Soon*, PHARMABIZ.COM (Jan. 22, 2013, 8:00 AM), <http://www.pharmabiz.com/NewsDetails.aspx?aid=73294&sid=1>.

106. *Id.*

107. *Id.*

108. Selina McKee, *Bayer Loses Appeal in Indian Compulsory Licence Case*, PHARMATIMES (Mar. 5, 2013), [http://www.pharmatimes.com/Article/13-03-05/Bayer\\_loses\\_appeal\\_in\\_Indian\\_compulsory\\_licence\\_case.aspx](http://www.pharmatimes.com/Article/13-03-05/Bayer_loses_appeal_in_Indian_compulsory_licence_case.aspx).

109. *Id.*

Perhaps emboldened by the Nexavar license, the government department in charge of intellectual property rights policy making, the Department of Industrial Policy and Promotion, is reportedly considering the issuance of more compulsory licenses to enable local Indian manufacturers to produce generic varieties of three specific anti-cancer drugs:<sup>110</sup> Sprycel (dasatinib), Ixempra (ixabepilone), and Herceptin (trastuzumab), each of which is currently patented by large foreign pharmaceutical companies.<sup>111</sup> Even though no compulsory licenses have been issued yet, the case of Nexavar may have opened the door to more compulsory licenses for lifesaving drugs in the near future.

#### IV. COMPULSORY LICENSING IN CANADA

Although India's recent experience with compulsory licensing has garnered substantial international attention, it is not the first country to implement a flexible pharmaceutical patent regime. Other countries have experimented with similar models, including Canada—which, like India, has a very strong generic drug industry.<sup>112</sup> A compulsory licensing provision has existed in Canada since 1923.<sup>113</sup> When the country was faced with high drug prices in the 1960s, it took subsequent legislative measures to moderate drug pricing. One of these measures was the modification of its compulsory licensing provisions.

In 1969, changes were made to Section 41(4) of the Canadian Patent Act that permitted licenses to be granted for imported drugs that were under patent protection.<sup>114</sup> The Commissioner of Patents set the royalty rate at 4 percent.<sup>115</sup> As a result of this legislative change, 290 licenses were issued for sixty-two drugs between 1969 and 1982.<sup>116</sup> It was during this period that the generic pharmaceutical industry in Canada developed and flourished.<sup>117</sup> In 1983, the Ministry of Consumer and Corporate affairs

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110. Unnikrishnan, *supra* note 104.

111. *Id.*

112. Benjamin P. Liu, *Fighting Poison with Poison? The Chinese Experiment with Pharmaceutical Patent Linkage*, 11 J. MARSHALL REV. INTELL. PROP. L. 623, 658–59 (2012); *see also* Ron A. Bouchard et al., *Structure Function Analysis of Global Pharmaceutical Linkage Regulations*, 12 MINN. J.L. SCI. & TECH. 391, 408–09 (2011) (noting arguments that Canada's substantial generics industry has been adversely affected by "patent linkage" provisions).

113. James J. McRae & Francis Tapon, *Compulsory Licensing as a Policy Instrument*, 10(1) CAN. PUB. POL'Y-ANALYSE DE POLITIQUES 74, 76 (1984).

114. Gorecki & Henderson, *supra* note 96, at 560.

115. *Id.*

116. Paul K. Gorecki, *Changing Canada's Drug Patent Law: The Minister's Proposals*, 10(1) CAN. PUB. POL'Y-ANALYSE DE POLITIQUES 77, 78 (1984).

117. *Id.*

released a report stating that the steady use of compulsory licensing for drugs in Canada had significantly reduced drug prices.<sup>118</sup> It further contained statistics suggesting that the use of compulsory licensing had not adversely affected manufacturing or investment in research and development (R&D).<sup>119</sup>

In response to this report, a number of briefs were submitted to the government. Among the briefs was that of the Pharmaceutical Manufacturers Association of Canada (PMAC), the trade association of the Canadian research-based pharmaceutical industry.<sup>120</sup> Predictably, PMAC argued that compulsory licensing had adversely affected the level of R&D<sup>121</sup> but had not led to price reductions at the consumer level.<sup>122</sup> Although the PMAC's position may come as no surprise given its interest in opposing compulsory licenses for patented drugs, it should be emphasized that whether compulsory license legislation advances the interests of "the pharmaceutical industry" depends on which part of the industry one considers—the generics industry or the research-based industry. In addition, although the importance of preserving incentives is one of the main arguments put forth by the research-based pharmaceutical industry, a number of other factors may be far more important in promoting innovation. The need to create new products and more efficient production methods is important in any industry, and even very old industries continue to innovate irrespective of the availability of patent protection. With respect to human disease, scientists at government institutions and universities will continue to search for effective treatments for reasons of tenure, status, benevolence, personal challenge, and career advancement. Although universities are unlikely to be able to fund the clinical trials necessary to bring drugs to market, governments can step in when the need is compelling.

Tax incentives can also be a tremendous motivation to engage in R&D. According to Paul K. Gorecki and Ida Henderson, the research-based industry responded positively to tax incentive schemes of the

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118. See DONALD M. CAMERON, CAMERON'S PATENT AND TRADE SECRETS LAW 9-2 (2012), available at <http://www.jurisdiction.com/patweb09.pdf> (stating that the Minister of Consumer and Corporate affairs called for a review of the Canadian compulsory licensing regime in 1983); *Reality Check: Analysis of the CGPA's Economic Impact Assessment of Proposed Pharmaceutical IP Provisions*, RX&D 7 (Mar. 31, 2011), [http://www.canadapharma.org/CMFiles/Media%20Centre/News%20Releases%20and%20Statements/2011/EN/March31\\_2011\\_RealityCheck\\_CGPA\\_Report\\_Analysis\\_FinalEN.pdf](http://www.canadapharma.org/CMFiles/Media%20Centre/News%20Releases%20and%20Statements/2011/EN/March31_2011_RealityCheck_CGPA_Report_Analysis_FinalEN.pdf).

119. See Gorecki, *supra* note 116, at 78.

120. *Our History, CANADA'S RESEARCH-BASED PHARMACEUTICAL COMPANIES*, <http://www.canadapharma.org/en/about-rxd/corporate-information/our-history> (last visited June 6, 2013).

121. Gorecki & Henderson, *supra* note 96, at 564.

122. *Id.* at 561.

governments of Puerto Rico and Ireland in the 1970s.<sup>123</sup> They point out that R&D in Canada in 1980 was greater than it was in 1969, a decade after the enactment of the compulsory licensing amendments.<sup>124</sup> In the United States, the tax incentives of the Orphan Drug Act<sup>125</sup> have been an important spur to innovation in the area of rare diseases.<sup>126</sup>

With a view to increasing investment in the pharmaceutical sector, bringing the Canadian Patent Act into consonance with international practices,<sup>127</sup> and preparing Canada for entrance into the Canada-US Free Trade Agreement of 1987,<sup>128</sup> the Act was amended in 1987. The amended law included a grandfather provision that left intact those compulsory licenses granted prior to June 27, 1986, so long as a Notice of Compliance had also been obtained by the licensee prior to this date.<sup>129</sup> The Notice of Compliance is analogous to FDA approval in that it is an authorization of government health authorities that a drug may be sold, in light of established efficacy and safety.<sup>130</sup> For drugs receiving a Notice of Compliance after 1986, patentees were entitled to an exclusivity period of at least seven years from the date of notice during which time no compulsory license could be asserted.<sup>131</sup> Furthermore, companies holding patents to any new drug that was invented and developed in Canada may apply to the Commissioner of Patents to acquire a special status that affords protection to the drug for the term of the patent.<sup>132</sup> First,

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123. *Id.* at 563.

124. *Id.* at 564.

125. 26 U.S.C. § 45C (2012).

126. See Michael J. Malinowski & Grant G. Guatreaux, *All That Is Gold Does Not Glitter in Human Clinical Research: A Law-Policy Proposal to Brighten the Global “Gold Standard” for Drug Research and Development*, 45 CORNELL INT’L L.J. 185, 202 (2012).

127. Thierry Orhlac, *The New Canadian Pharmaceutical Compulsory Licensing Provisions*, LEGER ROBIC RICHARD 5 (1990), <http://www.robic.ca/admin/pdf/514/167E-TO.pdf>; see also Lars Noah, *NAFTA’s Impact on the Trade in Pharmaceuticals*, 33 HOUS. L. REV. 1293, 1300 n.28 (1997); KRISTEN DOUGLAS & CÉLIA JUTRAS, LIBRARY OF PARLIAMENT, PATENT PROTECTION FOR PHARMACEUTICAL PRODUCTS IN CANADA – CHRONOLOGY OF SIGNIFICANT EVENTS 2 (2008), available at <http://www.parl.gc.ca/content/LOP/ResearchPublications/prb9946-e.pdf>.

128. See Christopher Scott Harrison, Comment, *Protection of Pharmaceuticals as Foreign Policy: The Canada-U.S. Trade Agreement and Bill C-22 Versus the North American Free Trade Agreement and Bill C-91*, 26 N.C. J. INT’L L. & COM. REG. 457, 518 (2001) (“No matter how much the Conservatives tried to distance Bill C-22 from the free trade talks, the connection between the two was inescapable.”).

129. Orhlac, *supra* note 127, at 6.

130. *Id.*

131. *Id.* at 7; Harrison, *supra* note 128, at 515.

132. Orhlac, *supra* note 127, at 9.

for drugs having this status, no compulsory license for the import (as distinct from domestic manufacture) can be issued during the entire term of the patent.<sup>133</sup> Second, licenses for domestic manufacture can be granted only after seven years have elapsed from the Notice of Compliance and then only if existing sources of supply do not adequately provide for the needs of the Canadian market.<sup>134</sup>

In 1993, the negotiation of the North American Free Trade Agreement presented an opportunity to again adjust Canada's system of compulsory licensing of pharmaceuticals. In February 1993, the Canadian parliament passed Bill C-91, abolishing compulsory licensing for pharmaceuticals and simultaneously extending the period of patent protection to twenty years.<sup>135</sup> This brought Canadian legislation in line with the then-forthcoming requirements of TRIPS, which was agreed to the following year.

After twenty years of legislative changes to promote R&D investment, there was nevertheless limited growth. In 1987, the research-based pharmaceutical industry in Canada committed to investing 10 percent of Canadian sales in R&D.<sup>136</sup> By 2007, however, the brand-name pharmaceutical industry was investing only 8.3 percent.<sup>137</sup> In 2005, Canada had the lowest ratio at 8.3 percent after Italy at 6.8 percent.<sup>138</sup> These figures were much lower than those of the United States<sup>139</sup> and certain European countries.<sup>140</sup> In fact, Apotex, the largest Canadian generic drug company,

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133. *Id.*

134. *Id.*

135. Bohumir Pazderka, *Patent Protection and Pharmaceutical R&D Spending in Canada*, 25 CAN. PUB. POL'Y-ANALYSIS DE POLITIQUES 29, 30 (1999); see also Harrison, *supra* note 128, at 520-21.

136. THE REAL STORY BEHIND BIG PHARMA'S R&D SPENDING IN CANADA, CANADIAN GENERIC PHARM. ASS'N 1 (2008), <http://www.canadiangenerics.ca/en/resources/docs/The%20Real%20Story%20Behind%20Big%20Pharma%27s%20RD%20Spending%20in%20Canada2008.pdf>

137. *Id.*

138. *Id.* at 2.

139. With regard to the United States, the pharmaceutical research and biotechnology enterprises invested a record \$65.3 billion dollars in research and development in 2009, which was more than a \$1.5 billion rise since investment in 2008. Between 2001 and 2010, American pharmaceutical companies consistently spent approximately 18 percent of domestic sales on research and development investments. *R&D Investment by U.S. Biopharmaceutical Companies Remains Strong Despite Ongoing Economic Challenges*, PHARMAMANUFACTURING.COM (Mar. 17, 2010), <http://www.pharmamanufacturing.com/industrynews/2010/057.html>.

140. See *The Pharmaceutical Industry in Figures: Key Data 2012*, EUROPEAN FED'N PHARM. INDUS. & ASS'NS 7, 9, <http://www.efpia.eu/sites/www.efpia.eu/files/EFPIA%20Figures%202012%20Final.pdf> (last visited May 25, 2013).

spends 17.6 percent of the company's sales on R&D and ensures huge savings to the Canadian Health system.<sup>141</sup> It appears, therefore, that the concessions granted to the brand-name companies in Canada by the Patent Act of 1987 may not have resulted in the hoped-for increases in R&D investment.<sup>142</sup>

Proponents of the value of patents in incentivizing R&D investment can point to some promising developments since the enactment of India's new patent laws. Prior to 2005, the pharmaceutical industry was reluctant to invest in India due to its lax patent rules.<sup>143</sup> After 2005, multinational firms like Pfizer, Novartis, GlaxoSmithKline, and AstraZeneca announced higher investment on drug discovery and clinical research in their Indian affiliates.<sup>144</sup> For example, in 2006, Lilly entered into an agreement with an Indian company, Suven Life Sciences, to develop drugs for central nervous system disorders.<sup>145</sup> Moreover, Indian companies have increased their investment in R&D from 1 percent ten years ago to between 6 and 8 percent in 2010.<sup>146</sup>

While these statistics might sound encouraging and seem to justify the implementation of stricter patent laws, they do not tell an important part of the story. Due to a lack of resources, some Indian companies are unable to produce new drugs on their own.<sup>147</sup> Instead, they must often develop new molecules and then license these to multinational companies for clinical developments.<sup>148</sup> As a result, the Indian companies are

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141. *The Real Story Behind Big Pharma's R&D Spending in Canada*, CANADIAN GENERIC PHARM. ASS'N 5 (2008), <http://www.canadiangenerics.ca/en/resources/docs/The%20Real%20Story%20Behind%20Big%20Pharma%27s%20RD%20Spending%20in%20Canada2008.pdf>.

142. *But see* Elizabeth R. Nesbitt, *Pharmaceuticals*, in POTENTIAL IMPACT ON THE U.S. ECONOMY AND SELECTED INDUSTRIES OF THE NORTH AMERICAN FREE-TRADE AGREEMENT 9-1, 9-2 (1993) (noting that "U.S. and foreign investment in the Canadian pharmaceutical industry has increased significantly since 1987, when Canada modified the Canadian Patent Act.").

143. LAURA BLOODGOOD ET AL., COMPETITIVE CONDITIONS FOR FOREIGN DIRECT INVESTMENT IN INDIA 8-1 (2007), available at <http://permanent.access.gpo.gov/lps86859/pub3931.pdf>.

144. D. Rahul Das & Nathan A. Evans, *India's New Patent Regime and Its Impact on the Global Pharmaceutical Industry*, FINNEGAN 5 (Sept. 2007), <http://www.finnegan.com/resources/articles/articlesdetail.aspx?news=24cedda7-28a3-4ac0-b100-ed9974123e67>.

145. *Id.* at 4.

146. *Id.* at 5.

147. *See* SUDIP CHAUDHURI, WORLD HEALTH ORG., R&D FOR DEVELOPMENT OF NEW DRUGS FOR NEGLECTED DISEASES: HOW CAN INDIA CONTRIBUTE 27 (2005), available at <http://www.who.int/intellectualproperty/studies/S.%20Chaudhuri.pdf>.

148. *Id.*



targeting drugs that interest large multinational corporations—at the expense of the development of treatments for tropical diseases.<sup>149</sup> According to Medicines Sans Frontiers, there has been extremely minimal R&D investment in tropical diseases.<sup>150</sup> Without research on these neglected indications, drugs for conditions such as malaria and tuberculosis are unlikely to be developed under the new law, and the acute health problems in India will not be addressed. Even if one assumes that the multinational corporations in partnership with the public sector might decide to develop drugs for tropical diseases, those drugs will be subject to patent protection and hence prohibitively expensive for most of the population in which they are needed. The use of compulsory licensing provisions will therefore be critical for access to drugs within India.

It is apparent that Canada benefitted from a thriving generics industry through compulsory licensing. The generous use of compulsory licensing provisions in the years following 1969 led to a reduction in drug prices.<sup>151</sup> In a similar vein, India could strengthen current flexibilities such as compulsory licensing to the full extent allowed under TRIPS Articles 30 and 31,<sup>152</sup> and thereby help to ensure the effective use of compulsory licensing.

## V. PHARMACEUTICAL INDUSTRY POLITICS

While the establishment of flexibilities is a necessary condition to ensure public health, it is not sufficient standing alone. Political pressure by the United States and European nations, including the threat of trade sanctions, has resulted in very limited usage of compulsory licensing even where national legislation permits it.<sup>153</sup> In some cases, “TRIPS-plus”

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149. Rama Lakshmi, *Foreign Takeovers of Indian Drug Companies Fuel Fear of Rising Prices*, WASH. POST (Mar. 11, 2011), <http://www.washingtonpost.com/wp-dyn/content/article/2011/03/11/AR2011031106335.html> (quoting a government official as stating: “The Indian industry was built to make cheap lifesaving medicines available for its poor. But the foreign takeovers may shift their focus toward exporting to developed nations.”).
150. See Jed Odermatt, *Investigating New Models of Pharmaceutical Innovation to Protect the Human Right to Health*, 40 INT’L REV. INTELL. PROP. & COMPETITION 173, 175 (2009).
151. Allan Z. Litovski, *The Law of Unintended Consequences: How Will the Affordable Prescription Drugs and Medical Inventions Act Affect American Health Care?*, 13 HEALTH L. 20, 21 (2012).
152. See Bryan C. Mercurio, *TRIPS, Patents, and Access to Life-Saving Drugs in the Developing World*, 8 MARQ. INTELL. PROP. L. REV. 217, 219 n.34 (2004) (“Article 30 authorises limited exceptions to patent rights for such things as research, prior user rights, and pre-expiration testing.”).
153. See Joseph E. Stiglitz, *Economic Foundations of Intellectual Property Rights*, 57 DUKE L.J. 1693, 1701 n.22 (2008); Cynthia M. Ho, *Patent Breaking or Balancing?: Separating Strands of Fact from Fiction Under*

provisions in bilateral treaties have limited the extent to which those countries can avail themselves of compulsory licenses or other TRIPS flexibilities.<sup>154</sup> Lobbyists and corporations that exercise political influence further aggravate the situation.

NGOs and academics interviewed between 2008 and 2010 believed that the government of India had not utilized the compulsory license provision of the 2005 IPA out of fear of being sanctioned by the United States, Europe, or Japan, a feeling exacerbated by the events in Thailand in 2007 (discussed below). During the interviews, all stakeholders expressed the view that the United States pressures developing countries to limit the use of compulsory licensing. Although NGOs and academics candidly spoke about their perspectives on this issue, policy makers were more restrained in their views regarding the influence of the United States. Experts like Professor B.K. Keayla,<sup>155</sup> Director of the National Commission on Patent Law, and Amit Sengupta,<sup>156</sup> Director of Delhi Science Forum, noted that the pressure from the United States, Europe, and Japan was considerable. Many interviewees cited the 2007 Thai experience with compulsory licensing as a prime example of US influence. Interviewees opined that the government of India might lack the will to grant a compulsory license as a result of potential sanctions.<sup>157</sup> To understand the adverse impact of bilateral pressures in the post-WTO political climate, it is imperative to comprehend the use of the compulsory licensing provision by Thailand in 2007 and the impact thereafter.

The Thai case study points to the role of the pharmaceutical industry in suppressing the use of compulsory licenses. In 2001, Thailand launched a very successful national drug program that has managed to treat more than 82,000 HIV-positive people.<sup>158</sup> By 2006, Thailand was home to

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*TRIPS*, 34 N.C. J. INT'L L. & COM REG. 371, 378 (2009) (noting that Thailand issued six compulsory licenses despite pressure from the United States and European Union).

154. See, e.g., Henning Grosse Ruse-Khan, *The International Law Relation Between TRIPS and Subsequent TRIPS-Plus Free Trade Agreements: Towards Safeguarding TRIPS Flexibilities?*, 18 J. INTELL. PROP. L. 1, 5 (2011).
155. Interview with Professor B.K. Keayla, Dir., Nat'l Comm'n on Patent Law, in New Delhi, India (July 2009).
156. Interview with Amit Sengupta, Dir., Delhi Sci. Forum, in New Delhi, India (June 2008).
157. *Id.*
158. *Countries Should Find Balance Between Affordable Drugs, Development Incentives*, WHO Director-General Says in Letter to Thai Health Minister, HEALTH WORLD (Feb. 20, 2007, 7:30 PM), <http://healthplanet.wordpress.com/2007/02/20/countries-should-find-balance-between-affordable-drugs-development-incentives-who-director-general-says-in-letter-to-thai-health-minister>.

580,000 people living with HIV/AIDS.<sup>159</sup> As newer, better, and more expensive treatments became available, however, the government program began to experience increasingly high drug costs.<sup>160</sup> To make the newer drugs available to its citizens at a reasonable cost, the Thai Ministry of Health issued compulsory licenses between 2006 and 2007 for two HIV drugs, Sustiva (efavirenz) and Kaletra (a combination of lopinavir and ritonavir).<sup>161</sup> Approximately 20,000 HIV/AIDS patients who developed resistance to conventional drugs relied on Kaletra, placing a severe financial burden on the public health service.<sup>162</sup>

Although Thailand's use of compulsory licenses was consistent with both national law and the TRIPS Agreement, pharmaceutical companies and governments of developed countries vehemently criticized the Thai government.<sup>163</sup> After Thailand issued the Kaletra compulsory license, Abbott withdrew all of its products currently undergoing registration in Thailand and announced that it would refuse to introduce any new products into the Thai market.<sup>164</sup> Six drugs are currently not registered in Thailand, among them an improved version of Kaletra. The response of the US Trade Representative was to place Thailand on its "priority watch list,"<sup>165</sup> a political sanction that has the effect of embarrassing the country against which it is directed.

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159. Sunee Sirivichayakul et al., *HIV Drug Resistance Transmission Threshold Survey in Bangkok, Thailand*, 13 ANTIVIRAL THERAPY, Suppl. 2 109, 109 (2008).

160. THE MINISTRY OF PUBLIC HEALTH & THE NATIONAL HEALTH SECURITY OFFICE OF THAILAND, FACTS AND EVIDENCES ON THE 10 BURNING ISSUES RELATED TO THE GOVERNMENT USE OF PATENTS ON THREE PATENTED ESSENTIAL DRUGS IN THAILAND 2 (2007), available at <http://apps.who.int/medicinedocs/documents/s18718en/s18718en.pdf> (noting a tenfold increase in public ARV spending between 2001 and 2007).

161. *Id.*

162. Piya Wong, *Thailand Backs Off Threat to Break Drug Patents*, SCIDEV (Feb. 8, 2007), <http://www.scidev.net/en/news/thailand-backs-off-threat-to-break-drug-patents.html>.

163. *Id.*

164. See Thomas Fuller, *Thailand Takes on Drug Industry, and May Be Winning*, N.Y. TIMES, Apr. 11, 2007, <http://www.nytimes.com/2007/04/11/world/asia/11iht-pharma.4.5240049.html>; Nicholas Zamiska, *Abbott Escalates Thai Patent Rift: Firm Pulls Plans to Offer New Drugs in Spat with Regime*, WALL ST. J., Mar. 14, 2007, <http://online.wsj.com/article/SB117378109135135324.html>.

165. OFFICE OF THE U.S. TRADE REPRESENTATIVE, 2007 SPECIAL 301 REPORT 27 (2007); see also 19 U.S.C. § 2242 (2012). The report also cited intellectual property violations related to optical disc media, book and software piracy, cable and signal theft, trademarked apparel and footwear. These issues, however, were described as "longstanding concerns," while the recent compulsory licenses were described as reflecting a "weakening of respect for patents." *Id.*

Given the Thai experience, there is uncertainty regarding to what extent the compulsory licensing flexibilities permitted by TRIPS can be effective in the real world. Provisions like compulsory licensing understandably make the pharmaceutical industry nervous. At the same time, it is discomfiting that developing countries using these lawful provisions to save the lives of their citizens are subjected to political pressure.

The Uruguay Round negotiations that eventually led to the creation of the WTO did not originally include discussions of the TRIPS regime.<sup>166</sup> The addition of intellectual property rights to the multilateral trade negotiations resulted from vigorous lobbying by the pharmaceutical industries of the United States, the European Union, and Japan.<sup>167</sup> It was an attempt by the pharmaceutical industry to stop developing countries' generic industries from growing. Additionally, the pharmaceutical industry feared that the manufacturing of cheaper drugs by the generics industry discredited their branded versions. Therefore, the developed world used the TRIPS regime as a political move to undermine the generic industry in the developing nations. More than five years after the 2001 Doha Declaration called upon WTO members to implement TRIPS in a manner supportive of WTO members' right to protect public health and access to medicine, Thailand acted upon that call. Every country that applauded the landmark 2001 Doha Declaration should also show respect for actions that expand access to medicines.

The international community should reevaluate the functioning of the compulsory licensing provisions and their implementation in developing countries, especially in light of the Thai experience. Each of the policy makers interviewed for this Article felt that the Indian government does not lack will, and if the necessity arose, that the Indian government would use the compulsory licensing provision.<sup>168</sup> This belief was partially vindicated by the compulsory license granted by India on Nexavar in 2012. It is pertinent to note, however, that this particular compulsory licensing was not a government-use one. The consequences could have been different for India if a government-use compulsory licensing was issued against a US-based pharmaceutical company as was done in the case of Thailand. At the same time, the individuals working at NGOs or in academia argued that political and economic pressures would continue to stymie the effective use of compulsory licenses in India. In support of their view, they could now point to the fact that only a single compulsory license has been granted since the 2005 legislation was enacted.

The initiative of India's Department of Industrial Policy and Promotion (DIPP) to invite comments on the need for a change in

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166. Robert C. Bird, *Defending Intellectual Property Rights in the BRIC Economies*, 43 AM. BUS. L.J. 317, 322 (2006).

167. *Id.*

168. Interview with Sanjay Kumar, Ministry of Fin., in New Delhi, India (July 2008).

India's compulsory licensing system<sup>169</sup> was a welcome move toward making the system more robust. The release of the DIPP Discussion Paper on compulsory licensing highlights the government's intent to have a meaningful compulsory licensing scheme that facilitates better access to essential drugs both in India and globally. The main objective of the Paper was to solicit views from various stakeholders on effective use of compulsory licensing and "to develop a predictable environment for use of such measures."<sup>170</sup> The DIPP has expressed concern over the availability of low-cost drugs during public health emergencies especially because many Indian pharmaceutical companies have been taken over by foreign companies, and these Indian companies might therefore be reluctant to seek a compulsory license.<sup>171</sup> The Indian government may avail itself of a number of policy tools to combat the crisis, such as more effectively using the existing compulsory license provision, increasing the robustness of that provision, revising policies regarding foreign ownership of Indian pharmaceutical companies, expanding drug price regulation, and invoking the Competition Act of 2002 to gauge whether the adverse drug pricing is due to anti-competitive behavior.<sup>172</sup>

Via the Discussion Paper, the DIPP invited comments from various stakeholders to assess various policy choices, such as whether there should be guidelines that limit the discretion of the Controller when considering a compulsory license<sup>173</sup> and whether the Controller should be required to examine matters of compulsory licensing within a specific time period.<sup>174</sup> The DIPP received twenty-seven response papers from various stakeholders, including twelve from pharmaceutical companies or law firms representing the industry.<sup>175</sup> The US-India Business Council, the Organization of Pharmaceutical Producers in India, and the Japan Pharmaceutical Manufacturer's Association expressed concerns over legislative reforms on compulsory licensing.<sup>176</sup> They argued that such reforms will inhibit and discourage innovation and will not attract foreign direct investment.<sup>177</sup> It is evident from these responses that the

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169. *Discussion Paper: Subject: Compulsory Licensing*, DEP'T OF INDUS. POL'Y & PROMOTION [INDIA], Aug. 24, 2010, available at <http://tinyurl.com/aksumch>.

170. *Id.* at 1.

171. *Id.* at 9–10.

172. *See id.* at 10–11.

173. *Id.* at 21–22.

174. *Id.* at 23.

175. C.H. Unnikrishnan, *Compulsory Licensing: Foreign Lobbies Say Initiative May Discourage FDI*, LIVEMINT, Oct. 2010 (on file with authors).

176. *Id.*

177. *See DIPP Discussion Paper on Compulsory Licensing in the Indian Pharmaceutical Sector: An 'Acquired' Afterthought?*, SPICY INDIA IP (Aug.

pharmaceutical industry has considerable concerns regarding legislative reforms related to compulsory licensing. The Thai case and these responses reflect the strong opposition that exists to implementing compulsory licensing reform.

Even though India has not resorted to using compulsory licensing in the context of ARV drugs, there soon may be a time when it becomes necessary. The above legal and political analyses provide evidence that the implementation of compulsory licensing in its current form may be difficult. The effective use of India's compulsory licensing system can be achieved only after legal ambiguities and cumbersome administrative procedures are clarified and revised. A proactive initiative by policy makers to reform the compulsory licensing scheme is imperative.

The interviews with stakeholders in this Article demonstrate that while the policy makers and government officials are optimistic about the compulsory licensing provision, some of the academics, and especially the NGOs, remain skeptical. The differences in perspective could result from policymakers who view the WTO as a whole and focus on the generous benefits accorded to India in the context of other WTO agreements. However, recent moves by the Indian government are encouraging and may pave the way for broader use of the compulsory licensing provision,<sup>178</sup> notably for ARV drugs.

Civil society and others are particularly skeptical due to the lack of robust legal provisions and the lingering memories from the 2007 events in Thailand. There is growing concern among these groups that the government may not utilize the TRIPS flexibilities when needed because of the fear of trade sanctions from countries like the United States.<sup>179</sup> The compulsory license on Nexavar that was recently issued in India affected a patent held by German drug giant Bayer—not a US pharmaceutical company—and it is important to consider whether the outcome might have been different if the pharmaceutical company had been based in the United States. At the same time, Indian policy makers insist that they would not hesitate to use the compulsory licensing provision if the need arose.<sup>180</sup> This is reassuring in light of the fact that it is this group that will eventually be a part of the body that makes decisions on the use of compulsory licensing in India.

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25, 2010), <http://spicipindia.blogspot.in/2010/08/dipp-discussion-paper-on-compulsory.html>.

178. See, e.g., *Health Ministry Recommends Compulsory Licensing of Three Anti-Cancer Drugs*, PHARMABIZ (May 3, 2013), <http://pharmabiz.com/ArticleDetails.aspx?aid=75138&sid=1>.

179. See *Getting to Zero AIDS-Related Deaths: TRIPS and the Potential Impact of Free Trade Agreements*, UNAIDS (June 1, 2012), <http://www.unaids.org/en/resources/presscentre/featurestories/2012/june/20120601tripsftas>.

180. Interview with Sanjay Kumar, Ministry of Fin., in New Delhi, India (July 2008).

There are some experts like Tahir Amin, co-founder of a nonprofit initiative that seeks to increase access to medicines, who think that compulsory licensing is not a workable provision and that the pre- and post-grant oppositions are a much better remedy.<sup>181</sup> The pre-grant and post-grant opposition provisions, primarily employed to filter out frivolous patents, seem to be very effective and have been recently utilized in numerous cases by civil society members. The Indian Patent Act of 2005 provides for both pre- and post-grant oppositions. A patent can be opposed on a number of grounds both pre- and post-grant, including lack of inventorship, anticipation (including anticipation by indigenous knowledge that is transmitted orally), obviousness, inappropriate subject matter, lack of adequate written description, failure to disclose material information to the patent office, and failure to describe the geographic source of biological material (a requirement designed to combat biopiracy).<sup>182</sup> Post-grant oppositions must be made no later than one year after the patent has been granted.<sup>183</sup>

The availability of opposition proceedings has resulted in a number of pivotal efforts that have successfully enhanced access to treatment in India. The Viramune (nevirapine) syrup opposition case set an important precedent for all future ARV patent oppositions in India. In that case, a pre-grant opposition was filed by HIV/AIDS groups in India challenging the patent application for nevirapine syrup, a pediatric drug used in the treatment of HIV-positive children who are unable to swallow conventional ARV drugs. In June 2008, the Indian Patent Office rejected the patent application of a German pharmaceutical company on both technical and public health grounds, finding that the syrup was merely a new form of a drug invented before 1995 and therefore ineligible for protection.<sup>184</sup> This landmark ruling renewed hope for the ongoing patent oppositions regarding other ARV drugs in India such as Reyataz (atazanavir), Sustiva (efavirenz), Valcyte (valganciclovir), and Viread (tenofovir).<sup>185</sup>

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181. See Corinna Wu, *India Overrides Patent on Cancer Drug*, *CANCER TODAY* (June 27, 2012), <http://www.cancertodaymag.org/Summer2012/Pages/india%20overrides%20patent%20for%20kidney%20and%20liver%20cancer%20drug.aspx> (quoting Tahir Amin on the difficulties of using compulsory licenses); Tahir Amin, *Tahir Amin: Patent Oppositions and Innovative Initiatives to Stimulate R&D*, *YOUTUBE* (July 29, 2012), [http://www.youtube.com/watch?v=Un\\_2p5XYcvA](http://www.youtube.com/watch?v=Un_2p5XYcvA) (discussing the value of oppositions).

182. Indian Patent Act (2005), § 23 (amending Sections 25 and 26 of the 1970 IPA).

183. *Id.*

184. DIPIKA JAIN & RACHEL STEPHENS, *THE STRUGGLE FOR ACCESS TO TREATMENT FOR HIV/AIDS IN INDIA* 119 (Laya Medhini ed., 2008).

185. *Id.*

Despite significant promise, the pre- and post-grant opposition provisions can be used only to prevent (or rescind) patent grants on new drugs. Access to earlier-patented drugs therefore remains an issue. It is also important to note that patent oppositions may not always be successful. Among the recent pre-grant opposition applications filed by the Lawyers Collective in India, at least one has been unsuccessful: a post-grant application filed by Sankalp Trust Roche for Pegasys was rejected by the Indian patent office in 2009.<sup>186</sup> Where oppositions fail, compulsory licenses remain an option. For at least two reasons, compulsory licensing may in any event be preferable. First, because transportation costs raise total costs if drugs must be imported. Drugs manufactured domestically under a compulsory license can substantially reduce costs. Second, compulsory licensing has been used by many countries in the past and is therefore a more familiar process. The United States and Canada have issued the largest number of compulsory licenses in the past,<sup>187</sup> with Canada generously using its compulsory licensing provision prior to the amendments discussed earlier.<sup>188</sup> Therefore, compulsory licensing may be a more promising means of facilitating access to drugs.<sup>189</sup>

There is an urgent need to amend the Indian Patent Act to simplify the administrative procedures and facilitate the issuance of compulsory licenses, including the fixing of a predictable and reasonable royalty. The compulsory licensing provision, if suitably amended, could be a robust provision that ensures access to essential drugs not only within India but also globally. Most of the access-to-treatment regimes of sub-Saharan African countries are heavily dependent on the Indian generics industry. The most elaborate programs to combat HIV/AIDS, such as the US President's Emergency Plan for AIDS Relief,<sup>190</sup> the Clinton Health

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186. *Indian Patent Office Rejects Post-Grant Opposition on Pegasys*, LAWYERS COLLECTIVE, HIV/AIDS UNIT, Apr. 14, 2009, available at <http://lists.essential.org/pipermail/ip-health/2009-April/013647.html>.

187. CARLOS CORREA, INTEGRATING PUBLIC HEALTH CONCERNS INTO PATENT LEGISLATION IN DEVELOPING COUNTRIES 97 n.157 (2000), available at <http://apps.who.int/medicinedocs/pdf/h2963e/h2963e.pdf>. According to Correa, the antitrust laws are responsible for the large number of licenses (not necessarily on pharmaceutical products) granted by the United States. *Id.*

188. Colleen Chien, *Cheap Drugs at What Price to Innovation: Does the Compulsory Licensing of Pharmaceuticals Hurt Innovation?*, 18 BERKELEY TECH. L. J. 853, 876-77 (2003).

189. On the other hand, compulsory licenses must be temporary under TRIPS Article 31(c) & (g), while a successful opposition prevents the patent from issuing or invalidates it permanently.

190. *See generally United States President's Emergency Plan for AIDS Relief*, U.S. DEP'T OF STATE, <http://www.pepfar.gov/> (last visited May 5, 2013).



Access Initiative,<sup>191</sup> and Medicine Sans Frontiers,<sup>192</sup> are all primarily dependent on Indian generics companies for affordable ARV drugs. Policy in India therefore impacts not only Indian citizens but also those living in other developing countries. In such a delicate situation, there is reason to be optimistic that the Indian government's decision to issue compulsory licenses to facilitate access to drugs globally may not be too strongly opposed by other nations such as the United States, which sponsors the largest AIDS relief program in the world and coordinates the importation of 98 percent of the drugs originating in India and destined for twenty-one sub-Saharan African countries.<sup>193</sup> Furthermore, recent changes in the balance of power due to the economic crisis in the West may significantly change the attitudes of developed countries toward growing economic powers such as India and China.

### CONCLUSION

The recent compulsory license granted in India coupled with the experiences of Thailand and Canada demonstrate that compulsory licensing, if used, can be an effective tool to provide access to essential medicines. However, numerous factors, including government will and external pressures, significantly affect the implementation of compulsory licensing regimes. Given existing international and bilateral pressures, compulsory licensing in India can be legally, administratively, and politically challenging.

Although Indian law provides for the issuance of compulsory licenses, the current provisions may be too cumbersome and time consuming for compulsory licensing on recently patented drugs such as second- or third-generation ARV drugs. The experts interviewed in this Article provided mixed views on the sufficiency of compulsory licensing in India. While some experts felt that compulsory licensing could be an effective tool, others were more skeptical.

The Canadian Patent Act provides a model for the use of compulsory licensing in moderating drugs prices and suggests the feasibility of similar changes in India. India must take full advantage of the flexibilities permitted under the TRIPS Agreement in order to realize the goal of providing life-saving health care to its population. To do so, the government must amend the Indian Patent Act so as to create a rapid and efficient process for granting compulsory licenses when necessary. These

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191. See generally *Clinton Health Access Initiative*, CLINTON FOUND., <http://www.clintonfoundation.org/main/our-work/by-initiative/clinton-health-access-initiative/about.html> (last visited May 25, 2013).

192. *About MSF*, MEDECINS SANS FRONTIERES (Dec. 1, 2011), [http://www.msf.org/3/www.msf.org/msf/about-msf/about-msf\\_home.cfm.htm](http://www.msf.org/3/www.msf.org/msf/about-msf/about-msf_home.cfm.htm).

193. *About PEPFAR*, U.S. DEP'T OF STATE, <http://www.pepfar.gov/about/index.htm> (last visited May 25, 2013).

licenses should be granted at standard and transparent royalty rates set by the Commissioner of Patents. The law should also be amended to provide the Commissioner with sensible guidelines to limit the Commissioner's discretion, provide a measure of predictability, and ensure a royalty rate that is both fair to the patent holder and within the financial reach of the licensee. Additional statutory limits are needed to prevent companies from deliberately obstructing the compulsory license process through litigation and delay. Finally, the government should consider issuing compulsory licenses on ARV drugs and other essential medicines with greater frequency to help ensure that these life-saving drugs continue to be priced competitively both in India and throughout the world.