

## THE JEKYLL AND HYDE STORY OF INTERNATIONAL TRADE: THE SUPREME COURT IN *PhRMA V. WALSH* AND THE TRIPS AGREEMENT

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### I. INTRODUCTION

Traditionally, intellectual property (“IP”) protection has been a national issue. International efforts at IP harmonization vested discretion on national governments in imposing standards to protect IP and prevent infringement.<sup>1</sup> Countries used their discretion to standardize IP in a manner that prioritized sovereign national responsibilities.<sup>2</sup> National responsibilities are issues like poverty, health care, and local economic conditions affecting IP implementation by having a stake in development, democracy, and *ordere public*.

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1. See Berne Convention for the Protection of Literary and Artistic Works, Sept. 9, 1886, as last revised July 24, 1971, 25 U.S.T. 1341, 1344, 828 U.N.T.S. 221, 223 [hereinafter Berne Convention]; see also Paris Convention for the Protection of Industrial Property, Mar. 20, 1883, as last revised July 14, 1967, art. 2, 21 U.S.T. 1583, 1631, 828 U.N.T.S. 305, 313 [hereinafter Paris Convention]. The lack of minimum international standards enabled countries to set their own standards of IP protection. For example, under Article 2 of the Paris Convention, countries can have individual levels of IP protection provided the nationals of member states are not discriminated against. *Id.*

2. Under the Paris Convention, countries could extend poor levels of IP protection to the nationals of all member states as long as their nationals were treated just as poorly. Robert Pechman, *Seeking Multilateral Protection for Intellectual Property: The United States “TRIPS” Over Special 301*, 7 MINN. J. GLOBAL TRADE 179, 181–82 (1998).

The Agreement on Trade Related Intellectual Property Rights (“TRIPS”)<sup>3</sup> set a new trend in harmonizing IP laws by introducing enforceable minimum international standards.<sup>4</sup> The enforcement provisions of TRIPS required countries to prioritize international obligations to avoid trade sanctions.<sup>5</sup> The resulting question was: What happens if prioritizing international obligations interferes with fulfilling national responsibilities? At issue, among other things, was the use of compulsory licensing and price control mechanisms by developing nations as tools to make medication accessible to the population.<sup>6</sup> TRIPS signatories questioned the extent to which these tools may be used to balance international trade obligations with their national welfare obligations.<sup>7</sup>

TRIPS implied that compulsory licensing could be used to preserve public health. Article 31 provides the right to compulsory licensing subject to certain conditions.<sup>8</sup> Under Article 27, TRIPS

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

4. *Id.* arts. 15–18. See generally J. H. Reichman, *Compliance with the TRIPS Agreement: Introduction to a Scholarly Debate*, 29 VAND. J. TRANSNAT’L L. 363 (1996).

5. See TRIPS, *supra* note 3, arts. 41–50. TRIPS embodies mandatory enforcement provisions to prevent derogation from the uniform minimum standards.

6. Patrick Marc, *Compulsory Licensing and the South African Medicine Act of 1997: Violation or Compliance of the Trade Related Aspects of Intellectual Property Rights Agreement?*, 21 N.Y.L. SCH. J. INT’L & COMP. L. 109, 121–22 (2001).

7. *Id.*

8. TRIPS, *supra* note 3, art. 31.

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

(a) authorization of such use shall be considered on its individual merits;

(b) such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be waived by a Member in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. In situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable. In the case of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly;

(c) the scope and duration of such use shall be limited to the purpose

advocates a product patent regime which requires all nations, including nations with low per capita income, to embrace expensive patented pharmaceuticals. Except for Article 31, TRIPS lacks alternatives for developing nations to enable marginalized people to access pharmaceuticals.<sup>9</sup> Thus, TRIPS implies that Article 31 provides the option for developing nations to fulfill national responsibilities.

Developed nations, however, challenged all attempts by the developing nations to use the right to compulsorily license patents.<sup>10</sup> Developed nations argued that prioritizing international trade obligations in TRIPS necessitated a level of patent protection that eliminated the option of exercising compulsory licensing and price control mechanisms even under a threat to public health.<sup>11</sup> The developed nations' persistence forced developing nations to compromise on national responsibilities, resulting in a "poverty penalty." The term "poverty penalty" refers to the cost poorer nations suffer from fulfilling international obligations that require prioritizing trade interests to the detriment of welfare.<sup>12</sup> Developing nations uniquely suffered the poverty penalty because, when economic conditions and public health threatened to deteriorate, developed nations practiced both price control and compulsory licensing. For example, an economic crisis within the states moved the Supreme Court of the United States, in *Pharmaceutical Research and Manufacturers of America ("PhRMA") v. Walsh*,<sup>13</sup> to validate indirect price control over pharmaceuticals.<sup>14</sup> The threat

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for which it was authorized, and in the case of semi-conductor technology shall only be for public non-commercial use or to remedy a practice determined after judicial or administrative process to be anti-competitive.

*Id.* Such uses are termed as compulsory licenses.

9. *Id.* art. 27.

10. See, e.g., Marc, *supra* note 6, at 121–22 (highlighting America's opposition to attempts by South Africa to legislate compulsory licensing provisions); see also discussion *infra* Part III.

11. See Marc, *supra* note 6, at 121–22. Developed nations, particularly the United States, disputed all efforts to compulsorily license, even under a public health exigency, and threatened to levy punitive trade sanctions. See, e.g., Sara M. Ford, *Compulsory Licensing Provisions Under the TRIPS Agreement: Balancing Pills and Patents*, 15 AM. U. INT'L L. REV. 941, 953–55 (2000) (discussing the United States' objections to compulsory licensing). See generally Cecilia Oh, *US Opposed to Moves to Address Public-Health Concerns About TRIPS*, Third World Network, at <http://www.twinside.org.sg/title/twr131f.htm> (last visited Mar. 31, 2004).

12. See discussion *infra* Part V.A.–B.

13. 123 S. Ct. 1855 (2003) (to be filed at 538 U.S. 644).

14. *Id.* at 1861–62.

of an anthrax crisis moved the United States and Canada towards compulsory licensing.<sup>15</sup> The poverty penalty has, in effect, undermined the ability of TRIPS to secure equivalent behavior from all parties.<sup>16</sup> It exempts developed nations from fulfilling obligations developing nations are forced to fulfill and thus punishes poor nations for being poor. Contrary to popular belief, the developing nations' loss is not from deviating from the TRIPS commitments, but from attempting to fulfill them.<sup>17</sup> The TRIPS objective of promoting "social and economic welfare"<sup>18</sup> cannot be achieved if the poverty penalty increases from forcing nations to neglect national responsibilities. Developed nations, in refusing to recognize developing nations' national responsibilities, stressed the "mutual interest" that "the commitments of TRIPS" generated.<sup>19</sup>

In articulating that Article 31 vests on the developing nations the right to prioritize national responsibilities, this paper argues that the poverty penalty has affected the legality of the developed nations' arguments and violates the mutual benefit provision in Article 7 of TRIPS.<sup>20</sup> TRIPS embodies "a reciprocal balance of exchange that yields net benefits to all";<sup>21</sup> however, "[i]f one focus[d] not on global economic welfare but on the *economic welfare of developing countries*, by contrast, conventional wisdom holds that the extension of patent protection to developing countries is harmful."<sup>22</sup> In reality, "net benefits to all"<sup>23</sup> and "global

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15. See discussion *infra* Part IV.B.

16. It resulted in TRIPS failing to enable developing nations to transition towards a trade regime without affecting local public health conditions. See discussion *infra* Part V.

17. Alan O. Sykes, *TRIPS, Pharmaceuticals, Developing Countries, and the Doha "Solution,"* 3 CHI. J. INT'L L. 47, 60 (2002) ("The fact that the commitment from which a nation seeks to deviate imposes a loss on that nation is of no moment, for that is always the case when a nation seeks to deviate."). *Id.* at 60.

18. TRIPS, *supra* note 3, art. 7.

19. Sykes, *supra* note 17, at 59–60 (discussing that the effect on welfare is irrelevant in expecting developing nations to fulfill the TRIPS commitments).

20. See *id.*

The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.

TRIPS, *supra* note 3, art. 7.

21. Sykes, *supra* note 17, at 60.

22. *Id.* at 58.

23. *Id.* at 60.

economic welfare”<sup>24</sup> have effectuated benefits only to the developed nations. It has necessitated a scrutiny of the extent to which developing countries ought to be committed to TRIPS because the mutual interest component of the commitment has been lost in the bargain. Without recommending textual amendments, this paper emphasizes the need to accommodate national responsibilities in the operation of TRIPS.

The developed nations’ argument that increased trade would positively impact per capita income and ultimately benefit the marginalized by trickling down does not convincingly account for welfare obligations during the interim period. The increasing marginalization of the poor within developing nations will worsen economic conditions before stabilizing them. Conventional prudence suggests that deteriorating economic conditions cannot serve as a means to improve developing nations over a period of time.

Part II introduces the different perceptions within developed and developing nations over the use of compulsory licensing and price control mechanisms. Part III discusses the developed nations’ objections when developing countries wanted to retain the right to compulsory licensing as a means to fulfill national responsibilities. It also argues that Article 31 supports the developing nations’ position. Part IV discusses how developed nations, under less-threatening circumstances, prioritized national responsibilities and used the same tools they prevented developing nations from using—compulsory licensing and price control mechanisms. Part V demonstrates that the United States’ reactions resulted in the developing nations paying a poverty penalty owing to their dependency on trade with the developed countries. The poverty penalty, quantified as the economic value developing nations lost due to national issues becoming international emergencies, meant to further global trade by benefiting the pharmaceutical industry, instead resulted in an opportunity cost to the industry.<sup>25</sup> Part V also argues that the interests of IP harmonization and the pharmaceutical industry will best be served through eliminating the poverty penalty—taking cognizance of sovereign

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24. *Id.* at 58.

25. Additionally, IP harmonization was affected when public health became a bigger issue and developing nations wanted to derogate from TRIPS’s terms *vide* the Doha Declaration. *See* World Trade Organization, Doha Ministerial Declaration, Nov. 14, 2001, 41 I.L.M. 746 (2002) [hereinafter Doha Declaration].

national responsibility to prevent a public health crisis. Part VI discusses solution options within the TRIPS framework to provide global access to medication. This paper concludes that the legality of the TRIPS provisions will be strengthened by its practical workability to address global issues.

## II. COMPULSORY LICENSING AND PRICE CONTROL MECHANISMS

The monopoly component of a patent consists of the right to prevent competition and to charge a maximum market price. Both compulsory licenses and price controls balance the patent owner's right with the societal need for the product, and operate where public interest concerns outweigh patent holders' rights.<sup>26</sup> Hence, both affect the patentee's monopoly thus representing a compromise between absolute revocation of patents and patentee's absolute property rights over the invention.<sup>27</sup>

Compulsory licenses force the patentee to license the patent to the government.<sup>28</sup> Compulsory licenses, as "involuntary contract[s] between a willing buyer and an unwilling seller imposed and enforced by the state,"<sup>29</sup> affect market exclusivity directly and market price indirectly. Price controls, being government-induced interferences with the market, restrict the maximum market price.<sup>30</sup> Prices can be controlled either directly or indirectly. Direct price control is where the government restricts the market

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26. Rafael V. Baca, *Compulsory Patent Licensing in Mexico in the 1990's: The Aftermath of NAFTA and the 1991 Industrial Property Law*, 35 IDEA 183, 184-85 (1994); see also David J. Henry, *Multi-National Practice in Determining Provisions in Compulsory Patent Licenses*, 11 GEO. WASH. J. INT'L L. & ECON. 325 (1977). See generally Ford, *supra* note 11, at 963-64 (discussing the general beliefs of developing nations in regard to compulsory licensing).

27. Baca, *supra* note 26, at 184. Compulsory licenses allow governments "to compensate for the economic shortcomings associated with not establishing a domestic industrial base when not working an invention within its borders." *Id.* at 187.

28. Ford, *supra* note 11, at 945 ("Compulsory licensing is defined generally as the granting of a license by a government to use a patent without the patent-holder's permission.").

29. Gianna Julian-Arnold, *International Compulsory Licensing: The Rationales and the Reality*, 33 IDEA 349, 349 (1993) (quoting PAUL K. GORECKI, REGULATING THE PRICE OF PRESCRIPTION DRUGS IN CANADA: COMPULSORY LICENSING, PRODUCT SELECTION, AND GOVERNMENT REIMBURSEMENT PROGRAMMES (Economic Council of Canada 1981)).

30. See Mary T. Griffin, *AIDS Drugs & the Pharmaceutical Industry: A Need for Reform*, 17 AM. J.L. & MED. 363, 402 n.260 (discussing the Department of Health and Human Services Reimbursement Board's establishment of price limits at the lowest prices at which the drug is available).

price of a product from exceeding a certain percentage above the cost of production.<sup>31</sup> Indirect price control is where the government uses an incentive, a deterrent, or both to prevent the manufacturer from realizing the highest marginal profit.<sup>32</sup>

The issues of compulsory licensing and price controls hold unique significance in the area of pharmaceuticals. Unlike consumer products, where the elasticity of individual human need may vary with affordability, in the case of pharmaceuticals, the demand for the product is independent of affordability.<sup>33</sup> The effect of cost efficiency on the demand for a medication is minimal due to the continued needs of patients, given the lack of alternatives.<sup>34</sup> In low per capita income markets, like developing countries, increasing the cost reduces affordability, increases the demand for medication as disease conditions worsen and thus raises the need to use tools like compulsory licensing to balance trade with welfare.<sup>35</sup> Thus, differences in economic development have an indirect bearing on the use of compulsory licensing.

In developed nations, the higher per capita income virtually eliminates the need for compulsory licensing except when there is an economic slowdown.<sup>36</sup> Hence the patentees generally enjoy a

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31. For a discussion of the types of direct and indirect restraint placed on drug prices across the world, see generally Michele L. Creech, Comment, *Make a Run for the Border: Why the United States Government Is Looking to the International Market for Affordable Prescription Drugs*, 15 EMORY INT'L L. REV. 593 (2001).

32. *Id.*

33. See Griffin, *supra* note 30, at 367–69 (discussing the unique price and demand aspects of the pharmaceutical market).

34. See *id.* at 370 (“Price competition is an integral part of the free market enterprise system in this country, but not of the pharmaceutical industry.”); *id.* at 372 (explaining how prices tend to increase when no treatment substitutes exist).

35. See Ellen ‘t Hoen, *TRIPS, Pharmaceuticals, Developing Countries, and the Doha “Solution,”* 3 CHI. J. INT'L L. 27, 28–29 (2002); see also David K. Tomar, *A Look into the WTO Pharmaceutical Patent Dispute Between the United States and India*, 17 WIS. INT'L L.J. 579, 583–85, 601 (1999) (discussing India as a specific case study and noting that patent protection will decrease pharmaceutical availability and increase prices because the consumers will bear the cost associated with research and development); Michelle M. Nerozzi, Note, *The Battle over Life-Saving Pharmaceuticals: Are Developing Countries Being “TRIPPed” by Developed Countries?*, 47 VILL. L. REV. 605, 605, 618–19 (2002) (stressing that over eighty-nine percent of the people living in poverty and with HIV/AIDS reside in developing and least developed nations); Nadia Natasha Seeratan, Comment, *The Negative Impact of Intellectual Property Patent Rights on Developing Countries: An Examination of the Indian Pharmaceutical Industry*, 3 SCHOLAR 339, 388 (2001) (stating that TRIPS will result in an increased cost of medication).

36. See Srividhya Ragavan, *Can't We All Just Get Along? The Case for a Workable Patent Model*, 35 ARIZ. ST. L.J. 117, 166 (2003).

total monopoly during the patent term.<sup>37</sup> Patents serve as market incentives enabling patentees to derive maximum economic efficiency irrespective of maximization of consumer welfare. The market incentive component is derived from the contractual nature of patents.<sup>38</sup> That is, the inventor reveals the invention in return for the government's promise of a specified statutory monopoly on the production of the idea.<sup>39</sup> Since competition is curtailed, patent owners charge the highest price that the market can bear, typically far exceeding the marginal cost.<sup>40</sup> Presumably, the increased cost covers the investor's past and future investments on research and development. Consumers, in turn, associate the higher cost for patented products with the privilege of using the invention.<sup>41</sup> Hence developed nations, particularly the United States, believe that patent owners with valuable products will market them and discourage government interference with patent monopolies.<sup>42</sup> Thus, compulsory licenses and price control mechanisms are viewed as disincentives to inventors and patent holders.<sup>43</sup> Generally, the United States does not favor restricting

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37. Comment, *Theft of Trade Secrets: The Need for a Statutory Solution*, 120 U. PA. L. REV. 378, 400 (1972); see also Cole M. Fauver, *Compulsory Patent Licensing in the United States: An Idea Whose Time Has Come*, 8 NW. J. INT'L L. & BUS. 666, 674–76, 681 (1998) (discussing why the United States views compulsory licenses as unnecessary).

38. See Fauver, *supra* note 37, at 680–81.

39. *Id.* at 681.

40. See Mark A. Lemley, *The Economics of Improvement in Intellectual Property Law*, 75 TEX. L. REV. 989, 1065–66 (1997) (noting that “producers will price at marginal cost only if they are forced to by the existence of competition. A producer who controls a market will cut output and raise prices, increasing its profits but reducing both consumer and aggregate social welfare”); see also Griffin, *supra* note 30, at 369.

41. See Lemley, *supra* note 40, at 996 (discussing the privilege issue).

42. See *id.*; see also Fauver, *supra* note 38, at 677–78. Scholars have argued that compulsory licenses are unconstitutional since the grant of the exclusive patent right is unconditional. *Id.* at 678. Others have compared compulsory licenses to government appropriation under the takings jurisdiction, implying that patent rights cannot be restricted by compulsory licenses without just compensation. *Id.*

43. See Joseph A. Yosick, *Compulsory Patent Licensing for Efficient Use of Inventions*, 2001 U. ILL. L. REV. 1275, 1291–92 (2001). For an example of judicial treatment of compulsory licensing, see *Continental Paper Bag Co. v. Eastern Paper Bag Co.*, 210 U.S. 405 (1908), where the Court outlined the traditional American posture on compulsory licensing. In considering whether the rights of a patent owner included the right not to put his inventions to manufacturing use, the Court recognized that exclusivity characterizes the absoluteness of the inventor's property rights. *Id.* at 424. The patent in question, the Liddell patent, related to a paper bag machine. *Id.* at 406. After the patent was issued in 1896, the owner neither manufactured nor licensed the patent. *Id.* at 408. In 1908, the patent owner sued the defendant for infringement for manufacturing the patent. *Id.* at 406. The defendant alleged that the owner of an unused patent was limited in law from alleging infringement. *Id.* at 428.

patent rights, despite a few judicial opinions to the contrary.<sup>44</sup> If an invention corresponds to basic necessities, such as pharmaceuticals, the United States uses mechanisms like Medicaid and Medicare to provide marginalized people with access to patents of which they would otherwise be deprived. The question, discussed in Part IV, is whether developed nations themselves would respond differently to a deterioration of economic circumstances affecting the government's ability to aid the marginalized or to market distortions caused by the presence of monopolies.<sup>45</sup>

Unlike the emphasis by developed nations on inventor incentives, developing nations emphasize the public accessibility of the invention.<sup>46</sup> The low per capita income in developing nations affects the government's ability to fulfill basic requirements and thus increases the probability of occurrence of health exigencies. Given the higher population and illiteracy rates, nations with low per capita income prioritize increased consumer maximization, especially for products catering to basic requirements.<sup>47</sup> Hence, traditionally, developing nations exercise price control, especially on pharmaceutical products, to ensure medication to the needy.<sup>48</sup>

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44. For example, the dissent of District Judge Aldrich, sitting on a panel of the United States Court of Appeals for the First Circuit, from which the *Paper Bag* case was appealed to the Supreme Court of the United States, favored restricting patent rights on the grounds that non-use of patents for private benefits discouraged inventive activity. See 150 F. 741, 744–45 (1st Cir. 1906) (Aldrich, J., dissenting). Judge Aldrich stated that patents were meant to encourage invention by “protect[ing] the right to make, use, and vend” the product in public interest. *Id.* at 745 (Aldrich, J., dissenting). Hence, he opined that the court should discourage activities hindering the objective by preventing the patent owner from alleging infringement. *Id.* (Aldrich, J., dissenting). In not restricting the patent owner's right, Judge Aldrich felt that the court of equity helped the patent owner to accomplish non-use for private gain and thus contravened the spirit of equity and public policy. *Id.* at 745, 757 (Aldrich, J., dissenting). Justice Douglas recaptured the substance of Judge Aldrich's opinion in *Special Equipment Co. v. Coe*, 324 U.S. 370, 380–384 (1945) (Douglas, J., dissenting). Justice Douglas argued that the Court should interfere where patent owners misuse patents since patents are constitutionally conditioned on public purposes. *Id.* at 383–84 (Douglas, J., dissenting). For further arguments against compulsory licensing, see Fauver, *supra* note 38, at 674–78.

45. See Simone A. Rose, *On Purple Pills, Stem Cells and Other Market Failures: A Case for a Limited Compulsory Licensing Scheme for Patent Property*, 5–10 (unpublished paper) (on file at Wake Forest Public Law and Legal Theory Research Paper Series, Research Paper No. 03-07, 2003), available at <http://ssrn.com/abstract=395421> (last visited Mar. 31, 2004) (discussing how patent rights, affected by the market distortions, lead to monopolistic markets); see also *infra* Part IV.

46. See Ragavan, *supra* note 36, at 184.

47. See *id.* at 137.

48. See *id.* at 133–34 (discussing price control measures taken by the government of India).

Thus, IP rights are balanced with consumer welfare. In a global sense, this is the balance between trade and welfare.

In theory, the price of a patented product cannot be controlled unless licensed compulsorily. Third-world governments, however, control the prices of not the patented pharmaceutical products, but the generic versions of the patented products, without compulsorily licensing the patent itself.<sup>49</sup> “Generic drugs,” in the context of developing nations, refers to copies of the patented pharmaceuticals made using a process different from the patented process and marketed at a lesser cost during the patent term.<sup>50</sup> The issue of whether using a new process in the attempt to copy a patent amounts to an innovation or an illegal activity is not completely resolved.<sup>51</sup> Apart from the issue of innovation, third-world governments directly control the prices of the generic drugs. For example, India has an overall Drug Price Control Order<sup>52</sup> and Brazil manufactures generic medication to treat Auto Immune Deficiency Syndrome (“AIDS”).<sup>53</sup> Price control increases the affordability of medication while assuring the manufacturer a limited percentage of profits.<sup>54</sup>

Since generic versions of all patented medications cannot be made readily available, developing nations prefer to statutorily

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49. See, e.g., *id.* at 159–60.

50. See Griffin, *supra* note 30, at 400 n.253.

51. See Srividhya Ragavan, A ‘Patent’ Restriction on R & D, 2004 U. ILL. J.L. TECH. & POL’Y (forthcoming 2004) (arguing that in limited cases the so-called ‘copycat’ drugs may actually be ‘inventions’); see also *Pfizer Inc. v. Dr. Reddy’s Laboratories Inc.*, Nos. 03-1227, 03-1258, 2004 U.S. App. LEXIS 3784 (Fed. Cir. Feb. 27, 2004). Dr. Reddy’s used a novel approach to make a generic compound of Norvasc. *Id.* at \*11. The United States Court of Appeals for the Federal Circuit held that it infringed on Pfizer’s patent on Norvasc. *Id.* at \*13–14.

52. See Ragavan, *supra* note 36, at 133–35 (discussing India’s Drug Price Control Order and its effects on the pharmaceutical industry). The Drug Price Control Order facilitated price control by compartmentalizing drugs into different categories. See Suresh Koshy, Note, *The Effect of TRIPS on Indian Patent Law: A Pharmaceutical Industry Perspective*, 1 B.U. J. SCI. & TECH. L. 4, para. 26 (1995) (listing 21 Category I drugs and 122 Category II drugs). It specified a maximum allowable post-manufacturing expense for each category. *Id.* For example, Category I consists of drugs for the National Health Program and Category II encompasses drugs for health needs. *Id.* The “Maximum Allowable Post-Manufacturing Expense” for price control in Category I is 75% and Category II is 100%. *Id.* The post-manufacturing expenses include advertising and distribution costs. *Id.* A National Pharmaceutical Pricing Authority reviews pharmaceuticals under price control and monitors prices of decontrolled pharmaceuticals. *Id.* at para. 27.

53. See Ragavan, *supra* note 36, at 135–37. Brazil locally manufactures generic versions of the AIDS medication at 70% below market price to treat 100,000 low-income patients each year. *Id.* at 136.

54. See Koshy, *supra* note 52, Rule 3.4 paras. 25, 27.

retain the right to compulsorily license, in order to maintain adequate supplies by local working of the invention.<sup>55</sup> Facilitating public accessibility to the invention is a preventative measure meant to safeguard public health.<sup>56</sup> India, for example, under the Patent Act of 1970, retained the right to compulsorily license a patent if it was not reasonably priced or manufactured locally.<sup>57</sup> Within developing countries, local manufacturing is cost effective and allows governments to exercise price control.<sup>58</sup> Similar to India, other developing nations like Brazil, Thailand, and South Africa also prefer to retain compulsory licensing rights.<sup>59</sup> Typically, the right retained by the developing nation does not affect the inventor's incentives to the point of deterring research and innovation.<sup>60</sup>

International conventions generally endorse balancing patent rights for limited reasons. For example, the 1967 Paris Convention allows the compulsory licensing of patents not worked by the patentee for "four years from the date of application, or three years from the member's grant of the patent."<sup>61</sup> Article 31 of

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55. See Ragavan, *supra* note 36, at 136 (explaining the ways in which compulsory licensing has benefited Brazil).

56. See Fauver, *supra* note 37, at 668–70 (discussing the "adequate supply" theory).

57. Patents Act of 1970, 27 INDIA A.I.R. MANUAL 450, §§ 84(1), 90(c), 94 (2d ed. 1979). Under the 1970 patent legislation, the government could compulsorily license a patent not reasonably priced or not worked in a manner "satisfy[ing] the reasonable requirement of the public." Ragavan, *supra* note 36, at 140. The reasonableness requirement of the public is deemed not satisfied unless the invention is manufactured locally. See *id.*

58. See Ragavan, *supra* note 36, at 136 (discussing the cost-effectiveness of Brazil's local manufacturing).

59. See *id.* at 172–74. See generally Baca, *supra* note 26, at 189, 196–204 (discussing Mexico's compulsory licensing system).

60. Ragavan, *supra* note 36, at 134–35. Inventive activity tends to be lower in developing nations due to other factors like low per capita income, lack of education, and high illiteracy rates. *Id.* at 137. Similarly, developing nations rarely use the compulsory licensing provisions to further parallel importation, although this is a legitimate concern of the pharmaceutical industry. See *infra* Part VI for a discussion of parallel importation.

61. Marc, *supra* note 6, at 112. The Convention seeks "to prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent, for example, failure to work." Paris Convention, *supra* note 1, art. 5A(2), 21 U.S.T. at 1636–37, 828 U.N.T.S. at 321. The origin of article 5A(2) can be traced to 1873, when the parties to the Vienna Congress resolved that compulsory licenses should be made available if warranted by "public interest." See Michael Halewood, *Regulating Patent Holders: Local Working Requirements and Compulsory Licenses at International Law*, 35 OSGOODE HALL L.J. 243, 266 (1997). The Vienna Congress culminated into the Paris Convention in 1883. *Id.* Although the Vienna Congress produced no binding legal instrument, in 1877, the provision was adopted into the German law. *Id.* Article 5A(2) of the Paris Convention details that "failure to work the patent could not result in forfeiture unless compulsory licensing was an inefficient remedy. Therefore, compulsory licensing replaced forfeiture as the favored

TRIPS allows members to compulsorily license patent rights during “a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use,” subject to certain restrictions meant to protect against abuses.<sup>62</sup> TRIPS, however, neither defines “national emergency” nor indicates, beyond generalization, circumstances likely to be construed as warranting compulsory licensing by member states.<sup>63</sup> Hence, member states lack consensus on when compulsory licensing can be exercised under TRIPS.<sup>64</sup> Therefore, although TRIPS, in Article 31, provides for compulsory licensing,<sup>65</sup> developing country parties have found it difficult to justify any circumstance as warranting the exercise of the right as detailed below.

### III. OBJECTIONS

At a time when an epidemic infection could have been curtailed, developed nations refused to interpret TRIPS as providing the flexibility to tackle a public health crisis.<sup>66</sup> The pressure on developing nations singularly focused on amending compulsory license provisions, ignoring the local effect of the amendments.<sup>67</sup> Developing nations, then fighting mass public health disasters, merely wanted to retain a right to tackle national public health exigencies, as opposed to exercising the right of compulsory licensing.<sup>68</sup> The global response, characterized by that of the devel-

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remedy to deter abuse by the patentee.” Marc, *supra* note 6, at 112. A compulsory licensing provision was first incorporated into the Paris Convention in 1925 at the Revision Conference at The Hague. Halewood, *supra*, at 266. Article 5 of the Hague Revision permitted compulsory licensing of patents not worked locally. *Id.* at 266–67; *see also* Marc, *supra* note 6, at 112.

62. TRIPS, *supra* note 3, art. 31(b). “[T]he scope and duration of such use shall be limited to the purpose for which it was authorized.” *Id.* art. 31(c); *see also* Marc, *supra* note 6, at 116. A patent can be compulsorily licensed provided the patentee rejects a request to market the product under “reasonable commercial terms and conditions.” TRIPS, *supra* note 3, art. 31(b). The license should be terminated “if and when the circumstances which led to it cease to exist and are unlikely to recur.” *Id.* art. 31(g).

63. *See* Naomi A. Bass, Note, *Implications of the TRIPS Agreement for Developing Countries: Pharmaceutical Patent Laws in Brazil and South Africa in the 21st Century*, 34 GEO. WASH. INT’L L. REV. 191, 199 (2002).

64. *Id.*

65. TRIPS, *supra* note 3, art. 31.

66. Bass, *supra* note 63, at 199–200.

67. *See id.* at 204–05 (discussing the difficulties of implementing TRIPS in developing nations because of socioeconomic differences).

68. *See* Brook Baker, U.S. Post-Doha Conditions Can Kill, HEALTH GAP (Mar. 3, 2002), available at <http://lists.essential.org/pipermail/ip-health/2002-March/002740.html>

oped nations, discussed below, highlights two important issues. First, the extent to which forcing developing nations to compromise their national responsibilities, in fear of trade sanctions, contributed to the epidemic increase in AIDS.<sup>69</sup> Second, whether TRIPS requires nations to prioritize international obligations when faced with dire national responsibilities.

### A. *Public Health Crisis Within Developing Nations*

#### 1. South Africa: Setting the Stride

In 1996, South Africa requested that the United States provide access to drugs at a reduced cost to tackle AIDS.<sup>70</sup> The matter was treated as routine non-compliance with TRIPS, and South Africa was asked to comply with TRIPS immediately or face trade sanctions.<sup>71</sup> The United States considered neither how a country requesting cost reduction to access drugs could afford expensive pharmaceuticals, nor that AIDS would assume epidemic proportions unless appropriately curtailed.

Fearing the economic consequences of a trade sanction, South Africa passed the Medicines and Related Substances Control Act of 1997 (“Medicines Act”).<sup>72</sup> The Medicines Act included sections 15 and 22, which, taking into account the deteriorating public health, allowed the health minister to import generic drugs, or compulsorily license patents under the limited exigency of a national emergency.<sup>73</sup> The United States condemned the health minister’s “sweeping authority to abrogate patent rights for

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(last visited April 4, 2004) (noting that it took South Africa three years and 400,000 lives before President Clinton issued the Executive Order to validate the Medicines Act).

69. Transitioning towards the trade regime affected welfare in developing nations. *See generally* Ruth Gana Okediji, *Copyright and Public Welfare in Global Perspective*, 7 *IND. J. GLOBAL LEGAL STUD.* 117 (1999) (discussing similar issues with reference to copyrights).

70. *See* Ragavan, *supra* note 36, at 172; *see also* Helene Cooper et al., *AIDS Epidemic Traps Drug Firms in a Vise: Treatment vs. Profits*, *WALL ST. J.*, Mar. 2, 2001, at A1 (discussing the 1996 meeting between Jones Popovich, the American trade representative, and AIDS activists on the South Africa issue).

71. *See* Ragavan, *supra* note 36, at 172–73.

72. *See id.* at 173; *see also* Bass, *supra* note 63, at 210. The 1997 legislation amended the South African Medicines and Related Substances Control Act of 1965. *See* Marc, *supra* note 6, at 116 n.85.

73. *See* Bass, *supra* note 63, at 210–11; Marc, *supra* note 6, at 116–17.

pharmaceuticals<sup>74</sup> and in 1998, denied South Africa preferential treatment under the generalized system of preference scheme ("GSP").<sup>75</sup> Meanwhile, the July 1999 statistics established that one in every five South Africans was infected with AIDS.<sup>76</sup> The fear of trade sanctions precluded South Africa from characterizing the AIDS situation as a health crisis or as a national emergency.<sup>77</sup> Defensive for having continuously promoted trade policies in a country where survival was the central question, the United States amended its policy to provide access to HIV/AIDS medicines.<sup>78</sup>

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74. See Bass, *supra* note 63, at 212 (quoting Gary G. Yerkey, *USTR Says South Africa Agrees to Provide WTO-Consistent Patent Protection for Drugs*, 16 Int'l Trade Rep. (BNA) 1541, 1541 (Sept. 22, 1999)).

75. Ragavan, *supra* note 36, at 173; see H.R. 4328, 105th Cong. (1998), enacted as Pub. L. No. 105-277, at 155 ("[N]one of the funds appropriated under this heading may be made available for assistance for the central Government of the Republic of South Africa, until the Secretary of State reports in writing to the appropriate committees of the Congress on the steps being taken by the United States Government to work with the Government of the Republic of South Africa to negotiate the repeal, suspension, or termination of section 15(c) of South Africa's Medicines and Related Substances Control Amendment Act No. 90 of 1997"). Pretoria had requested additional benefits under the generalized system of preference scheme. The scheme allows poor countries to export products to the United States at reduced duties. *Id.*; see Marc, *supra* note 6, at 119-21. Meanwhile, the Pharmaceutical Manufacturers Association of South Africa ("PMA") filed a suit against the South African government to suspend the Medicine Act. The PMA is the organization in South Africa representing pharmaceutical manufacturers in developed nations. In response, the South African government passed the Medicines and Medical Devices Regulatory Act of 1998, but the health crisis forced the government to retain controversial sections 15 and 22 of the Medicines Act. See Marc, *supra* note 6, at 117. The South African Medicines and Medical Devices Regulatory Act (SAMMDRA) repealed the Medicines Act and therefore the suit filed by the PMA focused on repealing SAMMDRA. See *id.* at 119.

76. The southern portion of Africa accounted for approximately twenty-five million, or roughly 70%, of the world's HIV infected patients. See INTERNATIONAL INTELLECTUAL PROPERTY INSTITUTE, PATENT PROTECTION AND ACCESS TO HIV/AIDS PHARMACEUTICALS IN SUB-SAHARAN AFRICA 4 (2000), available at <http://www.iipi.org/activities/Research/HIV%20AIDS%20Report.pdf> (last visited Mar. 31, 2004). In seven countries in southern Africa, 20% of the adults were infected with HIV. *Id.* Botswana accounted for the highest percentage of the disease with 35.8% infected adults. *Id.* For additional information and statistics, see, e.g., John Vidal, *The Stakes Could Not Be Higher*, GUARDIAN, Nov. 23, 2003, available at <http://www.guardian.co.uk/aids/story/0,7369,1092957,00.html> (last visited Mar. 31, 2004). For a discussion of South Africa's AIDS problem, see Ford, *supra* note 11, at 950-51.

77. See Bass, *supra* note 63, at 212.

78. Exec. Order No. 13,155, 3 C.F.R. 268-70 (2000). The Order prohibits the U.S. government from taking any "action pursuant to section 301(b) of the Trade Act of 1974 with respect to any law or policy in beneficiary sub-Saharan African countries that promotes access to HIV/AIDS pharmaceuticals or medical technologies and that provides adequate and effective intellectual property protection consistent with the TRIPS Agreement." *Id.*; see also Rosalyn S. Park, *The International Drug Industry: What the Future Holds for South Africa's HIV/AIDS Patients*, 11 MINN. J. GLOBAL TRADE 125, 138 (2002). Following the issuance of the executive order, five of the largest pharmaceutical companies agreed to

## 2. Thailand: Another Stumbling Block

In 1989, Thailand was included on the United States' watch list,<sup>79</sup> owing to the 1979 Thai patent legislation which facilitated the production of generic drugs.<sup>80</sup> As proof of its intent to impose trade sanctions, the United States moved Thailand to the status of "priority foreign country"—a status generally imposed on countries grossly violating IP rights.<sup>81</sup> Although by 1992 Thailand extended patent protection to pharmaceuticals,<sup>82</sup> the United States expressed dissatisfaction with the compulsory licensing provisions.<sup>83</sup> Fearing economic retaliation,<sup>84</sup> Thailand abolished compulsory licensing and the local working requirement.<sup>85</sup>

The increase in drug prices resulting from the patent-friendly amendments caused economically marginalized Thais to lose access to medication.<sup>86</sup> The high cost of treatment was coupled with the government's inability to fund medication.<sup>87</sup> When AIDS be-

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drastically reduce prices on HIV/AIDS drugs for impoverished countries. *Id.* The forty pharmaceutical multinational companies withdrew the suit previously filed through the PMA against the government for challenging SAMMDRA. *See* Marc, *supra* note 6, at 120.

79. *See* Rosemary Sweeney, Comment, *The U.S. Push for Worldwide Patent Protection for Drugs Meets the AIDS Crisis in Thailand: A Devastating Collision*, 9 PAC. RIM L. & POL'Y J. 445, 460 (2000). The United States threatened to impose sanctions unless amendments were introduced to the patent legislation before November 1989. *Id.*

80. *Id.* at 449.

81. *Id.* at 460.

82. *See* Stefan Kirchanski, Comment, *Protection of U.S. Patent Rights in Developing Countries: U.S. Efforts to Enforce Pharmaceutical Patents in Thailand*, 16 LOY. L.A. INT'L & COMP. L.J. 569, 592 (1994).

83. *See* Sweeney, *supra* note 79, at 461. The amended Thai patent legislation retained the authority to issue compulsory licenses of patented goods not locally manufactured. *Id.* at 451. A Pharmaceutical Patents Board was created with power to compulsorily license patents, control prices, and seek pricing and cost information of drugs. *Id.* at 451–52.

84. *Id.* at 461. In 1997, Thailand suffered a severe economic crisis, increasing the reliance on American exports. *Id.* at 462. The United States was Thailand's largest export market. *Id.* at 461.

85. *See id.* at 452. The amended Act also eliminated the local working requirement, and thus the importation of patented products by the patentee was deemed as working the patent locally. *See* Susannah Markandya, *Timeline of Trade Disputes Involving Thailand and Access to Medicines*, at <http://www.cptech.org/ip/health/c/thailand/thailand.html> (last visited Mar. 31, 2004).

86. *See* Jiraporn Limpananont, U.S. Trade Pressure on Thailand (Drug Study Group, Thailand), available at <http://www.oxfamgb.org/eastasia/documents/Thaibullyingoct 2002.doc> (last visited Mar. 31, 2004).

87. *See* Markandya, *supra* note 85, at <http://www.cptech.org/ip/health/c/thailand/thailand.html> (last visited Mar. 31, 2004) (stating that *The Nation*, a leading Thai newspaper, reported that in 1999 "only 5% of AIDS patients [had] access to the combination use of two major AIDS medications—AZT and ddI."); *see also* Sweeney, *supra* note 79, at 446. Within ten years of reporting the first case of AIDS in 1994, Thailand housed a million people

came the leading cause of death among Thais, the national responsibility of containing the disease became an international issue.<sup>88</sup> Consequently, despite asserting that compulsory licensing was unnecessary, the American trade representative indicated that “[i]f the Thai government determines that issuing a compulsory license is required to address its health care crisis, the U.S. will raise no objection, provided the compulsory license is issued in a manner fully consistent with the WTO TRIPS Agreement.”<sup>89</sup>

### 3. Brazil: Marking the First Act of Rebellion

Brazil’s amended patent legislation also incorporated compulsory licensing of patents not worked locally.<sup>90</sup> The United States, arguing that the local manufacturing requirement violated TRIPS, requested that the dispute resolution panel of the WTO review Brazil’s amended patent law.<sup>91</sup> Meanwhile, Brazil was economically exhausted from spending \$305 million annually on its program to treat HIV-infected patients.<sup>92</sup> Hence, Brazil threatened to compulsorily license antiretroviral drugs when its request to Roche Holding Ltd. to discount the price of drugs was denied.<sup>93</sup> The threat to compulsorily license patents, against the

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with AIDS. By 2000, about 3% of the Thai population was reportedly infected with AIDS. *Id.*

88. See Ruth Mayne & Michael Bailey, *TRIPS and Public Health: The Next Battle*, OXFAM BRIEFING PAPER (Mar. 2002), available at [http://www.oxfam.org.uk/what\\_we\\_do/issues/health/downloads/bp15\\_trips.rtf](http://www.oxfam.org.uk/what_we_do/issues/health/downloads/bp15_trips.rtf) (last visited Mar. 31, 2004).

89. Markandya, *supra* note 85 (quoting a letter from Joseph Papovich, Assistant United States Trade Representative, to Paisan Tan-Ud of PHA Network of Thailand) (Jan. 27, 2000).

90. See Paul Champ & Amir Attaran, *Patent Rights and Local Working Under the WTO TRIPS Agreement: An Analysis of the U.S.-Brazil Patent Dispute*, 27 *YALE J. INT’L L.* 365, 385–86 (2002).

91. See Helene Cooper, *U.S. Drops WTO Claim Against Brazilian Patent Law*, *WALL ST. J.*, June 26, 2001, at B7.

92. Melody Petersen & Larry Rohter, *Maker Agrees to Cut Price of 2 AIDS Drugs in Brazil*, *N.Y. TIMES*, Mar. 31, 2001, at A4; see also Mario Osava, *Government to Violate Patents on AIDS Drugs*, *INTER PRESS SERVICE*, Aug. 23, 2001, available at <http://www.aegis.com/news/ips/2001/IP010808.html> (last visited Mar. 31, 2004).

93. See Miriam Jordan, *Brazil To Break Roche Patent on AIDS Drug*, *WALL ST. J.*, Aug. 23, 2001, at A3. Brazil requested Roche Holding Ltd. to reduce the cost of the AIDS cocktail drug Viracept. *Id.* Roche Holding Ltd. refused to consider anything more than a 33% reduction in price. *Id.* Brazilian officials announced that the patent in Nelfinavir would be compulsorily licensed for local manufacture of generic versions unless the price was reduced. See Press Release, Brazilian Ministry of Health, Ministry of Health Announces Compulsory Licensing of Nelfinavir Patent, (Aug. 22, 2001), at <http://www.cptech.org/ip/health/c/brazil/nelf08222001.html> (last visited Mar. 31, 2004).

background of the tremendous success of the Brazilian AIDS drug distribution program, forced the United States to drop its claims against Brazil in the WTO.<sup>94</sup>

B. *Article 31: National Responsibility and International Obligation*

Despite the AIDS crisis, the European Union and the United States were not interested in either diluting TRIPS or allowing national governments the right to compulsorily license in emergencies.<sup>95</sup> Developed nations reiterated that compulsory licensing provisions under Article 31 should be read with Article 27.1.<sup>96</sup> Developed nations were, however, willing to allow countries suffering from an AIDS crisis compulsory licensing rights, provided they were exercised in a manner fully consistent with TRIPS.<sup>97</sup>

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94. Cooper, *supra* note 91. The United States Trade Representative issued a statement pledging cooperation to combat AIDS. Press Release, U.S. Dept. of State, Increasing Access to Drugs to Fight HIV/AIDS and other Public Health Crises (June 24, 2002), at <http://www.state.gov/eb/rls/othr/11399.htm> (last visited Mar. 31, 2004). Consequently, Roche and Merck reduced the cost of the AIDS drugs by 70% compared to the price paid by U.S. buyers. Jennifer L. Rich, *Roche Reaches Accord on Drug with Brazil*, N.Y. TIMES, Sept. 1, 2001, at C1 (“The new discount reduces the price of Viracept to about 30 percent of what Roche charges in the United States.”); see also Paulo Rebelo, *Brazil Targets Another AIDS Drug*, WIRED NEWS, Aug. 29, 2001, available at <http://www.wired.com/news/politics/0,1283,46353,00.html> (last visited Mar. 31, 2004). See generally Press Release, Roche Brazil, Roche Surprised by Authorities Declaration (Aug. 23, 2001), at <http://www.roche.com/med-corp-detail-2001?id=686> (last visited Mar. 31, 2004). Brazil provided the AIDS “cocktail” medication free for its citizens and thus reduced the national AIDS mortality rate from 10,592 in 1995 to 1,700 in 2001. Gustavo Capdevila & Mario Osava, *U.S. Drops Brazil Patents Case, Paves Way for Cheap Drugs*, INTER PRESS SERVICE, June 26, 2002, available at <http://www.aegis.com/news/ips/2001/IP010624.html> (last visited Mar. 31, 2004). To ensure supplies of the drugs to 100,000 HIV/AIDS patients, Brazil manufactured seven of the twelve medications in a local company, Farminguinhos. *Id.*

95. See Cecilia Oh, *US Opposed to Moves to Address Public-Health Concerns About TRIPS*, Third World Network (Nov. 1, 2002) at <http://www.twinside.org.sg/title/twr131f.htm> (last visited Mar. 31, 2004); see also Cecilia Oh, *Developing Countries Call for Action on TRIPS at Doha WTO Ministerial Conference*, Third World Network (Nov. 1, 2002) at <http://www.twinside.org.sg/title/twr131d.htm> (last visited Mar. 31, 2004).

96. TRIPS, *supra* note 3, art. 27.1. TRIPS asserts that all products or processes should be patented. *Id.* When read with Article 31, Article 27.1 will prevent compulsory licensing as intervening over the rights vested on patents. See *id.* art. 27.1, 31. That is, using the compulsory licensing provisions to secure essential drugs would violate Article 27.1. See *id.*

97. See Exec. Order No. 13,155, 3 C.F.R. 268–70; see also *supra* notes 66–71 and accompanying text.

The argument that compulsory licensing violates Article 27.1 contradicts the idea of a TRIPS-consistent licensing scheme.<sup>98</sup> Assuming compulsory licensing can be exercised in a manner fully consistent with TRIPS, the developed nations' previous position to remove all compulsory licensing provisions in the patent laws of developing nations would violate TRIPS. This change in position makes developed nations answerable as to why developing nations were not given the option of a TRIPS-compliant compulsory license at a stage when the epidemic spread of AIDS could have been prevented. The delay in recognizing the scope of the AIDS epidemic contributed to the increase in the disease, thus making TRIPS directly responsible, as discussed below.

The refusal to reduce the price of medication also included the price of diagnostic kits, thus preventing early detection.<sup>99</sup> Therefore, some of the AIDS-infected, unaware of their condition, continued to spread the infection.<sup>100</sup> Detection at a later stage left the infected with a sense of frustration against the government's inability to provide adequate care, triggering irresponsible behavior that further spreads the infection.<sup>101</sup> Moreover, "absent the possibility of treatment, people have little incentive to learn whether they have the virus or not."<sup>102</sup> When neither medication nor diagnosis was available, government initiative, in the form of AIDS education, proved futile.<sup>103</sup> AIDS experts note that, although the AIDS medication merely treats the patients, the treatment "actually help[s] prevention."<sup>104</sup> "When dying people

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98. See TRIPS, *supra* note 3, art. 31(b).

99. Former President Clinton's foundation has recently negotiated with companies to reduce the cost of AIDS diagnostic kits. See Celia W. Dugger, *Clinton Gets Five Companies to Reduce the Cost of AIDS Tests*, N.Y. TIMES, Jan. 15, 2004, at A11.

100. See Holly Burkhalter, *The Politics of AIDS: Engaging Conservative Activists*, FOREIGN AFF., Jan.-Feb. 2004, at 9.

101. See Letter from Nancy Scheper-Hughes, Professor of Medical Anthropology, University of California at Berkeley, to Helen Epstein (Nov. 20, 2003) (published in N.Y. REV. OF BOOKS, Nov. 20, 2003, at 57).

102. See Burkhalter, *supra* note 100, at 9.

103. See *id.*

104. *Id.*

Jim Kim, a senior official at the World Health Organization ("WHO") and one of the world's leading AIDS experts, has noted that making treatment available would actually help prevention. He testified before the U.S. Senate that even in Uganda, where prevention efforts have been among the most successful in Africa, prevalence seems resistant to reduction below eight percent when preventive approaches are used alone. Along with most other infectious disease experts, therefore, he advocates comprehensive programs that integrate prevention and treatment into a mutually supporting package.

are restored to health before the eyes of the community, the ambiguity, myths, and denial about the viral cause of AIDS deaths are put to rest and treatment becomes the best educational tool available.”<sup>105</sup> The operation of TRIPS precluded AIDS treatment, and thus AIDS prevention, in developing countries.<sup>106</sup>

Had TRIPS not been an impediment, developing nations could have negotiated arrangements with generic drug companies in much the same way the United States and Canada did during the anthrax crisis.<sup>107</sup> Developing nations could have used the money saved from opting for generic drugs towards AIDS education, thus curtailing the spread of the infection. Hence the operation of TRIPS contributed directly to the spread of the AIDS infection. Soon, becoming a signatory of TRIPS ceased to be a beneficial commitment for developing nations when developed nations forced national responsibilities to become a subset of international obligations.<sup>108</sup>

The TRIPS language, however, does not necessarily require national responsibility to be subject to international obligations. Article 31 specifies that “[w]here the law of a Member allows for other use of the subject matter of a patent without the authorization of the right holder,”<sup>109</sup> any use, including that of the government, “shall be considered on its individual merits.”<sup>110</sup> Each of the countries discussed in the previous section suffered from health exigencies warranting the exercise of Article 31.<sup>111</sup> Moreover, Article 31(b) permits use of a patented product, provided the user unsuccessfully attempted to “obtain authorization from the right holder on reasonable commercial terms.”<sup>112</sup> The affected countries fulfilled this subsection by either directly approaching the United States’ trade office, as did South Africa, or the patent owner, as did Brazil. Importantly, the affected nations fulfilled the re-

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*Id.*

105. Scheper-Hughes, *supra* note 101, at 58.

106. See Ruth Moyne, *U.S. Bullying on Drug Patents: One Year After Doha*, Oxfam Briefing Paper 4, Nov. 2002, available at [http://www.oxfam.org.uk/what\\_we\\_do/issues/health/downloads/bp33\\_bullying.pdf](http://www.oxfam.org.uk/what_we_do/issues/health/downloads/bp33_bullying.pdf) (last visited Mar. 31, 2004).

107. See *infra* Part IV.

108. See generally Moyne, *supra* note 106, at 11 (noting that the actions of developed nations limited access to cheaper medicines and thus run counter to the spirit of TRIPS).

109. See TRIPS, *supra* note 3, art. 31.

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

111. See *supra* Part III.A.

112. TRIPS, *supra* note 3, art. 31(b).

quirements of Article 31(b) despite the Article 31(b) language stating that “[t]his requirement may be waived by a Member in the case of a national emergency or other circumstances of extreme urgency.”<sup>113</sup>

Article 31 also addresses the rightful concerns of developed nations from parallel importation.<sup>114</sup> Developed nations reacted, however, with a disregard for the sovereign national responsibilities of other countries.<sup>115</sup> Moreover, after vehemently opposing compulsory licensing and price controls at a time when an epidemic could have been prevented, in the wake of an AIDS crisis, developed nations lacked alternate solutions to tackle the crisis.<sup>116</sup> Consequently, as able-bodied people died from the infection due to lack of treatment, the impoverished nations underwent a further decline in economic productivity due to the AIDS virus.<sup>117</sup> The increasing medical expenses furthered the decline in productivity.<sup>118</sup> Slowly, becoming a party to TRIPS ceased to be a mutually beneficial proposition—as contemplated under Article 7—for developing nations. Thus, the economic and political advantage of avoiding a public health crisis became imminent for developing nations.<sup>119</sup>

#### IV. REACTIONS

This part demonstrates how the developed nations, particularly the United States, exercised the exact options it advised develop-

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113. *Id.* The developing nations also fulfilled the other conditions in Article 31 being local, non-exclusive use. *See id.*

114. *See id.* art. 31(f) (“[A]ny such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use.”).

115. *See* Leanne M. Fecteau, Note, *The Ayahausca Patent Revocation: Raising Questions About Current U.S. Patent Policy*, 21 B.C. THIRD WORLD L.J. 69, 81 (2001) (discussing how developing countries have been pressured into signing TRIPS by developed countries).

116. *See infra* Part IV (arguing that during the anthrax crisis the developed nations came up with no novel or alternate solution except what the developing countries were practicing).

117. LORI BOLLINGER & JOHN STOVER, THE POLICY PROJECT, U.S. AGENCY FOR INT’L DEV., *THE ECONOMIC IMPACT OF AIDS IN SOUTH AFRICA* 3 (1999).

118. *See id.*

119. Highlighting the economic and social challenges from poverty and public health issues, developing nations sought a broad and balanced program along the lines of Article 31 within TRIPS. *See* Helene Cooper & Geoff Winestock, *Poor Nations Win Gains in Global Trade Deal as U.S. Compromises*, WALL ST. J., Nov. 15, 2001, at A1 (discussing issues raised by the Indian Commerce and Industry Minister in the WTO session at Qatar); *see also* Doha Declaration, *supra* note 25.

ing countries against taking when faced with comparable issues, albeit in a much smaller degree. The reactions of the United States are examined in light of two circumstances—a slowing economy and a threat of public health crisis.<sup>120</sup>

### A. *Economic Downturn*

The economy in the United States slowed in 2001, resulting in a deficit from tax revenues in several states.<sup>121</sup> Simultaneously, the cost of the most frequently used prescription drugs rose at four times the rate of inflation.<sup>122</sup> The declining tax revenues left states with the choice of either reducing the state funds for Medicaid or confronting the cost of drugs.<sup>123</sup> Owing to the economic

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120. The political and economic changes refer to the economic downturn in the United States after September 11, 2001, the anthrax crisis, and the Enron scandal. *See generally* Rose, *supra* note 45, at 5 (discussing the need for compulsory licensing provisions in light of September 11, 2001 and the anthrax crisis).

121. Russell Gold et al., *States Square Off Against Drug Firms in Crusade on Prices*, WALL ST. J., Dec. 7, 2001, at A1; *see also* *The Head Ignores the Feet*, ECONOMIST, May 24, 2003, at 27. American states faced a budget shortfall of over \$50 billion and an additional \$60–85 billion was required to balance the books. *See Chopped Out*, ECONOMIST, Jan. 25, 2003, at 30. In 2003, the revenue shortfall in states totaled up to \$21.5 billion. *See The Head Ignores the Feet, supra*, at 27. The sum of \$21.5 billion represents a 23% increase over what was a predicted shortfall in November. *Id.* For the fiscal year 2004, the predicted revenue shortfall was \$80 billion affecting 10% of the expenditure in some states. *Id.* at 28.

122. The rising prescription drug costs became a larger factor in the total health expenditures of states, and led to an increase of 16%, or \$142 billion, on prescription medication. Ron Winslow et al., *States, Insurers Find Prescriptions for High Drug Costs*, WALL ST. J., Sept. 11, 2002, at A1 (explaining that the total spending in the U.S on prescription drugs accounts for 10% of American health care spending and that the rate of inflation for prescription drug prices exceeded the rate of general inflation). *See generally* Whitney Magee Phelps, Comment, *Maine's Prescription Drug Plan: A Look into the Controversy*, 65 ALB. L. REV. 243, 245 (2001) (reporting that total drug expenditures are expected to double from 1999 to 2004).

The increasing drug prices, coupled with deteriorating economic conditions, contributed to the prescription drug crisis. Between 1982 and 1988, prescription drug costs increased at an average annual rate of 9.5%, more than any other component of the health care sector. “Between 1998 and 2000, Medicaid’s average annual spending on prescription drugs grew by 19.7%.” Sarah Lueck, *States Efforts To Cut Drug Prices Get Boost From Medicaid Chief*, WALL ST. J., May 30, 2003, at A1; *see also* Sara M. Ford, *Congressional Research Service Report to Congress, Medicaid: Reimbursement for Outpatient Prescription Drug*, CRS-15 (Mar. 7, 1991). From 1980 to 1989, payments for Medicaid prescription drugs increased 179%. Medicaid expenditures for all other services increased by only 134%. *Id.* *But see* Phelps, *supra*, at 245 (discussing that PhRMA estimated that the increase in price inflation of drugs remained at a low 4.2% in 1999).

123. Ragavan, *supra* note 36, at 167–68; *see also* *Miracle. On Ice*, ECONOMIST, May 17, 2003, at 29 (stating that although in the past Minnesota consistently ranked among the top in health care, education, and quality of life, a two-year deficit of \$4.2 billion threatens

slowdown, state governments sought what the federal government advocated against in developing nations—balancing the rights of manufacturers and consumers by interfering with the market price of pharmaceuticals.<sup>124</sup> Efforts were taken to reduce state expenditures on prescription drugs without affecting accessibility of drugs to the needy.<sup>125</sup> States restricted patents either by using generic drugs,<sup>126</sup> or by indirectly influencing the price of branded pharmaceuticals.<sup>127</sup> Both options targeted different pharmaceutical cycles. The option of using generic drugs produced in developed nations quickened the post-patent entry of the cost effective generics into the market.<sup>128</sup> The second option reduced the cost of patented Medicaid pharmaceuticals.<sup>129</sup> Together, both options improved accessibility of the medication by providing low-cost alternatives.

The emphasis of the state governments on providing access to medication conflicted with developed nations' traditional advice to third-world countries. The United States government has specifically opposed prioritizing accessibility to the needy and reiterated that global trade interests far outweigh the local welfare obligations of providing medication to impoverished citizens.

### 1. Option 1: Generic Drugs

Generic drugs have the advantage of cost effectiveness in comparison with branded medication.<sup>130</sup> Within developed nations, the term "generic drug" refers to copies of pharmaceutical patents made and marketed at a lesser cost *after* the expiration of the

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the state's programs).

124. See Ragavan, *supra* note 36, at 168.

125. See *id.*

126. See *infra* Part IV.A.1.

127. See *infra* Part IV.A.2.

128. See *infra* notes 130–33 and accompanying text.

129. See *infra* note 140–41 and accompanying text.

130. Generic Pharmaceutical Access and Choice for Consumers Act of 2003, S. 51, 108th Cong. § 2 (2003). In general, "generic pharmaceuticals cost between 25 percent and 60 percent less than brand-name pharmaceuticals, resulting in an estimated average savings of \$15 to \$30 on each prescription filled." *Id.* § 2(a)(3)(B). "Independent studies have estimated that generics provide an average savings of \$45.50 for each prescription drug sold." *Id.* § 2(a)(4). For example, the same quantity of anxiety drugs costs \$133.98 for ninety tablets of the branded Xanax while ninety tablets of the generic Alprazolam costs \$10.97. See Drugstore.com Website: Drug Prices and Information, at [www.drugstore.com/pharmacy](http://www.drugstore.com/pharmacy) (last visited Mar. 31, 2004).

patent period.<sup>131</sup> The entry of generic drugs into the market after the patent term is typically delayed due to several factors like bio-equivalency testing, approval by the Food and Drug Administration (“FDA”), and others.<sup>132</sup> Patent holders generally compound the delay using various tactics, in effect extending market exclusivity beyond the patent term.<sup>133</sup>

The Hatch-Waxman Act of 1984<sup>134</sup> represents the congressional initiative to balance the rights of patent holders with the public’s need for the medication<sup>135</sup> by reducing the post-patent market exclusivity period for pharmaceuticals.<sup>136</sup> In 1984, the effect of deteriorating economic conditions on employment and income elevated the health care interests of the public above the pecuniary

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131. The term “generic drugs” does not refer to the third-world generics. See Griffin, *supra* note 30, at 400 n.23; see also S. 51, 108th Cong. § 2(a)(1) (2003) (stating that generic pharmaceuticals must be approved by the Food and Drug Administration).

132. See 35 U.S.C. § 271(e)(1) (2000), which was enacted in 1984 by Congress to reduce undue delay from bio-equivalency testing and to introduce the public to new products at competitive prices after the expiration of the patents; see also *Roche Prods., Inc. v. Bolar Pharm. Co.*, 733 F.2d 858, 864–65 (Fed. Cir. 1984).

133. See, for example, *Mylan Pharms., Inc. v. Thompson*, 268 F.3d 1323 (Fed. Cir. 2001), where the issue concerned not the actual patent, but a metabolite produced *in vivo* after the drug was swallowed. *Id.* at 1328. Nevertheless, it delayed the introduction of the generic drug. See *id.* Similarly, obtaining add-on patents unrelated to the actual compound delays the introduction of generic drugs.

134. Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended at 15 U.S.C. § 355 (2000)).

135. Amendments to the Hatch-Waxman Act were enacted after intense lobbying from the generic drug industry. See 35 U.S.C. § 271(e)(1) (2000); see also *Intermedics, Inc. v. Ventritex, Inc.*, 775 F. Supp 1269, 1272–73 (N.D. Cal. 1991).

136. See generally Janice M. Mueller, *No “Dilettante Affair”: Rethinking the Experimental Use Exception to Patent Infringement for Biomedical Research Tools*, 76 WASH. L. REV. 1, 22 (2001) (discussing *Roche*, 733 F.2d. at 858). *Roche* resulted in the enactment of the Hatch-Waxman Act, which introduced § 271(e) to the Patent Act, *id.*, allowing the use of a patented invention solely for gathering data to support a Federal Drug Administration (FDA) application for generic versions of previously approved drugs. See 35 U.S.C. § 271(e)(1) (1994). However, the generic drug industry has been concerned that pharmaceutical companies have blocked competition for much longer by filing additional patent claims and seeking injunctions on various grounds. See *Eli Lilly & Co. v. American Cyanamid Co.*, 82 F.3d 1568, 1570 (Fed. Cir. 1996) (applying the process patent amendment in § 271(g) to intermediates); see also Chris Adams & Greg Hitt, *Bush Deals Blow to Big Drug Makers*, WALL ST. J., Oct. 22, 2002, at A3; Robert Pear, *Bush Seeks Faster Generic Drug Approval*, N.Y. TIMES, Oct. 22, 2002, at A24. The 2003 amendment provides for the FDA to enact complimenting rules limiting the challenges available for pharmaceutical companies to delay or block the sale of generic drugs. These rules will not require congressional approval and would take effect in 2004. See FDA WHITE PAPER: NEW FDA INITIATIVE ON “IMPROVING ACCESS TO GENERIC DRUGS,” (June 12, 2003), at <http://www.fda.gov/oc/initiatives/generics/whitepaper.html> (last visited Mar. 31, 2004); see also Amy Goldstein, *Bush Plan to Increase Generic Drugs Draws Flak*, WASH. POST, Oct. 22, 2002, at A6.

interests of the patent holders—a measure uniformly reflected in all price control legislation of developing nations. Ironically, Article 31 provides for the same balance by allowing members to take appropriate measures in the event of a national emergency.<sup>137</sup>

The deterioration of economic conditions in 2002 resulted in the Senate complementing the Hatch-Waxman Act by approving a bill limiting regulatory delays of generic drug applications.<sup>138</sup> The bill quickened the market entry of generics in the post-patent period by “penaliz[ing] companies that reach agreements with makers of brand-name drugs to delay the introduction of generic versions.”<sup>139</sup>

## 2. Option 2: Influencing the Market Price of Prescription Drugs

Under the second option, state programs reduced prices of pharmaceuticals catering to Medicaid customers by indirectly compelling companies to offer discounts.<sup>140</sup> In each of the programs discussed below, government initiatives obstructed the patent from realizing full market potential. As in developing countries, the government balanced the patent holder’s and the patient’s interests. Unlike developing nations where market price is directly restricted to a percentage of the cost of production, the state governments indirectly reduced a percentage of the market price. That it amounts to a price control is evidenced by the affidavits of drug manufacturers describing how the state programs sharply reduced the market share of drugs.<sup>141</sup>

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137. See TRIPS, *supra* note 3, art. 31(b).

138. See Greater Access to Affordable Pharmaceuticals Act of 2003, S. 54, 108th Cong. (2003) [hereinafter Greater Access Act]. The use of generic pharmaceuticals for brand-name pharmaceuticals could save purchasers of pharmaceuticals between 8 and 10 billion dollars per annum. *Id.* at § 2(a)(6)(A); see also Drug Competition Act of 2003, S. 946, 108th Cong. (2003) (detailing the provision for timely notice to the Department of Justice and the Federal Trade Commission regarding agreements between companies with patent rights concerning manufacturing generic versions of branded drugs); Leila Abboud, *Bush Acts to Speed Generics to Market*, WALL ST. J., June 12, 2003, at A3. See generally Gardiner Harris, *Bush to Back Measures on Generic Drugs*, N.Y. TIMES, June 12, 2003, at C1.

139. Harris, *supra* note 138, at C1.

140. See Russell Gold, *Minnesota Sues Pharmacia Over Drug Pricing*, WALL ST. J., June 19, 2002, at D3 (stating that state budgets had the maximum expenditure for Medicaid to residents without drug coverage).

141. For example, SmithKline claimed that the program in Nevada reduced the market share of four of their drugs. *Pharm. Research & Mfrs. of Am. v. Walsh*, 123 S. Ct. at 1864. Within six months of the Medicaid amendment, the market share of Augmentin (used to

a. The Maine Experiment

The State of Maine passed the Fairer Pricing for Prescription Drugs Act of 2000, which created the “Maine Rx Plus Program” (“Rx Plus Program”).<sup>142</sup> The Rx Plus Program dealt with pharmaceutical drug pricing and profits—terms, incidentally, used in several third-world nations to refer to price control.<sup>143</sup> The Rx Plus Program allowed Maine’s uninsured citizens to cope with prescription drug prices by negotiating a discounted rebate with the pharmaceutical manufacturers.<sup>144</sup> Under the Rx Plus Program, names of manufacturers who did not “voluntarily” enter into rebate agreements with the Commissioner of Maine Care—the state Medicaid administrator—were released to health care providers and the public.<sup>145</sup> Sales made by noncompliant manufacturers were subject to the *prior authorization requirements* of Maine Care.<sup>146</sup> The procedural burdens imposed by the prior authorization requirement shifted patient and physician loyalty to competing drugs of manufacturers not subject to the authorization.<sup>147</sup> Thus, Maine indirectly influenced the market price of pharmaceuticals by prevailing on drug manufacturers’ need to retain customers.<sup>148</sup>

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treat bacterial infections) declined from 49% to 18%. *Id.*

142. ME. REV. STAT. ANN. tit. 22 § 2681 (West. Supp. 2003).

143. The Rx Plus Program prohibited manufacturers from “profiteering” by charging unreasonable prices for prescription drugs or from refusing to sell prescription drugs. *Id.* § 2697(2). The statute prohibited a manufacturer from demanding an “unconscionable price” or “[e]xact[ing] or demand[ing] prices or terms that lead to any unjust or unreasonable profit” as “illegal profiteering.” *Id.* Violating the provision by profiteering resulted in civil damages, including punitive damages. *Id.* § 2697(3). The Attorney General had the power to investigate any suspected violations. *Id.* § 2698. The provision was found to be unconstitutional by the United States District Court for the District of Maine, and Maine did not appeal this issue to the United States Court of Appeals for the First Circuit. *See Pharm. Research & Mfrs. of Am. v. Concannon*, 249 F.3d 66, 72 n.2 (1st. Cir. 2001), *cert granted*, 536 U.S. 956 (June 28, 2002) (No. 01-188).

144. ME. REV. STAT. ANN. tit. 22, § 2681(4) (West. Supp. 2003). The Rx Plus Program protected residents without a prescription drug plan. All residents of Maine, who met income and drug expenditure requirements, were eligible to enroll. *Id.* § 2681(2)(F). Enrollees purchased discounted prescription drugs from participating Maine pharmacies. *Id.* § 2681(5). The discounts of the pharmacies were reimbursed from a state-established fund consisting of “rebate payments” collected from participating drug manufacturers. *Id.* § 2681(9).

145. *Id.* § 2681(7).

146. *Id.*

147. *See, e.g., Concannon*, 249 F.3d at 77.

148. *See, e.g., Pharm. Research & Mfrs. of Am. v. Concannon*, No. 00-157-B-H, 2000 U.S. Dist. LEXIS 17363, at \*4 (D. Me. Oct. 26, 2000).

The Pharmaceutical Research and Manufacturers of America (“PhRMA”) moved for a preliminary injunction to prevent Maine from enforcing the Rx Plus Program.<sup>149</sup> On appeal, the United States Court of Appeals for the First Circuit upheld the Rx Plus Program as consistent with the congressional intent to provide medical services to those with insufficient resources in “the best interests of the recipients.”<sup>150</sup> The court added that state law was not preempted since the substantial local benefit outweighed any effect on interstate commerce.<sup>151</sup> PhRMA argued that although voluntary, the Maine program would result in a loss of profits the manufacturer would otherwise gain from distributors.<sup>152</sup> The First Circuit maintained that the effect on prices was inconsequential so long as manufacturers were not directly required to sell their drugs to a wholesaler for a certain price.<sup>153</sup> In vacating the district court injunction, the First Circuit exhibited no disdain toward price controls under limited conditions, and favored the indirect rather than direct form of controlling prices of pharmaceuticals.<sup>154</sup>

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149. *Id.* at \*11. The district court held that the Rx Plus Program violated the commerce clause by regulating sales of out-of-state manufacturers and distributors. *Id.* at \*14. The court construed that sales to in-state distributors are implicitly preempted by the federal Medicaid program, *id.* at \*20, and granted a preliminary injunction against implementing the Rx Plus Program. *Id.* at \*24. The court added that the Maine legislation extended the Congressional intent by altering the federal Medicaid program. *Id.* at \*20.

150. *Concannon*, 249 F.3d at 75. The court noted that there was no express, implied, or field preemption and, therefore, addressed the issue of implied conflict preemption. *Id.* at 74–75 & n.6.

151. *See id.* at 84. The court considered whether the Maine amendments had an express extraterritorial reach affecting interstate commerce and held that the out-of-state transaction is not regulated since the rebate program is voluntary. *Id.* at 82. Using the *Pike* balancing test, the court held that “the local benefits appear[ed] to outweigh the burden on interstate commerce.” *Id.* at 84. The court maintained that the Rx Plus Program addressed a legitimate state interest, since the harm to interstate commerce alleged by PhRMA would be the same regardless of whether manufacturer compliance is completely voluntary or a product of coercion through the Rx Plus Program. *See id.* at 82.

152. *Id.*

153. *See id.* In addressing the issue of what would happen if all states followed the Maine program, the court noted that it would result in a loss of profits for the manufacturers, but indicated that the effect on interstate commerce, along with the benefits to the recipients, far outweighed the loss to the pharmaceutical companies. *Id.* at 82–84.

154. *See id.* at 81–82. An intervention petition filed by a shareholder specifically argued that the Maine program conflicted with the federal patent law by controlling prices and conditions for the sale of patented prescription drugs. *Pharm. Research & Mfrs. of Am. v. Comm’r*, 201 F.R.D. 12, 14 (D. Me. 2001). The district court denial of the motion to intervene was confirmed by the United States Court of Appeals for the Federal Circuit. *Pharm. Research & Mfrs. of Am. v. Schinder*, 25 Fed. Appx. 865, 867 (Fed. Cir. 2001).

## b. Florida's Price Influencing Amendments

In 2001, the State of Florida's amendments excluded drugs produced by manufacturers not providing a 10% discount from the preferred list of the Florida Medicaid program.<sup>155</sup> Drugs excluded from the preferred list, if prescribed to Medicaid beneficiaries, were subject to *prior approval* from the pharmacist.<sup>156</sup> By advising physicians on cheaper alternatives, the approval procedure pressured pharmaceutical companies into being on the preferred list by providing the government-specified discount.<sup>157</sup>

PhRMA sought a preliminary injunction on the basis that the amendments were preempted by section 1927(d)(4) of the federal Social Security Act ("SSA").<sup>158</sup> The SSA mandates that states offer *all* federally approved prescription drugs to Medicaid beneficiaries.<sup>159</sup> PhRMA argued that unless there is a written finding that a specified drug offers no clinically meaningful benefit, Medicaid beneficiaries should not be denied prescription drugs on other grounds.<sup>160</sup> The district court considered the loss of market share of drugs—not on the preferred list but subject to prior authoriza-

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155. See FLA. STAT. ANN. §§ 409.91195(A), 409.912(40)(a)(7) (2003). In 2001, drug companies filed a case challenging the Florida Program. See *Pharm. Research & Mfrs. of Am. v. Meadows*, 184 F. Supp. 2d 1186 (N.D. Fla. 2001).

156. FLA. STAT. ANN. § 409.91195(8) (2003).

157. See *Pharmaceutical Research & Mfrs. of Am. v. Meadows*, 304 F.3d 1197, 1208 n.9 (11th Cir. 2002). Only 821 out of the 1,876 branded drugs were present in Florida's preferred list. See Conrad F. Meier, *PhRMA Asserts Itself in Court Action*, HEALTH CARE NEWS, Oct. 2001, at 2. Because manufacturers refused to enter into such agreements, 50% of the branded drugs in the Medicaid program were not on the preferred list. *Meadows*, 184 F. Supp. 2d at 1189.

158. 42 U.S.C. § 1396r-8(d) (2000) [hereinafter SSA]; *Meadows*, 184 F. Supp. 2d at 1186.

159. *Meadows*, 184 F. Supp. 2d at 1189; see also 42 U.S.C. § 1396r-8(a)(1). The Medicaid program was enacted by Congress in 1965 under Title XIX of the SSA. 42 U.S.C. § 1396r-8(a)(1); *Meadows*, 184 F. Supp. 2d at 1188. The program is a joint venture between the federal government and each state. *Meadows*, 184 F. Supp. 2d at 1188. The federal government pays about 56% of the cost in the respective states while the states pay the rest of the expenses. *Id.* The Medicaid program directly reimburses pharmacists for drugs that they provide to Medicaid beneficiaries. *Id.* The pharmaceutical manufacturers sell prescription drugs in states through the Medicaid program. *Id.* The SSA requires pharmaceutical companies to charge the same price to state and preferred customers for Medicaid supplies. Ragavan, *supra* note 36, at 168. The price is discounted as a part of the agreement negotiated by the drug companies for Medicaid supplies. 42 U.S.C. § 1396r-8(a)(1). In Florida, manufacturers offered the required discount of 15.1% with limited exceptions. *Meadows*, 184 F. Supp. 2d at 1189. The amendment restricted manufacturers not under the agreement from marketing their drugs to Medicaid beneficiaries. *Id.*

160. *Id.*

tion—irrelevant.<sup>161</sup> On appeal, the United States Court of Appeals for the Eleventh Circuit concurred and validated the economic criterion of the approval program, which forms the crux of the indirect price reduction.<sup>162</sup>

Meanwhile, other states, including Illinois, North Carolina, Oregon, and Hawaii, copied the Maine and Florida Medicaid programs.<sup>163</sup> Encouraged by the success of inducing indirect rebates for the Medicaid drugs, other states (e.g., Michigan), sought rebates for non-Medicaid drugs, as discussed below.

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161. *Id.* at 1196 (“The federal law does not purport to guarantee a market share. It only requires that a State Medicaid program make available all of the drugs on the federal drug formulary.”). The court found no conflict between the federal and the state law since 42 U.S.C. § 1396r-8(d)(4) authorized the establishment of a prior authorization requirement subject to conditions. *Id.* The condition was that no drug should be excluded from the federal drug formulary. *Id.* The court concluded that the Florida program did not exclude the formulary since it adopts the federal drug formulary and adds a prior authorization component. *Id.* at 1197.

162. *Meadows*, 304 F.3d at 1208. PhRMA argued that under the federal law, *clinical* factors are the only permissible criteria for excluding a drug from the formulary. *Id.* at 1207; *see also* 42 U.S.C. § 1396r-8(d)(4)(C) (“A covered outpatient drug may be excluded . . . only if . . . the excluded drug does not have a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcome of such treatment for such population over other drugs included in the formulary and there is a written explanation (available to the public) of the basis for the exclusion.”). In addressing whether the decision to remove a drug from a § 1396r-8(d)(4) formulary must be based solely on clinical factors, the court specifically mentioned that the prior approval requirement included an economic factor. *Meadows*, 304 F.3d at 1208. It gave substantial deference to the administering agency within the state, however, in deciding that coverage would presumably be based on medical information conveyed by the prescribing doctor to the state agency that administers the Medicaid program. *Id.* Hence, although it included an economic criterion, the court concluded that the decision was based on clinical factors. *Id.* The United States Court of Appeals for the Eleventh Circuit concluded that Florida law does not deny coverage of Medicaid-eligible drugs since the program does not exclude any Medicaid-eligible outpatient drugs from coverage. The court noted that there was “no reason to believe that a prescribing physician would compromise the medical care of his patient in order to avoid making a telephone call to obtain a twelve-month authorization of medication not on the preferred drug list.” *Id.* at 1207 n.8. The Eleventh Circuit concluded, therefore, that the Florida amendment does not exclude any drugs from the list. *See id.* The court affirmed that there was no implied conflict preemption of the federal law since the Florida program had the potential to provide better medical services and hence was not an obstacle to the Congressional objectives. *Id.* at 1209. Soon Florida increased the prerequisite discount rate for the preferred list by an additional 6%. Ragavan, *supra* note 36, at 168.

163. Winslow et al., *supra* note 122, at A1. For example, Oregon supplied doctors and consumers with information on cost and effectiveness of alternative generic drugs. *Id.*

c. Michigan's Program for Rebates on Non-Medicaid Drugs

Michigan set a low common denominator for all drug prices by instituting the Best Practices Initiative ("Initiative").<sup>164</sup> The Initiative identified drugs bearing negotiated rebates as "best in class."<sup>165</sup> Drugs not so identified were subject to the prior authorization requirement.<sup>166</sup> Manufacturers could avoid the prior authorization procedure by entering into two agreements with the State of Michigan.<sup>167</sup> The first agreement required the manufacturer to match the price of the lowest priced "best in class" drug in the "relevant therapeutic class."<sup>168</sup> The second agreement required the manufacturer to discount prices of certain non-Medicaid drugs.<sup>169</sup>

Instead of challenging the validity of the program, PhRMA challenged the authority of the Secretary of Health and Human Services ("Secretary") to approve the Michigan program in *Pharmaceutical Research and Manufacturers of America v. Thompson*.<sup>170</sup> With reference to the agreement on non-Medicaid drugs,

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164. See *Pharm. Research & Mfrs. of Am. v. Thompson*, 259 F. Supp. 2d 39, 45 (D.D.C. 2003); Winslow et al., *supra* note 122, at A1 (discussing that Michigan also introduced a program called "Generic Drugs: The Unadvertised Brand," and allowed health insurers to promote wider use of generics); see also Gold et al., *supra* note 121, at A1.

165. See *Thompson*, 259 F. Supp. 2d at 45.

166. See *id.* at 46.

167. See *id.*

168. See *id.* This agreement is termed the "Supplemental Drug Rebate Agreement" because the rebate is above the discount that a manufacturer is required to provide under the SSA. See *id.*

169. See *id.* This agreement is termed the "Non-Medicaid Agreement." See *id.*

170. 259 F. Supp. 2d 39, 47 (D.D.C. 2003). The Medicaid program created under the SSA requires the Secretary to approve the state Medicaid program. See *id.* at 46. PhRMA questioned the Secretary's authority to approve the state programs alleging that the Secretary acted arbitrarily in approving the state Medicaid programs and thus violated the Administrative Procedure Act. 5 U.S.C. § 701 (2000); *Thompson*, 259 F. Supp. 2d at 61. PhRMA alleged that the Secretary acted arbitrarily, violating the SSA, the Commerce Clause, and the Supremacy Clause. See *Thompson*, 259 F. Supp. 2d at 44. In *Pharmaceutical Research and Manufacturers of America v. United States*, 135 F. Supp. 2d 1 (D.D.C. 2001), *rev'd*, 251 F.3d 219 (D.C. Cir. 2001), PhRMA argued that under the SSA, manufacturers paid rebates only on drugs "for which payment [was] made under the State [Medicaid] plan." *Id.* at 4. The *Thompson* court rejected PhRMA's argument and held that under the SSA, the Supplemental Rebate Agreement should be construed as an addition to the rebate program. See *Thompson*, 259 F. Supp. 2d at 68. The court explained that under the state Medicaid plans, pharmacies would charge the new Medicaid beneficiaries discounted prices for prescription drugs. *PhRMA*, 135 F. Supp. 2d at 5. The court stated that the price for a prescription drug would equal the difference between the Medicaid price for a prescription—the price the state has agreed to pay pharmacies for prescriptions filled under Medicaid—and a fixed-percentage rebate initially set at 17.5% of that price. *Id.* at 6. The

the United States District Court for the District of Columbia held that “it was reasonable for the Secretary to conclude that the best interests of the Medicaid program would be advanced, not impaired, by imposing a prior authorization requirement that would preserve [the Non-Medicaid programs] and thus prevent diversion of participants into Medicaid.”<sup>171</sup> The court’s ruling allowed Michigan to influence pharmaceutical prices of both Medicaid and non-Medicaid drugs.

Meanwhile, Vermont imitated the Florida and Maine programs and saved more than \$1.6 million in three months.<sup>172</sup> PhRMA contended that the SSA required the Medicaid program to pay the cost of medication under a “state plan.”<sup>173</sup> Instead, the state initiatives shifted the cost of funding the Medicaid programs to the pharmaceutical companies, requiring them to cover 18% of the cost of prescription drugs.<sup>174</sup> The district court rejected PhRMA’s suit against the federal government.<sup>175</sup> But the United States Court of Appeals for the District of Columbia upheld PhRMA’s argument holding that, barring Congressional approval, the SSA does not include manufacturers’ rebates as part of the state expenditure.<sup>176</sup> Hence, the appellate court decided

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states would reimburse the pharmacy but would bill manufacturers quarterly to collect the combined rebate amount. Thus, the respective states would eventually recoup their advance when the rebate was refunded. *Id.* PhRMA contended that this would result in “no state funds [being] expended.” *Id.* Therefore, PhRMA argued, states could not require the manufacturers to pay rebates on drugs dispensed unless the Secretary waived the statutory requirement of payment under the state plan. *See id.* at 4. PhRMA further contended that the Secretary did not have the authority to grant such a waiver in any event. *See id.*

171. *See Thompson*, 259 F. Supp. 2d at 75. In *Thompson*, the court held:

The Secretary did not act arbitrarily, capriciously, or otherwise not in accordance with law in approving portions of the Initiative, including the prior authorization program, the efforts to secure supplemental rebates, and the requirement that drug manufacturers provide rebates in non-Medicaid programs in order to avoid prior authorization for drugs offered for Medicaid use.

*Id.* at 85–86; *see also* Lueck, *supra* note 122, at A1.

172. *See Winslow et al.*, *supra* note 122, at A8. On March 11, 2001, the state introduced a preferred drugs list for more than 120,000 residents enrolled in Medicaid. *Id.* The program encouraged manufacturers to mandatorily rebate a portion of the price of drugs purchased directly by individuals who were not otherwise covered by the state’s Medicaid program. *See id.*

173. *See PhRMA*, 135 F. Supp. 2d at 4–5; *see also* Social Security Act, 42 U.S.C. § 1396 (2001).

174. *See PhRMA*, 135 F. Supp. 2d at 4.

175. *Id.* at 3.

176. *PhRMA v. Thompson*, 251 F.3d 219, 225–26 (D.C. Cir. 2001) (holding that the fed-

that the Secretary had no authority to approve the Medicaid program in Vermont.<sup>177</sup> Based on the Vermont decision, the United States Court of Appeals for the District of Columbia also found that the Maine program violated the SSA.<sup>178</sup>

d. The Supreme Court of the United States: Balancing Care and Cost

In light of conflict between the circuits, the Supreme Court granted certiorari<sup>179</sup> and held in *Pharmaceutical Research and Manufacturing of America v. Walsh*<sup>180</sup> that the Maine Program did not impose a disparate burden on out-of-state manufacturers in violation of the Commerce Clause.<sup>181</sup> The Court affirmed the First Circuit's decision to vacate the district court's injunction preventing Maine from implementing the Program as an abuse of discretion.<sup>182</sup> Interestingly, much like how TRIPS was not considered during the anthrax crisis, the Supreme Court also failed to consider whether indirect price controls violated TRIPS.<sup>183</sup> The Supreme Court, however, specifically favored indirect price controls for non-Medicaid drugs.<sup>184</sup>

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eral government over-stepped its authority in allowing Vermont seniors and uninsured residents to enroll in Medicaid to avail themselves of the program's low drug prices).

177. *Id.* at 221, 226.

178. After the appellate court found Vermont's program unlawful, Maine added a 2% state contribution to the manufacturer rebates. But PhRMA filed suit in the United States District Court for the District of Columbia, charging that the Maine program was illegal under the SSA and consequently, the Secretary's previous approval of the program was unreasonable under the APA. *See PhRMA v. Thompson*, 191 F. Supp. 2d 48, 51–52 (D.D.C. 2002). The appellate court found in favor of PhRMA since the program mirrored the Vermont program. Thus the Maine Medicaid program, which was initially approved by the First Circuit was held to violate the SSA by the D.C. circuit. *See PhRMA v. Thompson*, 313 F.3d 600, 604–05 (D.C. Cir. 2002).

179. *Pharm. Research and Mfrs. of Am. v. Concannon*, 249 F.3d 66 (1st Cir. 2001), *cert. granted*, 536 U.S. 956 (June 28, 2002) (No. 01-188).

180. 123 S. Ct. 1855 (2003).

181. *See id.* at 1871.

182. *See id.* at 1871. On the question of preemption, Justice Thomas concurred in the judgment and validated the Secretary's approval of the state programs, concluding that where an agency or an authority, like the Secretary, is charged with administering a federal statute, there is an insurmountable barrier to an obstacle preemption claim. *Id.* at 1877 (Thomas, J., concurring).

183. *See infra* Part IV.B.; *see also Walsh*, 123 S. Ct. at 1870.

184. *See Walsh*, 123 S. Ct. at 1870 (noting that "prior authorization may well have a significant adverse impact on the manufacturers of brand name prescription drugs" and that "any transfer of business to less expensive products will produce savings for the Medicaid program").

Justice Stevens concluded that the Medicaid Act did not preempt Maine's and Michigan's programs insofar as manufacturers are coerced into reducing prices of non-Medicaid sales.<sup>185</sup> Justice Thomas, concurring, agreed with the Secretary's interpretation that the Medicaid Act does not preclude states from negotiating prices for non-Medicaid drugs.<sup>186</sup>

Referring to public health obligations, the Court ruled that a state's "interest in protecting the health of its uninsured residents also provides a plainly permissible justification for [subjecting drug manufacturers that elected not to participate in its prescription drug rebate program to] a prior authorization requirement."<sup>187</sup> The Court added that the cost-benefit from the prior authorization program served the interests of both federal and state governments. The Court further explained that "[t]he impact on manufacturers is not relevant because any transfer of business to less expensive products will produce savings for the Medicaid program."<sup>188</sup> Justice Thomas noted that the Program achieved the delicate balance sought by the Medicaid statute between competing interests, care and cost, for example.<sup>189</sup>

Justice Thomas's opinion on balancing care and cost indirectly answers an issue left open and never revisited by the United States Court of Appeals for the Ninth Circuit in *Vitamin Technologists, Inc. v. Wisconsin Alumni Research Foundation*,<sup>190</sup> where the court was asked to decide whether compulsory licensing of a patent was warranted if the patent owner's actions or inactions affected public interest.<sup>191</sup> The standard followed by Justice Thomas indicates the need to balance, if not prioritize, public interest with the patent monopoly.<sup>192</sup> To that extent, Justice Thomas favors restricting patent rights for limited purposes. The

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185. *See id.* at 1867, 1870.

186. *Id.* at 1877 (Thomas, J., concurring).

187. *Id.* at 1869.

188. *Id.* at 1870.

189. *Id.* at 1874 (Thomas, J., concurring).

190. 146 F.2d 941 (9th Cir. 1945). The case related to a patent for producing vitamin D in food by exposure to ultraviolet radiation. *Id.* at 942. The patentee refused to license the process for producing vitamin D in oleomargarine, "one of the foods of the poor." *Id.* at 943. The court noted that the suppression of a patent essential to public health was arguably "vastly more against public interest" than even antitrust or price tying arrangements. *Id.* at 946-48. Although the court's dictum indicated that patent owners may be denied relief if the patent was against public interest, it refused to rule on the issue. *See id.* at 944-46.

191. *Id.*

192. *Walsh*, 123 S. Ct. at 1874-78 (Thomas, J., concurring).

favorable tone toward indirect price control implies that developed nations are concerned with the form of price control, as opposed to price control itself. It is unclear why the United States argued with developing nations that price control itself—and not merely the form—mattered.

### B. *Health Crisis—Anthrax*

In the past, developed nations, particularly the United States, supported drug companies' rhetoric highlighting the need for high-price branded drugs in order to fund further research and development.<sup>193</sup> Developing nations were encouraged to keep up with international obligations at the cost of not providing inexpensive drugs to the current generation in order to save a future generation.<sup>194</sup> The anthrax crisis, however, demonstrates how the United States, in the wake of a mere threat to public health, relegated the importance of branded prices and future generations to a secondary position and considered the compulsory licensing option to ensure access to drugs.

Anthrax, first reported in the United States on October 4, 2001, increased to ten confirmed cases by November.<sup>195</sup> The circumstances surrounding the release of the infectious anthrax spores accentuated the fear of an epidemic spread.<sup>196</sup> Safeguarding public health, by making an imminent supply of anthrax medication available at affordable cost, became a national security issue.<sup>197</sup>

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193. See 145 CONG. REC. H9176-02 (daily ed. Sept. 30, 1999) (statement of Rep. Brown); see also Press Release, Biotechnology Industry Organization, BIO Strongly Opposes Compulsory Licensing (Sept. 23, 1999), available at <http://lists.essential.org/pharm-policy/msg00274.html> (last visited Mar. 31, 2004); Letter from Rep. Sherrod Brown, to America's Pharmaceutical CEOs (Sept. 29, 1999), available at <http://lists.essential.org/pharm-policy/msg00261.html> (last visited Mar. 31, 2004); Bass, *supra* note 63, at 199–200.

194. See, e.g., Ragavan, *supra* note 36, at 181 n.546.

195. Centers for Disease Control of America, *Bioterrorism-Related to Inhalation Anthrax: The First 10 Cases Reported in the United States*, EMERGING INFECTIOUS DISEASES (Nov. 2001), available at <http://www.cdc.gov/ncidod/EID/vol7no6/jernigan.htm> (last visited Mar. 31, 2004).

196. *Id.* Anthrax was linked to bio-terrorism caused by the intentional release of *Bacillus anthracis* spores.

197. See *id.*; see also James W. Parrett, Jr., *A Proactive Solution to the Inherent Dangers of Biotechnology: Using the Invention Secrecy Act to Restrict Disclosure of Threatening Biotechnology Patents*, 26 WM. & MARY ENVTL. L. & POL'Y REV. 145, 156 (2001); Russell Mokhiber & Robert Weissman, *The Cipro Rip-Off and Public Health*, ZNET COMMENTARIES, (Dec. 2, 2001), at <http://www.zmag.org/sustainers/content/2001-12/02/Mokhiber-Weissman.cfm> (last visited Mar. 31, 2004). The frontline response lacked the

The United States determined that public affordability of the medication was a priority—signifying a change from its traditional disregard to public affordability of medication in developing nations.<sup>198</sup> The United States considered reducing the cost of Cipro, the recommended anthrax medication, by either compulsorily licensing Bayer's Cipro patent or purchasing Cipro from generic sources.<sup>199</sup>

Incidentally, the United States government opposed the use of both options by developing countries as violating TRIPS. Under a threat to local public health, the issue of compliance with TRIPS was not even raised internally by the United States government. Both options restricted the extent of Bayer's ability to price the drug above marginal cost. For example, compulsorily licensing Cipro interfered with Bayer's right to exploit its patent. Presumably, the United States government reasoned that the increased sales of Cipro—generated by the high-volume need for the drug—would offset Bayer's profits from a higher market price with comparatively limited sales. This is the reasoning the government repeatedly rejected when put forward by third-world governments seeking AIDS medication at lower prices for millions of poverty stricken citizens.<sup>200</sup> The second option of procuring generic ciprofloxacin restricted Bayer's market share as a patent owner and cut into the profits allocated for research and development.<sup>201</sup> The generic ciprofloxacin refers to the third-world

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training to react to the emergency of rapid contaminations from infectious diseases. Importantly, the lack of training potentially exposed the local health care providers to the risk of contracting the disease, leaving the prospect of prevention of the epidemic at stake. Parrett, *supra* at 158. The government estimated the need for approximately 1.2 billion Cipro pills, Mokhibar & Weissman, *supra*. Cipro, the recommended treatment for anthrax, was sold at \$4.50 per pill. *Id.* The treatment regimen included two pills for sixty days. *Id.*

198. See, e.g., Mokhibar & Weissman, *supra* note 199.

199. See *id.* (discussing the options available to, but not taken by the government). In this context, the term "generic" refers to the generic drug industry of developed nations, which introduces drugs after the expiration of patents, and of developing nations. See *supra* note 131 and accompanying text. For the purpose of this section, however, where appropriate, the term also refers to the drug industry in developing nations, which competes with the producers of patented products.

200. See *supra* Part III.A.1.

201. The Center for Disease Control also began to recommend using the more affordable drug doxycycline instead of Cipro. See *Canada Contracts for Generic Cipro*, CNN, Oct. 19, 2001, at <http://www.cnn.com/WORLD/americas/10/19/CANADA/generic.cipro/index.html> (last visited Mar. 31, 2004); *Cipro*, at <http://www.cipro.pharma.bayer.com> (last visited Mar. 31, 2004); Senator Charles Schumer approached Ranbaxy Ltd., an Indian generic drug company, to check availability of generic ciprofloxacin at low cost. See Melinda T. Willis, *Officials Move Toward Doxycycline as First-Line Anthrax Treatment*, ABC News,

generic drugs produced in violation of patents.<sup>202</sup> The third-world generics are anywhere from 200% to 250% as cost effective in comparison with branded pharmaceuticals since they lack research and development overhead.<sup>203</sup> That the United States turned to the pariah of the drug industry—third-world generics—demonstrates the anxiousness governments face in the wake of a public health crisis.

Meanwhile, Canada, a long and trusted ally of the United States, ignored the patents and bought Cipro from a generic drug maker.<sup>204</sup> Influenced by Canada, the United States Department of Health and Human Services (“DHHS”) threatened to compulsorily license Bayer’s patent unless Cipro was available at what the government considered fair price.<sup>205</sup> Thus DHHS did not compulsorily license the patent, but indirectly controlled the price of Cipro at \$0.95 a pill.<sup>206</sup> The DHHS’s actions are comparable to what third-world countries would do under similar circumstances.<sup>207</sup> Meanwhile, the Public Health Emergency Medicines Act (“Emergency Bill”) was introduced to incorporate compulsory licensing provisions in the patent legislation.<sup>208</sup> Significantly,

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Oct. 30, 2001, available at <http://abcnews.go.com/sections/living/DailyNews/doxycycline011030.html> (last visited Mar. 31, 2004); see also *See Indian Pharmaceutical Companies Prepared To Provide Generic Cipro*, REUTERS HEALTH, Nov. 25, 2001, at <http://www.infectioncontroltoday.com/hotnews/1ah2511050.html> (last visited Mar. 31, 2004). See generally Manu Joseph, *Indian Cipro Copies Don't Pay Off*, WIRED NEWS, Nov 8, 2001, at <http://www.wired.com/news/medtech/0,1286,48153,00.html> (last visited Mar. 31, 2004).

202. Generic drug companies like Cipla Ltd. and Dr. Reddy’s Laboratories (Indian corporations) were willing to sell Cipro for less than twenty cents per pill. See Andrew Tanzer, *Pill Factories to the World*, FORBES, Dec. 10, 2001, at 70.

203. *Id.*

204. See Amy Harmon & Robert Pear, *Canada Overrides Patent for Cipro to Treat Anthrax*, N.Y. TIMES, Oct. 19, 2001, at A1. Canadian officials stockpiled medication from Apotex, Inc., a Toronto-based generic drug manufacturer to treat 100,000 people. Canada overrode Bayer’s patent for ciprofloxin and ordered a million tablets of the generic version from Apotex, which sold Cipro for \$0.63 less than the approximately \$1.25 Bayer charged for a 500-milligram tablet.

205. See Charles Schumer, Editorial, *The Cipro Circus*, WALL ST. J., Oct. 25, 2001, at A20; see also Manu Joseph, *supra* note 201.

206. Mokhiber & Weissman, *supra* note 197.

207. *Id.*

208. Public Health Emergency Medicines Act, H.R. 3235, 107th Cong. § 2 (2001) [hereinafter *Emergency Bill*]. The *Emergency Bill* sought to amend Title 35 of the United States Code to allow the government to compulsorily license patents during health care exigencies. The *Emergency Bill* contemplated “reasonable remuneration” for the patent holder based on factors associated with the invention including the risk and costs and extent of public investments. *Id.* § 2(b). The *Emergency Bill* was referred to the House Committee on the Judiciary, but it died in committee—probably because the bio-terrorism attempts ceased.

other similar bills introduced in the past were also not passed due to strong opposition by both industry and practitioners.<sup>209</sup> The Emergency Bill, although not passed because the bio-terrorism attempts ceased, faced limited industrial opposition most likely due to the obvious government interest in securing public needs.<sup>210</sup> This limited industry opposition to the reaction of the United States government staunchly contradicted the industry's move in third-world nations, especially South Africa, where scant regard to public interest was displayed.<sup>211</sup> Part of the blame for the industry's reaction can be apportioned to the American government, which continuously supported the industry and prevented the respective governments from prioritizing national responsibilities.

## V. LEGAL ANALYSIS

The American policies implemented in the wake of its own economic and health crises are comparable to the very policies objected to by the United States in developing nations reacting to AIDS.<sup>212</sup> Considering this, the economic loss developing nations suffered from being unable to fulfill national responsibilities is quantified as the poverty penalty. Part V explains the poverty penalty and argues that the provisions of TRIPS do not envision more flexibility to developed nations. It argues that the poverty penalty adversely affected both global trade and the pharmaceutical industry.

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209. See Affordable Prescription Drugs and Medical Inventions Act, H.R. 1708, 107th Cong. (2001) [hereinafter Affordable Bill]. The Secretary of Health and Human Services could grant compulsory licenses: (a) if the patent is not used; (b) public health emergencies require it; (c) the patent holder engages in anti-competitive behavior; or (d) the patent blocks other patented inventions. H.R. 1708 § 2; see also Allan Z. Litovsky, *The Law of Unintended Consequences: How Will the Affordable Prescription Drugs and Medical Inventions Act Affect American Health Care?*, 13 HEALTH LAWYER 20 (2001) (discussing the Affordable Bill in detail). The Affordable Bill was referred to the House Committee on the Judiciary and the Committee on Energy and Commerce. The committees referred the Bill to the Subcommittee on Courts, Internet, and Intellectual Property and the Subcommittee on Health respectively; however, no further action was taken. See The Affordable Prescriptions Drug Act, H.R. 2927, 106th Cong. (1999). See generally Yosick, *supra* note 43, at 1278 n.20 (for a discussion on House Bill 2927). Generally, the Affordable Bill, the Hart Bill, and House Bill 2927 proposed compulsory licensing of patents affecting public health, safety, or protection of the environment.

210. See Bass, *supra* note 63, at 211–13.

211. See *Patent Problems Pending*, ECONOMIST, Oct. 25, 2001, at 14; see also *supra* notes 74–75 and accompanying text.

212. *Patent Problems Pending*, *supra* note 211, at 14. (“The rich world should apply the same rules to drugs in poor countries as at home.”).

### A. *The Validity of the Poverty Penalty*

#### 1. Prevalence of the Poverty Penalty

When developing nations cited weak local economic conditions as necessitating a balancing of patent rights, the United States opposed any such balancing. However, in the United States, domestic initiatives balanced care and cost to ensure adequate access to drugs every time local economic conditions deteriorated. The introduction of the rebate system for Medicaid in the 1990s<sup>213</sup> and amendments to the Hatch-Waxman Act reducing post-patent exclusivity in 2001 serve as examples of such balancing.<sup>214</sup>

In developing nations, TRIPS compliant amendments may significantly increase the cost of medication.<sup>215</sup> Yet the WTO and the developed nations, in preventing balancing measures, ignored the impact of the poor economic conditions of developing nations on accessibility of medication. The United States encouraged many impoverished countries to follow IP policies by requiring such

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213. When prescription drug expenditure increased by 179% for Medicaid drugs due to the bad economic conditions of the 1990s, Congress enacted the cost saving rebate system. See Ford, *supra* note 122, at 15 (showing that Medicaid expenditures for all other services increased by only 134%). The Medicaid statute mandated drug companies to pay rebates to states on their Medicaid purchases. *Id.* at 32–33. But the percentages of rebates were not meant to be enforced by the state. *Id.* (discussing federal limitations on state drug selection). States were also not empowered to discriminate between companies based on the percentage of the discounts.

214. The United States promoted generic drugs by amending the Hatch-Waxman Act in 1984. See 98 Stat. 1585 (1984); see also FEDERAL TRADE COMM'N, GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY 1–11 (2002) (discussing the history of the Hatch-Waxman Act). The amendment encouraged earlier introduction of generic drugs by introducing § 271(e) of the United States Code, which provided that it is not an infringement to use a patented invention for gathering data to support an FDA application for generic drugs. Section 271(1)(e) was enacted to ensure faster reach of less expensive medication. See 98 Stat. 1585. Similarly, the slowing economy of 2001, in the background of an increase in expenditure on prescription drugs by 19%, forced state governments to indirectly control the price of Medicaid drugs. In 2003, when the economy deteriorated further, the federal government proposed another amendment to quicken the introduction of generic drugs. See 98 Stat. 1585. The amendment limits the challenges available for pharmaceutical companies to delay or block introduction of generic drugs by filing additional claims or seeking injunctions. Earlier it was assumed that the longer the exclusivity, the higher the incentive to innovate. The amendment 136, at A24; see also Goldstein, *supra* note 136, at A6.

215. In 1996, Jayashree Watal argued that the static price impact of patent protection in India could raise average drug prices by perhaps 50% from a 1994 base. See Jayashree Watal, *Introducing Product Patents in the Indian Pharmaceutical Sector: Implications for Prices and Welfare*, WORLD COMPETITION: L. & ECON. REV., Dec. 1996, at 5, 18.

countries to pay the cost of branded drugs. Examples of these developing nations include: Eritrea with a GDP of \$750;<sup>216</sup> Ethiopia with a per capita gross domestic product (“GDP”) of \$560;<sup>217</sup> Somalia with a GDP of \$600;<sup>218</sup> Tanzania with a GDP of \$550;<sup>219</sup> and Zambia with a GDP of \$880.<sup>220</sup> Included among these African nations are other developing nations like India, with 320 million people living below the poverty index,<sup>221</sup> and Brazil with 597,000 HIV patients.<sup>222</sup>

Historically, the United States has advised developing countries exercising price controls over essential commodities prompted by bad economic conditions to find means to fund the price of branding.<sup>223</sup> When bad economic conditions deprived the relatively richer American state governments’ funds, instead of finding funding to support brand prices, the state governments opted for indirect price control measures.<sup>224</sup> In *PhRMA v. Walsh*, Justice Thomas argues that the state governments’ attempts are an essential, if not commendable, “delicate balance . . . between competing interests.”<sup>225</sup>

The “delicate balance” Justice Thomas refers to is precisely what the price control measures of all developing countries seek to achieve. If Justice Thomas envisions a “delicate balance” in a nation with a higher per capita income to assist the poverty stricken, the exercise of balancing between economic and social welfare in developing countries is bound to be dire and less delicate. Instead, in opposing efforts by developing nations, higher priority was placed on manufacturers’ profits and not on cost-effectiveness for the government. In dealing with local issues,

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216. *Id.* at 68.

217. INTERNATIONAL INTELLECTUAL PROPERTY INSTITUTE, PATENT PROTECTION AND ACCESS TO HIV/AIDS PHARMACEUTICALS IN SUB-SAHARAN AFRICA 69 (2000).

218. *Id.* at 88.

219. *Id.* at 91.

220. *Id.* at 94.

221. INDIA PLANNING COMM’N, NINTH FIVE YR. PLAN, 1997–2002, § 2.1.1 (1999), available at <http://planningcommission.nic.in/> (last visited Mar. 31, 2004).

222. NAT’L STD/AIDS PROGRAMME, NATIONAL AIDS DRUGS POLICY 5 (2001), available at [http://www.aids.gov.br/new\\_drug\\_policy.pdf](http://www.aids.gov.br/new_drug_policy.pdf) (last visited Mar. 31, 2004); see also Ragan, *supra* note 36.

223. See *supra* Part III.A.

224. See *Pharm. Research and Mfrs. of Am. v. Walsh*, 123 S. Ct. 1855, 1860 (2003) (noting that the “state legislatures have enacted supplemental rebate programs to achieve additional cost savings on Medicaid purchases”).

225. See *id.* at 1874 (Thomas, J., concurring).

Justice Thomas dismissed manufacturers' profits as "irrelevant," so long as it was cost-effective for the government.<sup>226</sup> Thus, within the United States, impact on manufacturers was irrelevant in ensuring medical services to the needy. However, the United States considered manufacturer profits as the main reason to preclude developing nations' efforts to make medical services affordable to the poor.<sup>227</sup> Thus, drug manufacturers who appreciated the American need to balance between the rich and needy failed to extend the same appreciation to those living below poverty levels in developing nations. This policy resulted in developing nations being unable to balance patent rights and public interest and, therefore, prevent public health disasters. The United States Court of Appeals for the First Circuit noted in appreciation of balancing measures:

[W]hen people whose incomes fall outside Medicaid eligibility are unable to purchase necessary medication, their conditions may worsen, driving them further into poverty and into the Medicaid program, requiring more expensive treatment that could have been avoided had earlier intervention been possible.<sup>228</sup>

Earlier intervention was exactly what developing nations like South Africa wanted to achieve by making medication more accessible to the poorer sections of the society. Developing countries sought early intervention for the noble and economically sound objective of avoiding more expensive treatment if AIDS became an epidemic. The issue of early intervention has a greater relevance in developing nations since the cost of medication is borne by patients. Instead, the proposed plans of South Africa, Thailand, and Brazil were touted as economically unsound human rights initiatives.<sup>229</sup>

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226. See *id.* at 1876 (Thomas, J., concurring). The Court held that "[a]voiding unnecessary costs in the administration of a State's Medicaid program obviously serves the interests of both the Federal Government and the States that pay the cost of providing prescription drugs to Medicaid patients." *Id.* at 1868 (Thomas, J., concurring).

227. See Bass, *supra* note 63, at 199 (noting that developed countries claim that compulsory licensing deters investment in the pharmaceutical industry). See generally Grace K. Avedissian, Comment, *Global Implications of a Potential U.S. Policy Toward Compulsory Licensing of Medical Inventions in a New Era of "Super Terrorism,"* 18 AM. U. INT'L L. REV. 237, 244 (2002).

228. *Pharm. Research & Mfrs. of Am. v. Concannon*, 249 F.3d 66, 76 (1st Cir. 2001), cert. granted, 536 U.S. 956 (June 28, 2002) (No. 01-188).

229. For a discussion of such initiatives, see generally Bass, *supra* note 63.

## 2. TRIPS Resulting in Poverty Penalty

As previously discussed, the United States prioritized preventing an epidemic infection during the anthrax crisis, when a mere threat existed.<sup>230</sup> Ten cases of one disease resulted in the reconsideration of the option of compulsory licensing—a proposition that the United States has traditionally never believed to be an option.<sup>231</sup> Canada went ahead and exercised the compulsory licensing option.<sup>232</sup> Thus, the mere *threat* of an epidemic forced developed nations to compromise principles they advocated to other nations and abided by for decades. In contrast, the impoverished and economically deprived developing countries—which host millions of citizens infected with several diseases—were precluded from using any flexibility within TRIPS.<sup>233</sup> When these developing and least-developed nations opted for compulsory licensing provisions, they were actually *in the midst of* a public health crisis. Yet the developed nations prevented them from exercising this option, despite the fact that the United States felt compelled to consider the same option when there were ten cases of anthrax.

Thus, the United States, because of its global leadership position in trade, contemplated exactly what it encouraged third-world governments to abstain from. The poverty penalty of third-world governments lies in those governments' inability to prioritize their national responsibilities because their economic interests depend on trade with the developed nations. Thus developing nations were forced to fulfill obligations under TRIPS which the developed nations themselves were unwilling to fulfill. The poverty penalty resulting from the operation of TRIPS merely forced developing nations—and not developed nations—to compromise their national responsibilities.

Some critics, however, would categorize the United States' reaction to anthrax as an exception, rather than a precedent.<sup>234</sup>

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230. Ragavan, *supra* note 36, at 167.

231. *Id.*

232. *Id.*

233. See Bass, *supra* note 63, at 199–201 (showing that the United States and other developed countries interpreted TRIPS narrowly and that many developing nations abandoned their compulsory licensing plans due to threats of trade sanctions from developed nations).

234. See, e.g., Richard Armitage, Senior Vice President and General Counsel, Eli Lilly, Address at the Cardozo Law School Symposium on Patent Law, Social Policy, and Public Interest: The Search for a Balanced Global System (Nov. 7, 2002).

Even these critics do not argue that had anthrax become an epidemic within the United States, American citizens who could not afford the patented ciprofloxin should die. Even if academics committed to intellectual property rights did make such an argument, the United States Constitution would prevent the government from endorsing such a view.<sup>235</sup> Hence, most proponents of the “anthrax as an exception” doctrine have shown preference for the use of an alternate solution to compulsory licensing, without diluting patents in a public health crisis.<sup>236</sup> The world, however, does not possess such an alternate solution.<sup>237</sup> The world would be rid of its problems if we only had a doctrine—other than compulsory licensing—that catered to anthrax-like exceptions on a larger scale. Moreover, a precedent does not lose its value unless overturned. Even the United States and Canadian governments have not devised alternate strategies to combat future threats of bio-terrorism, thus signifying the value of their reactions to the anthrax crisis as precedent. Until developed nations adhere to patents in the face of a public health crisis—which should never happen—anthrax will continue to be a precedent. Therefore, developing nations are well within their rights to call the reaction to anthrax a precedent. Just as American citizens who cannot afford ciprofloxin should not die, citizens of other nations, even poor nations, do not deserve death due to lack of affordability. No strict interpretation of TRIPS can dilute the sovereign duty of respective governments to uphold the right to life of their nationals.

### 3. Violation of TRIPS from Poverty Penalty

The reaction of the United States to crises outside its borders resulted in developing nations being subjected to a more rigorous operation of TRIPS. In effect, the value placed on the life of a poor

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235. See U.S. CONST. art. I, § 8, cl. 8. Article I, section 8, clause 1 specifies that “[t]he Congress shall have Power To lay and collect Taxes, Duties, Imposts and Excises, to pay the Debts and provide for the common Defence and general Welfare of the United States” while clause 8 vests the power “[t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.” *Id.* Thus, the power to promote intellectual properties vested in clause 8 is subject to the general welfare condition in Article I, section 8. *Id.*

236. See generally TRIPS, *supra* note 3, pmb1.

237. See generally Avedissian, *supra* note 227, at 286–88 (recommending the incorporation of compulsory licensing provisions in national laws worldwide—including the United States—as the only solution to tackle public health crises).

person living within developing nations was not considered sufficient to warrant affecting manufacturers' profits or patents. Developed nations placed more value on the life of a poor person in a developed nation *vis-à-vis* the protection of IP rights. Such treatment violates the national treatment clause in Article 3 of TRIPS, which no member is allowed to derogate.<sup>238</sup> Article 3 specifies that "[e]ach Member shall accord to the nationals of other Members treatment no less favourable than that it accords to its own nationals with regard to the protection of intellectual property."<sup>239</sup> However, as evidenced by the anthrax scare, favors enjoyed by nationals of developed nations include accessing medication without being precluded by TRIPS.

Such treatment amounts to "abuse of intellectual property rights by right holders" under Article 8—warranting appropriate corrective measures.<sup>240</sup> Additionally, it violates Article 65, which provides for a transitional period for the developing and least-developed country members.<sup>241</sup> Article 65(3) indicates that the period of delay is provided as a form of discrimination meant to protect least-developed nation members.<sup>242</sup> Instead, the poverty penalty operates as a form of punitive discrimination punishing poor nations simply for being poor. Article 65(3) illustrates that the protective discrimination was meant to "benefit" the poor nations, but the punitive discrimination that these nations suffered actually detrimentally affected their economies and the public health.<sup>243</sup>

The TRIPS commitments in Article 1, which do not require members to "implement in their . . . law more extensive protection than is required by this Agreement," should be respected.<sup>244</sup> The flexibilities in Article 31 and the protective discrimination in

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238. See TRIPS, *supra* note 3, art. 3.

239. *Id.*

240. See *id.* art. 8 ("Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders.").

241. See *id.* art. 65 (establishing Transitional Arrangements).

242. *Id.* ("Any other Member which is in the process of transformation from a centrally-planned into a market, free-enterprise economy and which is undertaking structural reform of its intellectual property system and facing special problems in the preparation and implementation of intellectual property laws, may also benefit from a period of delay as foreseen in paragraph 2 . . .").

243. *Id.*

244. See *id.* art. 1 ("Members may, but shall not be obliged to, implement in their domestic law more extensive protection than is required by this Agreement, provided that such protection does not contravene the provisions of this Agreement.").

Article 65 signify that IP protection that destroys national economies and consequently adversely affects international trade<sup>245</sup> is not what is envisaged by the phrase “required by this Agreement” in Article 1.<sup>246</sup>

Finally, all the Objectives of TRIPS enshrined in Article 7 will be violated.<sup>247</sup> The disproportionate increase in cost of medication *vis-à-vis* the per capita income will violate the “social welfare” objective.<sup>248</sup> The adverse effect on productivity, detailed in the next section, will affect “economic welfare.”<sup>249</sup> Lack of social and economic welfare itself deters foreign investment especially in countries facing public health crisis.<sup>250</sup> Thus, the “promotion of technological innovation” contemplated in Article 7 will be affected. In effect the Article 7 promise of mutual benefit from TRIPS to producers and users of technology will be compromised.<sup>251</sup> Such barriers also defeat the purpose of TRIPS enshrined in the preamble.<sup>252</sup> The preamble of TRIPS cautions against, “[m]easures and procedures to enforce intellectual property rights” from becoming “barriers to legitimate trade.”<sup>253</sup> TRIPS conveniently does not address what happens if enforcing IP rights itself becomes a barrier to trade.

Intellectual property laws have the ultimate objective of promoting the “public good” or “public benefit.”<sup>254</sup> TRIPS itself was drafted to reduce distortions in trade so that all members could benefit.<sup>255</sup> Therein lies the public benefit rationale envisaged by

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245. See *supra* Part III.B.

246. See TRIPS, *supra* note 3, art. 1.

247. See TRIPS, *supra* note 3, art. 7.

248. See also ‘t Hoen, *supra* note 35, at 30; Seeratan, *supra* note 35, at 388 (discussing that TRIPS will result in increase in cost of medication).

249. See *supra* Part IV.B.

250. Seeratan, *supra* note 35, at 382–86, 389–90; see also EDWIN MANSFIELD, INTELLECTUAL PROPERTY PROTECTION, FOREIGN DIRECT INVESTMENT, AND TRANSFER OF TECHNOLOGY (International Finance Corporation, Discussion Paper No. 19, 1994) (arguing that in the long run TRIPS is likely to facilitate foreign investment). *But see* Paul Heald, *A Critical Analysis of Mansfield’s Canonical Study*, INTERNAT’L FIN. CORP. DISCUSSION PAPER #19 (1994).

251. See TRIPS, *supra* note 3, art. 7.

252. See TRIPS, *supra* note 3, art. 7, pmbl.

253. *Id.* pmbl.

254. The public good and benefit theories are essentially mandated by the Constitution of the United States. See U.S. CONST. art. I, § 8, cl. 8. See generally Divya Murthy, *The Future of Compulsory Licensing: Deciphering the Doha Declaration on the TRIPs Agreement and Public Health*, 17 AM. U. INT’L L. REV. 1299, 1327 (2002) (deciphering the definition of the term public health).

255. See TRIPS, *supra* note 3, pmbl. A major objective of the TRIPS Agreement is to

TRIPS.<sup>256</sup> Moreover, the preamble of TRIPS recognizes the “public policy objectives of national systems . . . including developmental . . . objectives” and supports the proposition that public benefit is the cornerstone of the intellectual property rights theory.<sup>257</sup> Currently, the function of TRIPS, especially concerning the poverty penalty, can be justified only if those who live outside of developed nations are excluded from the definition of “public.” Neither intellectual property law nor international law adequately supports such a construction. Because of this construction, the public benefit doctrine should be treated as a limitation on intellectual property rights—particularly patents. Article 31 of TRIPS, read with the Doha Declaration, supports such a construction by authorizing governments to use the “flexibilities” approach of Doha to tackle national objectives.<sup>258</sup> Moreover, the reaction of developed nations to the anthrax crisis should serve as a precedent in support of the public benefit rationale of Article 31.

### B. *The Effect of the Poverty Penalty on Developing Nations*

All nations embrace intellectual property rights as a means to further development. Patents largely have enabled the residents of developed nations to access high-priced life-saving drugs.<sup>259</sup> TRIPS implies that patents will further research and development.<sup>260</sup> This section demonstrates the effect of the poverty penalty on local conditions.

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“reduce distortions and impediments to international trade, and tak[e] into account the need to promote effective and adequate protection of intellectual property rights, and to ensure that measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade . . .” *Id.*

256. *Id.*

257. *Id.*

258. *See id.*, art. 31; *see also* Doha Declaration, *supra* note 25, at cl. 5.

259. *See* Tina Rosenberg, *Look at Brazil*, N.Y. TIMES MAG., Jan. 28, 2001, at 26, 28, available at <http://www.nytimes.com/library/magazine/home/20010128mag-aids.html> (last visited Mar. 31, 2004). In Brazil, drug manufacturers, in return for the risks of developing new drugs, receive a twenty-year market exclusivity. *Id.* at 28.

260. *See* Avedissian, *supra* note 227, at 251 (citing the discovery of new drugs through incentives for future research and development as a long-term objective of TRIPS). However, owing to the lack of the developing nation markets to bear the cost of patented products, patents have resulted in lack of research on diseases unique to developing nations and deprived these markets from access to essential medication. Only nations with a vibrant generic drug market like India have been able to provide access to medication and thus offset the cost of TRIPS. Jeffrey Sachs, *Helping the World's Poorest*, ECONOMIST, Aug. 12, 1999, at 18–19. *But see* Rosenburg, *supra* note 259 (arguing that even India should do more).

For instance, within developing nations, AIDS-infected people with limited access to testing and medication have spread the infection. Lack of medication has affected standards of living, sometimes permanently, either from loss of loved ones or loss of good health. An epidemic increase of AIDS reduced life expectancy and affected labor and economic output, as the younger casualties increase.<sup>261</sup> Consequently, national productivity declined in several developing nations since the loss of labor from the loss of each life affected a proportionate value of output.<sup>262</sup> That is, when AIDS assumed epidemic proportions, the loss of adult labor impacted overall economic output in every sector, ranging from health, to tourism, to agriculture and to mining.<sup>263</sup>

Assuming that a person's productivity is derived from several indicators, such as: living conditions; earning potential; or per capita income; the loss of each adult life in his/her most productive age represents an equivalent deprivation of productivity to the economy.<sup>264</sup> Thus, the loss each developing nation suffers by not taking adequate steps to curtail AIDS at the appropriate juncture is represented by the resulting cumulative loss of productivity ("V<sub>p</sub>") as follows:

$V_p = (v * (m-n))$ ; where, "v" represents the average individual productivity; "n" represents the number infected with AIDS at a time when an epidemic infection could have been prevented by supplying adequate medication;<sup>265</sup> and "m" represents the total infected population in any given year. Assuming that every year the AIDS-infected population, in turn, infects an average percentage of healthy population represented by "x," the number in-

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261. See BOLLINGER & STOVER, *supra* note 117, at 3. Epidemic outbreaks potentially affect several sectors of the international economy and stunt international markets. *Id.*; see also Rebecca Buckman, *Outbreak Crimps Toy Industry's Buying Season*, WALL ST. J., Apr. 30, 2003, at B1 (discussing that the outbreak of SARS in China has affected sales in even smaller industries, like the toy industry, and impacted the sales of several American retailers).

262. See BOLLINGER & STOVER, *supra* note 117, at 12.

263. See *id.* at 5-11.

264. For example, the United States Environmental Protection Agency values human life at an average of \$6 million, while the Department of Transportation valued human life at \$3 million. See John J. Fiakla, *Balancing Act: Lives vs. Regulations*, WALL ST. J., May 30, 2003, at A4 (discussing some of the issues concerning amendments to the standard statistical measures to value human life).

265. See *supra* Part III.A.1. For example, for South Africa, *n* will be represented by the number of AIDS infected persons in 1996, when South Africa requested medicines at low costs from the United States.

fectured in “y” years would be “ $m = n * (1+x)^y$ .” Thus  $V_p = v * (m-n)$ <sup>266</sup> represents the cumulative loss of productivity for each developing nation because of not being able to take adequate action at the appropriate time.

The cumulative loss of productivity is limited to the loss from labor alone. It specifically does not include the total loss from other factors of productivity—“total factor productivity”—from costs affecting the economy. Examples of other costs range from the increasing cost of employee medical benefits to the deterrence such costs create for foreign investments.<sup>267</sup> For example, the increased incidence of AIDS in South Africa will raise the cost of employee medical benefits from 7% of income in 1995 to 19% of income by the year 2005.<sup>268</sup> The increased cost of employee benefits have impacted the overall economic productivity and output, especially since the additional costs have been at the same time that productivity is declining.<sup>269</sup> This is represented by the formula,  $L_p = [V_p + \text{Cost of AIDS care} + \text{other miscellaneous costs}]$ . “ $L_p$ ” represents the total loss of productivity. “ $L_p$ ” refers to the decline in economic productivity in developing nations alone because they were prevented from prioritizing national responsibilities.<sup>270</sup> The poverty penalty is, at the minimum, equal to the loss of productivity represented by  $L_p$ .

Critics may argue that labor productivity is not the only element of economic development and that TRIPS facilitates foreign investments. However, in most poor nations, labor has been, and continues to remain, the main factor of productivity.<sup>271</sup> TRIPS, unfortunately, has affected the sole source of economic productivity without supplementing or substituting the loss of labor productivity with other sources of economic development. The diminishment of the main factor of productivity—labor, in this case, due to increased disease conditions—has detrimentally affected other sources of economic development, like foreign investments.<sup>272</sup> Foreign investors naturally lose incentive to invest in countries where the main factor of productivity is quickly declin-

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266.  $L_p = v * (n * (1+x)^y - n)$ ; i.e.,  $L_p = v * (m-n)$ .

267. See, e.g., BOLLINGER & STOVER, *supra* note 117, at 6.

268. *Id.*

269. *AIDS Toll on Regional Economies*, SOUTHERN AFRICAN ECONOMIST, May 15, 1997.

270. See *supra* Part IV.B.

271. See also BOLLINGER & STOVER, *supra* note 117, at 3.

272. See *id.* at 3.

ing due to disease. Thus, the deterrence of the AIDS epidemic to foreign investors is higher than the incentive to investment from signing TRIPS. For example, AIDS affected the profitability of Anglo American, a mining conglomerate with operations in Africa, by causing absenteeism, deaths, and increased medical costs for AIDS-related illnesses.<sup>273</sup> The company was on the verge of losing 30,000 members of its South African workforce to AIDS.<sup>274</sup> As such, Anglo American decided to bear the cost of treating its infected employees and their spouses.<sup>275</sup>

Such increases in medical expenditures serve as disincentives to investment. The existing application of TRIPS does little to alleviate the disincentives caused by AIDS and other communicable diseases. Some studies project that the benefits from TRIPS will manifest themselves only in the long run.<sup>276</sup> The AIDS epidemic, however, threatens to wipe out nations from existence in the short run<sup>277</sup>—long before the benefits from TRIPS can be manifested. So far, the only economically perceivable result of the post-TRIPS era for poorer African countries has been the increase in the AIDS epidemic. There certainly has been no evidence of any significant increase in foreign investment from TRIPS in any of these poorer countries.<sup>278</sup> On the other hand, measurable eco-

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273. See *Follow My Lead*, *ECONOMIST*, Oct. 11, 2003, at 68–69.

274. *Id.*

275. *Id.* at 68–69.

276. See Robert M. Sherwood, *The TRIPS Agreement: Implications for Developing Countries*, 37 *IDEA* 491, 493–95 (1997). “[T]he impact of the TRIPS Agreement on most developing countries is likely to be slightly negative in the short run (one to two years) and increasingly favorable as local firms and individuals begin to realize the potential benefits for their activities.” *Id.* at 510. Sherwood, however, notes that TRIPS may be able to promote foreign investment, but will not be an aide in encouraging domestic research and development. *Id.* at 495, 508. See generally Keith E. Maskus, *Intellectual Property Challenges for Developing Countries: An Economic Perspective*, 2001 *U. ILL. L. REV.* 457 (2001) (arguing that expanded property rights protection is needed to promote long-term economic growth and technological innovations in developing countries).

277. See *The World Today: Bush To Visit African Nations*, (ABC NEWS television broadcast, July 7, 2003), available at <http://www.abc.net.au/worldtoday/content/2003/s896693.htm> (last visited Mar. 31, 2004) (detailing the plight of African nations and their fight for survival); see also Jenni Fredriksson-Bass & Annabel Kanabus, *HIV & AIDS in Botswana*, *AVERT* (2003), at <http://www.avert.org/aidsbotswana.htm> (last visited Mar. 17, 2004).

278. See Carlos A. Primo Braga & Carsten Fink, *The Relationship Between Intellectual Property Rights and Foreign Direct Investment*, 9 *DUKE J. COMP. & INT'L L.* 163, 181 (1998) (concluding that there is no evidence that IP rights result in increased foreign direct investments—although IP rights have such a potential, provided other political, social, and economic factors coincide—and arguing that developing countries now reforming their IP rights regimes offer a unique opportunity for before and after studies).

conomic growth has in fact occurred in China and India, both of which refuse to fully comply with TRIPS.<sup>279</sup> This argument does not undermine the requirement that poor countries need to encourage foreign investment by improving fiscal discipline, promoting IP rights, and reducing government regulatory burdens.

Other critics argue that some countries, especially African nations, were poor before signing TRIPS. Poor nations, however, signed TRIPS not out of an ideological commitment to intellectual property rights but in the hope of improving national living conditions.<sup>280</sup> Implicit in the decision to sign TRIPS was either improving living standards or leaving the status quo unaltered. TRIPS, however, has not only made these countries poorer but has also eroded national health.<sup>281</sup> The poverty in these nations before TRIPS was signed cannot become a justification for the WTO to worsen or even maintain the status quo of living conditions. The success of TRIPS and intellectual property rights will not be judged by its ideological righteousness, but in the ability to improve living conditions.

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279. See DOMINIC WILSON & ROOPA PURUSHOTHAMAN, GLOBAL ECONOMICS PAPER NO. 99: DREAMING WITH BRICS: THE PATH TO 2050, GOLDMAN SACHS GLOBAL ECONOMICS RESEARCH (Oct. 1, 2003), available at <http://www.gs.com/insight/research/reports/99.pdf> (last visited Mar. 31, 2004) (arguing that Brazil, Russia, India, and China—the BRICs economies—in less than forty years, will together account for over half the size of the G6); see also *Follow the Yellow BRIC Road*, ECONOMIST, Oct. 11, 2003, at 74 (arguing that the Chinese economy will become bigger than any of the G7 economies, which consist of the United States, Japan, Germany, France, Britain, Italy, and Canada); *Ying and yuan*, ECONOMIST, Aug. 30, 2003, at 53–54 (stating that the GDP grew at an annual rate of 8.2% in the first half of this year, compared with an official target of 7%); Press Release, Embassy of the People's Republic of China in the Kingdom of Norway, China to Achieve 8% Growth in Late-Half (Sept. 4, 2003), at <http://www.chinese-embassy.no/eng/55520.html> (last visited Mar. 31, 2004) (detailing that the projected increase in the Chinese annual growth is 8% of the GDP); Drew Kershen, *Innovations in Biotechnology—Public Perceptions and Cultural Attitudes: An American's Viewpoint*, Presentation at the Department of Justice—Canada, 2002 Biotechnology Conference, Ottawa, Canada, Feb. 21, 2002, (contrasting the setbacks from the Imperial Chinese's attitude towards globalization against the gains from the American willingness to take domestic risks by opening global trade as a trendsetter for the rest of the world). See generally *Tilting at Dragons*, ECONOMIST, Oct. 25, 2003, at 65 (detailing that America's exports to China rose by 21% during the past year, compared with an increase of 2% in sales to the rest of the world). The study by Goldman Sachs adds that the total output of the BRICs (Brazil, Russia, India and China) economies will overtake that of the G6 in less than forty years). See WILSON & PURUSHOTHAMAN, *supra*.

280. See Thomas F. Mullin, *AIDS, Anthrax, and Compulsory Licensing: Has the United States Learned Anything?*, 9 ILSA J. INT'L & COMP. L. 185, 188 (2002).

281. See Vincent Chiappetta, *The Desirability of Agreeing to Disagree: The WTO, TRIPS, International IPR Exhaustion and a Few Other Things*, 21 MICH. J. INT'L L. 333, 337 (2000).

### C. National Distress and the Effects on Global Welfare

This section argues that neither on a national nor on a global level did the poverty penalty suffered by developing nations yield any perceivable benefit justifying the manner of operation of TRIPS. Without discussing the general benefits of TRIPS, this section argues that there has been no economic benefit from TRIPS to offset the loss of productivity developing nations suffered from the TRIPS impediment to accessing medication.

Within the developing nations TRIPS has not resulted in any significant increase in foreign direct investments (“FDI”) or other economic benefits to offset the economic loss suffered from not preventing or treating AIDS adequately at the appropriate juncture. This may be expressed as [*National gains from FDI*] <  $L_p$ . Similarly, at a global level, TRIPS has not resulted in any perceivable trade or economic benefit to offset the cumulative loss of productivity—expressed as (“ $L_{PC}$ ”)—in several developing countries. Therefore, global economic gain is less than  $L_{PC}$ , where  $L_{PC}$  refers to the total loss of productivity of all developing nations.

Instead, international trade is bound to have been affected from the consequential impact of AIDS on labor productivity in developing countries.<sup>282</sup> The effect of Severe Acute Respiratory Syndrome (SARS) on national economies is a case to the point.<sup>283</sup> The outbreak of SARS in China affected several economies by impacting international air travel and tourism.<sup>284</sup> The SARS precedent only reinforces the argument that preventing an outbreak by providing medication (even by reducing the price of medication) can be more cost effective solution for achieving the TRIPS objective of betterment of international trade. In fact, on a global level, the loss of economic productivity in developing nations due to AIDS has not significantly improved global trade or welfare enough to justify imposing TRIPS in a manner that prevented ac-

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282. See generally, Interview by Siddhartha Prakash, WTO Consultant with B.K. Raizada and Ajit Yadav, Vice-President and Legal Services Director, Ranbaxy India Limited, Trade and Development Case Studies, (1998) [hereinafter Raizada Interview], available at [http://www.itd.org/issues/india\\_5a.htm](http://www.itd.org/issues/india_5a.htm). (last visited Mar. 31, 2004).

283. See Rebecca Buckman, *supra* note 261, at B1 (discussing that the outbreak of SARS in China has affected sales in even smaller industries like the top industry and impacted sales of several American retailers); see also Nadia Natasha Seeratan, *The Negative Impact of Intellectual Property Patent Rights on Development Countries: An Examination of the Indian Pharmaceutical Industry*, 3 SCHOLAR 339, 346, 388–89 (2001).

284. Buckman, *supra* note 283, at B1, B5.

cess to life saving medication. Global trade additionally suffered because the commitment to save the AIDS infected translated into costs for the developed nations.<sup>285</sup> It is too soon to analyze whether the cost to the United States—assuming AIDS remains uncontained—will exceed the gains that the American economy would have realized had the developing world embraced patented pharmaceuticals at the outset. In any case, the war on terror has highlighted that destroying the sense of hope by depriving medication in already fragmented, poor societies results in furthering fundamentalism rather than global trade.<sup>286</sup> Global development and democracy has inevitably become a subset of the global and United States trade paradigm.<sup>287</sup> The symbiotic relationship that should result between the developed and developing nations will hopefully reduce the poverty penalty by exemplifying that global trade regimes cannot be isolated from global welfare.<sup>288</sup> The success of international conventions is not in ignoring global welfare by favoring global trade, but in making welfare efforts, like Article 31 of TRIPS, functional within the trade agenda.

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285. For example, the American government budgeted \$480 million in foreign assistance to contain AIDS. Later, the United States promised \$200 million to fight AIDS in Africa specifically. See Michael M. Phillips, *Rapt Powell Hears of AIDS Suffering*, WALL ST. J. EUR., May 29, 2001, at 2; see also Michael M. Phillips, *Big Boost in U.S. AIDS Spending Eases Powell's Reception in Africa*, WALL ST. J., May 24, 2001, at A24. The President's Emergency Plan for AIDS Relief releases \$15 billion over five years for HIV/AIDS relief. See Martin Hutchinson, *Will U.S. AIDS Cash Make a Difference?*, BBC News, at <http://news.bbc.co.uk/2/hi/health/2943572.stm> (last visited Feb. 25, 2004). Additionally, the United States announced, on December 20, 2002, its intention to permit poor countries to override patents of medications used to treat HIV/AIDS, malaria, tuberculosis, and other infectious epidemics, including those that may arise in the future. Press Release, Office of the Press Secretary, Fact Sheet: The President's Emergency Plan for AIDS Relief (Jan. 29, 2003), available at <http://www.whitehouse.gov/news/releases/2003/01/20030129-1.html> (last visited Mar. 31, 2004). After resisting developing nations until AIDS became an epidemic, the United States government determined that overriding patents "is an immediate, practical solution that will provide life-saving drugs to those truly in need." *Id.*

286. See Robert Zoellick, *Free Trade, Free People*, WALL ST. J., Nov. 4, 2002, at A14. The United States realized that when poor people are denied basic necessities, they become easy prey to destructive fundamentalism. *Id.*

287. See *id.* The current trade policy of the United States is not limited to internal trade interests. Today's trade agenda emphasizes that the entire world has a stake in development and democracy. *Id.* Developed nations need the help of developing countries like India, Pakistan, and even underdeveloped nations like Somalia, as much as these countries need the developed nations for trade.

288. See Cooper & Winestock, *supra* note 119, at A1 (stating that "[i]n an effort to keep poorer nations on their side in the war on terrorism," United States and European negotiators made big concessions reflecting the new realities of the post-September 11, 2001 world).

#### D. *Poverty Penalty and Loss to Pharmaceutical Industries*

This section argues that the poverty penalty has in fact resulted in a loss of opportunity cost to the pharmaceutical industry. It questions the economic and legal viability of the pharmaceutical industry's policies that refuse to consider alternate but mutually beneficial solutions.

The AIDS crisis in developing nations has altered the drug industry's standing in the United States.<sup>289</sup> For example, immediately following the South African AIDS crisis, the drug industry's dominance over the American trade policy suffered, leading to a reversal of policy by the Clinton administration.<sup>290</sup> The influence over the Bush administration is circumscribed by the international nature of the AIDS issue.<sup>291</sup> The local paradigm shift has enabled developing nations to consolidate their demands.<sup>292</sup> The

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289. See generally Rosenberg, *supra* note 259, at 26 (detailing that the breaking of the "trade in fear" effect of violating IP laws has coincided with the internal pressures to fulfill national responsibilities). The awareness that displeasing American pharmaceutical manufacturers can no longer automatically land them on a trade watch list provides a dramatic bargaining power for developing countries. *Id.*

290. See *supra* notes 76–78 and accompanying text.

291. See Adams & Hitt, *supra* note 136, at A3. See generally Rose, *supra* note 47.

292. The WTO Ministerial Conference was held in Qatar on September 19, 2001. The Conference highlighted the importance for WTO members to use the TRIPS flexibilities to deal with pandemics. See *WTO News: Members Discuss Drafts for Ministerial Declaration*, WORLD TRADE ORGANIZATION, Sept. 19, 2001 at [http://www.wto.org/english/news\\_e/news01\\_e/trips\\_drugs\\_010919\\_e.htm](http://www.wto.org/english/news_e/news01_e/trips_drugs_010919_e.htm) (last visited Mar. 31, 2004). The Conference culminated in the Doha Declaration. See Doha Declaration, *supra* note 25, cls. 4, 5, 6. The Declaration provides wide discretion to member countries. *Id.* Clause 5(b) of the declaration, in granting the right to compulsory licensing, establishes the right to either seek reduction of price or local manufacture of drugs. *Id.* cl. 5(b). In recognition of the "special needs" of developing nations, the Declaration validates establishment of generic drug industries locally, even during the patent term. *Id.* cl. 7. While maintaining commitments in the TRIPS agreement, member states can establish national regimes of exhaustion and determine whether and what constitutes a national emergency to compulsorily license IP rights. The transition period for the least developing signatories extends until 2016 with a right to seek further extensions. See TRIPS, *supra* note 3, art. 66(1). Article 65(1), read with Article 66(1) of TRIPS, provides the least developed countries until 2005 to implement TRIPS. *Id.* arts. 65(1), 66(1). The Doha Declaration has extended the transition period until 2016 specifically with reference to pharmaceutical products. See Doha Declaration, *supra* note 25, cls. 5, 7. Part II of TRIPS deals with standards concerning the availability, scope and use of IP rights. See TRIPS, *supra* note 3, Part II. Section 5 discusses standards for patent harmonization and section 7 discusses the standards for protection of undisclosed information. *Id.* Part II.5. In countries where production of generic drugs are impossible, Clause 6 delegates the task of seeking the solution to enable local production of generic drugs. By the end of 2002, the Council for TRIPS was entrusted with the task of finding an appropriate solution. *Id.* For a general discussion of the drug indus-

resulting declaration at Doha (“Doha Declaration”) established that IP laws cannot operate exclusively from national responsibilities.<sup>293</sup> The Declaration itself represents a loss of opportunity for the pharmaceutical industry to gain entry into the developing nations’ markets, which can be illustrated as follows.

The pharmaceutical industry refused the option of differential or discounted pricing at the earlier stages of the AIDS crisis when an epidemic infection could have been averted.<sup>294</sup> Negotiating a uniform discounted price for developing nations would have generated the following revenues for the pharmaceutical industry:

$$\text{Revenue}_{\text{Negotiated}} = X * (\text{Price}_{\text{Negotiated}}) * (\text{Consumers}_{\text{Negotiated}})$$

Here,  $X$  represents all the developing nations that would have embraced patented pharmaceuticals as required under TRIPS.  $\text{Price}_{\text{Negotiated}}$  represents the average negotiated price.  $\text{Consumers}_{\text{Negotiated}}$  represents the average number of consumers.

When AIDS assumed epidemic proportions, price cuts at a much higher percentage occurred.<sup>295</sup> Further bulk price discounts replaced negotiated price cuts when third-world governments,

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try’s response to the World Trade talks in Qatar, see Gardiner Harris & Rachel Zimmerman, *Drug Makers Say WTO Setback Will Not Have Significant Impact*, WALL ST. J., Nov. 15, 2001, at B5.

293. See James Thuo Gathii, *The Legal Status of the Doha Declaration on TRIPS and Public Health Under the Vienna Convention on the Law of Treaties*, 15 HARV. J. L. & TECH. 291, 296 (2002). See generally ‘t Hoen, *supra* note 35, at 34–35.

294. TRIPS, *Pharmaceutical Patents, and the HIV/AIDS Crisis: Finding the Proper Balance Between Intellectual Property Rights and Compassion*, 7 WIDENER L. SYMP. J. 175, 195 (2001).

295. Merck dropped the price of two antiretroviral drugs, Crixivan (indinavir sulfate) and Stocrin (efavirenz), from \$6,000 to \$600 and \$500, respectively. Sarah Bosely, *Embarrassed Firms Slash AIDS Drug Prices*, GUARDIAN, (March 12, 2001), available at <http://www.guardian.co.uk/aids/story/0,7369,450388,00.html> (last visited Mar. 31, 2004.). Glaxo–SmithKline offered Combivir at \$730 from \$6,289. Gardiner Harris, *AIDS Gaffes in Africa Come Back To Haunt the Drug Industry in the U.S.*, WALL ST. J., Apr. 23, 2001, at A1. Roche Holdings lowered prices by more than 63% of the original cost. See generally Charlotte Denny, *A Spoonful of Sugar Will Not Help*, GUARDIAN, Apr. 19, 2001, available at <http://www.guardian.co.uk/aids/story/0,7369,475344,00.html> (last visited Mar. 31, 2004); Rosenberg, *supra* note 259, at 26; Michael Waldholz & Rachel Zimmerman, *Bristol–Myers Offers to Sell Two AIDS Drugs in Africa at Below Cost*, WALL ST. J., Mar. 15, 2001, at B1 (detailing that Bristol–Myers lowered its price well below cost and Merck lowered price by 55% to compete with the prices offered by an Indian generic drug company—Cipla Pharmaceuticals).

unable to fulfill dire national responsibilities, assumed an offensive posture.<sup>296</sup> This may be represented as:

$$Revenue_{Discounted} = Y * (Price_{Discounted}) * (Consumers_{Discounted}).$$

In this formula,  $Y$  represents countries embracing branded pharmaceuticals— $Y$  being less than  $X$  since countries with low per capita income and high incidence of AIDS will embrace generic drugs.  $Price_{Discounted}$  represents the discounted price in the wake of the AIDS crisis.  $Consumers_{Discounted}$  represents the increased number of consumers since AIDS assumed epidemic proportions.

Although the  $Price_{Discounted}$  is less than the  $Price_{Negotiated}$ , the increase in  $Consumers_{Discounted}$  would offset the loss the pharmaceutical industry would suffer from discounting the prices.<sup>297</sup> The real cost to the industry because of failing to price differentially<sup>298</sup>—termed the “Late Negotiating Cost” (“LNC”)—derived as follows:

$$LNC = (Revenue_{Negotiated} - Revenue_{Discounted}) + Revenue_{Generic}$$

In this formula,  $Revenue_{Generic} = G * (Price_{Generic}) * (Consumers_{Generic})$  where  $G$  represents countries using the option under clause 6 of the Doha Declaration to produce generic drugs locally—for example, countries such as India, Brazil or Thailand.

The loss to the industry, owing to the legitimization of the generic drug industry, will largely be from the  $Revenue_{Generic}$ . That is, an increase in  $Revenue_{Generic}$  will represent a proportionate loss of opportunity for the pharmaceutical industry to tap the respective markets.<sup>299</sup> For example, the drug industry lost the opportunity

296. For example, Brazil's threat to compulsorily license AIDS drugs forced Merck to slash prices of two AIDS drugs by 65% and 95%. Roche followed with a 40% discount, finally settling for a price 70% less than the original cost. See Rich, *supra* note 94, at C1. Brazil's reaction was triggered by Roche's refusal to reduce the cost of AIDS medication beyond 13% of the cost. See Jennifer Rich & Melody Peterson, *Brazil Will Defy Patent on AIDS Drug Made by Roche*, N.Y. TIMES, Aug. 23, 2001, at C6.

297. The reduction in price has resulted in an increased volume of purchases by third-world countries. For example, the Brazilian government is buying 20,000 daily doses of Crixivan, Merck's brand of indinavir, a tenth of the drug's worldwide sales. See Rosenberg, *supra* note 259, at 26. Moreover, the volume of sales remains high since people newly infected with HIV become AIDS patients soon. Thus the increased volume sales compensates for the reduction of prices. *Id.*

298. Differential pricing could either be different prices for different nations depending on the per capita income and other relevant considerations specific to the nation, or a different price for developing and developed nations. See *Brains v. Bugs*, ECONOMIST, Nov. 10, 2001, at 6 (supporting the idea of differential pricing).

299. For example, in 1995 alone the USTR estimated a loss from the then illegitimate

until 2016 to handhold least-developed nations into the product patent regime.<sup>300</sup> Least-developed nations are most likely to promote generic drug companies, for the obvious benefits, and will not be the best potential future markets for the pharmaceutical companies.

LNC is also affected by other intangible factors. For example, within fifty years of its inception, the generic drug industry has emerged as an alternate, affordable supplier of patented medication in developing countries. Countries like India, Thailand, and Brazil even export the low-cost drugs. At a time when TRIPS was interpreted strictly, without any flexibility, the generic drug industry managed not only to survive, but to legitimize itself through the Doha Declaration.<sup>301</sup> Given this fact, the probability that the generic drug industry could consolidate itself in the future is greater. If the industry consolidates, it will result in a further erosion of market share for the “traditional” pharmaceutical industry.<sup>302</sup> Moreover, having gained the option to use generic drugs, third-world governments could, in the future, resist increases to drug prices thus keeping *Price<sub>Discounted</sub>* low, or *Revenue<sub>Generic</sub>* high. Developing nations, having consolidated their challenges to branded pharmaceuticals, will use the strategy of altering the pricing terms of patents to access medication. The pharmaceutical industry should work toward a solution that is mutually beneficial. Instead, the pharmaceutical industry continues to lobby to limit the Doha Declaration to specific diseases.<sup>303</sup> Drug manufacturers presume that limiting the number of diseases falling within the Doha Declaration will prevent undermining of their patent rights.<sup>304</sup> The strategy of blocking developing nations from

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Indian generic drugs at \$450 million per annum. 1995–1996 USTR ANNUAL TRADE REPORT: INDIA, available at [http://www.ustr.gov/html/1995\\_india.html](http://www.ustr.gov/html/1995_india.html) (last visited Mar. 31, 2004.).

300. The Doha Declaration exempts the least developing nations from the pharmaceutical patents provisions in TRIPS. See Doha Declaration, *supra* note 25, cl. 6.

301. See *id.*

302. See Marilyn Chase, *Lilly Plans*, WALL ST. J., Jun. 5, 2003, at B1 (detailing that Eli Lilly has embarked on a program to work with generic drug companies in India, China, Russia, and South Africa to transfer the technology of making and marketing tuberculosis drugs).

303. See Roger Thurow & Scott Miller, *As U.S. Balks on Medicine Deal, African Patients Feel the Pain*, WALL ST. J., June 2, 2003, at A1. Limiting the Doha Declaration to specific diseases will result in depriving populations within developing nations of medication for diseases such as diabetes and heart disease.

304. *Id.*

accessing drugs lacks legal validity and is distinctly shortsighted for failing to take current global realities into consideration.<sup>305</sup>

This strategy lacks legal validity because the Doha Declaration relates to HIV, malaria, and “other epidemics,” thus establishing that the term epidemics cannot be restrictively defined.<sup>306</sup> Clause 4 of the Declaration subjects the TRIPS commitments to the members’ right to protect public health by promoting access to “medicines for all.”<sup>307</sup> The Declaration also establishes the right of members to interpret TRIPS in light of their public policy objectives and establishes the use of the TRIPS flexibilities to protect public health.<sup>308</sup> Since an epidemic from any disease can potentially affect public health, restricting the definition of “epidemics” will violate the Doha commitment to public health. If the pharmaceutical industry tries to restrict the definition of the term “epidemics,” developing nations are likely to argue that third-world generic drugs fall within the definition of “flexibilities” and thus will produce generics for all of the excluded diseases.<sup>309</sup> The term “epidemics” has been left undefined in the Doha Declaration, enabling nations to decide what an epidemic is based on national standards.<sup>310</sup> Hence the pharmaceutical industry’s restricted use of the term for its own benefit will be construed to violate TRIPS.

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305. *Id.* at A9. The industry’s inability to forge long-term solutions has earned it a reputation comparable to that of the tobacco industry. *See Is Big Pharma the Next Target for Attack?*, *ECONOMIST*, Apr. 26, 2003, at 53 (“Big Tobacco, Big Banking—and now Big Pharma? . . . Like the tobacco firms and investment banks before them, drugs firms face a dynamic, grass-roots movement, centered on the states and driven by powerful economics, that by-passes their well-financed defences in Washington D.C.”); *see also* Russell Gold & Andrew Caffrey, *States Suing Drug Makers Spurn Former Allies on Tobacco*, *WALL ST. J.*, May 29, 2002, at B1.

306. *See* Doha Declaration, *supra* note 25, cl. 5(c). Clause 5(c) establishes that developing nations can decide what an epidemic is and whether an epidemic is prevalent based on national standards. “Each member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.” *See id.* cl. 1.

307. *Id.* cl. 4 (“[W]hile reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members’ right to protect public health and, in particular, to promote access to medicines for all.”).

308. *Id.* cl. 4.

309. *Id.* cl. 5.

310. *Id.* art. 1. In return for such freedom, countries have kept their sovereign commitment not to reduce the line between important and necessary drugs.

The strategy of blocking developing nations from access to drugs is also shortsighted because, if deprivation of medication and worsening disease conditions were the two decisive factors, developing nations would have moved to the patent regime in the 1950s. Instead, this strategy led to the genesis of the generic drug industry.<sup>311</sup> A combined impact of several diseases in more than one nation, even over a period of time, will be detrimental to world economic progress. As more economies succumb to diseases, the impact on trade will force a dilution of either pharmaceutical patents or prices. Moreover, the strategy of depriving developing nations of medication until they find the means to fund branded products caused the WTO to reestablish the TRIPS Agreement's public benefit rationale of patents through the Doha Declaration.<sup>312</sup> Continuing to deprive developing nations of essential medication, even for a limited number of diseases, will increase the prevailing suspicions over the ability of IP rights as incentives and thus strengthen the generic drug industry.<sup>313</sup> Even

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311. The generic drug industry itself did not develop as a business model, but rather as a desperate, alternate means to access drugs. Developing countries searched for alternatives when they realized that the pricing structure of pharmaceuticals lacked a coherent connection with local economic realities. For example, when India became independent in 1947, multinational drug companies supplied 90% of the medicines. The drug prices were so high that in 1961, India ranked among the highest priced nations in the world for drugs. Around 50% of India's population lived in poverty and were unable to afford drugs. A United States Senate committee headed by Senator Estes Kefauver remarked that drug prices in India were among the highest in the world. Around the same period, the first five-year plan reflected that India had the largest reservoir of epidemic diseases, accounting for 5.1% of the total mortality. See GOV'T OF INDIA PLANNING COMM'N, FIRST FIVE-YEAR PLAN § 32.3 (1956) [hereinafter FIRST FIVE-YEAR PLAN], available at <http://planningcommission.nic.in/plans/planrel/fiveyr/default.html> (last visited Mar. 31, 2004); see also Press Release, The World Bank, India Shows Mixed Progress in the War Against Poverty (Aug. 25, 1997), at <http://www.worldbank.org> (last visited Mar. 31, 2004) (discussing mortality rates). Making pharmaceuticals affordable became an emergency requirement. Since multinational drugs companies were not willing to negotiate cost, India established Hindustan Antibiotic Limited in 1954 to manufacture drugs at a cheaper cost for the public. Hindustan Antibiotics Limited Health-Care and Agrovet Products, Profile (1999), at <http://www.hindantibiotics.com/htdocs/profile.html> (last visited Feb. 25, 2004). This first step led to a thriving generic industry in India. *Id.* Critics argue that India would have benefited more had they established a patent regime with thriving research and development as early as 1950. Unfortunately, during that period, India neither had the financial potential to invest in research and development nor did it possess the intellectual prowess of the current period. The First Five-Year Plan records that a mere 14% of the population was engaged in industry. See FIRST FIVE-YEAR PLAN, *supra*, § 2.3, available at <http://planningcommission.nic.in/plans/planrel/fiveyr/default.html> (last visited Mar. 31, 2004).

312. See generally Samuel Oddi, *TRIPS—Natural Rights and a “Polite Form of Economic Imperialism,”* 29 VAND. J. TRANSNAT'L L. 415 (1996) (discussing natural rights and suggesting strategies for developing countries to cope with TRIPS).

313. See *Brains v. Bugs*, *supra* note 298, at 6 (discussing the developing countries' sus-

when deprivation of medication was combined with the threat of a public health crisis and the pressure of trade sanctions, developing nations chose to legitimize the generic drug industry rather than move toward a patent regime.<sup>314</sup> As demonstrated above, had the pharmaceutical industry averted health crises in impoverished nations by providing low cost drugs, it could have gained entry into the developing country markets. By now, the industry could have achieved the exclusivity it craves, since the generic drug industry would not have developed. Instead, the industry and developed nations overestimated the ability of economic sanctions to force governments to trade social justice for economic needs.<sup>315</sup>

## VI. SOLUTION

The possibility of a solution revolves around the question of whether a legal regime can be devised with a TRIPS system that caters to the needs of the developing nations, while at the same time ensures a return on investment for the drug industry. The drug industry's skepticism toward the impact of low-cost drugs will be justified if the success of the third-world generics either results in parallel importation or increases the demand within the United States for cheap imports or price controls.

While Article 31 of TRIPS and the Doha Declaration categorize specific remedies for countries facing a public health crisis, both address different stages of the problem. Article 31 responds to situations fulfilling the sovereign responsibility of providing immediate and imminent treatment to use a patent, if required, "without the authorization of the right holder."<sup>316</sup> Article 31 may be used to deal with an unexpected national public health emergency.

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pictions that the pharmaceutical industry devotes only a very limited percentage of its assets to research medication for diseases unique to developing nations). *See generally* Ragan, *supra* note 36.

314. *See generally* Doha Declaration, *supra* note 25.

315. Pricing realistically based on local economics can result in better return of investment rather than channeling enormous sums of money to find ingenious solutions to safeguard the lucrative home markets from copying. Typically, the expenditure involves promoting candidates who favor pharmaceutical patents, lobbying, advertisements, etc. *See* Tom Hamburger, *Drug Industry Moves to Boost Image Before Vote*, WALL ST. J., Sept. 16, 2002, at A6.

316. *See* TRIPS, *supra* note 3, art. 31.

The Doha Declaration, on the other hand, discusses measures governments may take proactively to provide access to medication.<sup>317</sup> The governmental right to take proactive measures was introduced into the Declaration late in 2001.<sup>318</sup> From 1992, when TRIPS was signed, until 2001, TRIPS lacked legal language recognizing the ability of third-world governments to take preventative measures that could in fact be globally significant.<sup>319</sup> Clause 4 of the Declaration authorizes use of measures “supportive of the WTO Members’ right to protect public health and, in particular, to promote access to medicines for all.”<sup>320</sup> On a plain reading it is unclear whether governments’ initiatives to “promote access to medicines” should only be to protect public health as opposed to preventing a public health crisis.<sup>321</sup> However, Clause 4, if interpreted in light of the objectives of TRIPS as provided for under Clause 5(a), will allow members to take proactive, preventive measures.<sup>322</sup> Moreover, Clause 5 also provides the flexibility for members to determine when a “circumstance[] of extreme urgency” exists—as opposed to a national emergency—warranting the use of TRIPS “flexibilities.”<sup>323</sup> Similarly, the “promote access to medicines” portion of Clause 4 enables governments to establish generic drug industries locally.<sup>324</sup> Special categories of members, that cannot or are unable to effectively use the compulsory

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317. Doha Declaration, *supra* note 25, cl. 4.

318. *Id.*

319. *Id.* See generally TRIPS, *supra* note 3.

320. Doha Declaration, *supra* note 25, cl. 4.

We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members’ right to protect public health and, in particular, to promote access to medicines for all.

*Id.*

321. *Id.*

322. *Id.* cl. 5(a). “[I]n applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles.”

*Id.*

323. *Id.* cl. 5.

324. *Id.* cl. 4; see Keith E. Maskus, Final Report to WIPO: Parallel Imports in Pharmaceuticals: Implications for Competition and Prices in Developing Nations (April 2001), available at [http://www.wipo.org/about-ip/en/studies/pdf/ssa\\_maskus\\_pi.pdf](http://www.wipo.org/about-ip/en/studies/pdf/ssa_maskus_pi.pdf) (last visited Mar. 31, 2004) (defining parallel importation as “goods produced genuinely under protection of a trademark, patent, or copyright, placed into circulation in one market, and then imported into a second market without the authorization of the local owner of the intellectual property right”).

licensing benefit due to lack of manufacturing capacity, are recognized under Clause 6.<sup>325</sup>

The pharmaceutical industry can work with governments promoting access to medication, proactively, at low cost, subject to an undertaking by the governments to prevent parallel importation. Article 31 authorizes such restrictions in adding that any use of compulsory licensing should be limited for domestic supply.<sup>326</sup> The industry may be able to separate out Clause 4 nations, which are capable of using the compulsory licensing scheme by producing low-cost generic drugs and Clause 6 nations which may be allowed to import the medication from Clause 4 nations. The agreements with the industry can be specifically designated to limit the marketing rights of Clause 4 nations to cater only to their national markets and to Clause 6 markets. In turn, the Clause 4 nations will be eligible for transfer of technology to make low-cost generic medication, according to Clause 7 of the Doha Declaration read with Article 66(2) of TRIPS.<sup>327</sup> Such agreements can cater to the transfer of technology to private or government parties approved by their respective governments to manufacture generic medications. In return for the technology transferred, the government should take the responsibility to prevent parallel importation at all levels, including through the Internet. Alternately, the industry can enter into agreements with Clause 6 nations to market patented medication at marginal cost or at comparable levels with the assurance from the respective government to prevent parallel importation.<sup>328</sup>

Using the opportunity, the industry can also make extensive efforts to educate people about intellectual property rights. This scenario will create an environment more appreciative of IP rights, rather than simply depriving the sick of medication. The solution will have the advantage of introducing the patent system in other fields of science and technology in developing nations, which could ultimately pave the way for harmonized, uniform IP regimes.

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325. Doha Declaration, *supra* note 25, cl. 6.

326. TRIPS, *supra* note 3, art. 31.

327. Doha Declaration, *supra* note 25, cl. 7; TRIPS, *supra* note 3, art. 66(2).

328. Doha Declaration, *supra* note 25, cl. 6. In any case, some of the world's poorest countries are in no economic position to even produce enough drugs for their national needs let alone import them from developed nations. See *Pill Paupers*, *ECONOMIST*, Dec. 19, 2002, at 10–11 (arguing that if differential pricing does not work, then the developed nations may be forced to bear the cost of some of the AIDS treatment for sheer lack of alternatives).

In devising a solution, the video and computer industries, by example, demonstrate that re-importation of spurious products can be curtailed without resorting to deprivation.<sup>329</sup> Importantly, there has not been a single case of large-scale re-importation to substantiate the argument that deprivation is the only solution to safeguard the home market. Had Microsoft and Intel decided to shun India as a market because of copyright issues, India would not have realized competitive position in the software industry.<sup>330</sup> Instead, the investment of foreign software companies enables the local industry to tackle piracy in India.<sup>331</sup> Creating global competitiveness in newer areas of trade complies with the objective of TRIPS, which in its preamble states that the special needs of the least-developed countries are recognized to enable members to “[c]reate a sound and viable technological base.”<sup>332</sup>

The advantage of countries like India assuming a dominant position in a particular trade is that the government then intervenes to contain piracy and to maintain international standards of trade due to growing industry pressures. Governments respond better when local industries empowered with international trade aspects demand amendments in IP laws.<sup>333</sup> Moreover, when amendments are prompted by local businesses, it increases the probability of the businesses contributing to the modernization of IP.<sup>334</sup> Part of the reason why third-world governments are unable to implement IP laws after they are amended in accordance with TRIPS is the cost involved.<sup>335</sup> Getting the local businesses excited about the prospects of international trade will alleviate the rigor of this problem.

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329. See generally KEITH E. MASKUS, INST. FOR INT’L ECON., INTELLECTUAL PROPERTY RIGHTS IN THE GLOBAL ECONOMY 53–81 (2000).

330. See *Software Piracy: Understanding the Larger Picture*, Express Computers, July 21, 2003, available at <http://www.expresscomputeronline.com/20030721/indtrend1.shtml> (last visited Mar. 31, 2004) (describing the economic consequences of piracy on foreign direct investment).

331. See Salmad Saeed, *China & India-Major Global Economic Players by 2005: Foreign Investors in India’s Information Technology*, THE SOUTH-ASIAN.COM, Jan. 2002, available at <http://www.the-south-asian.com/Jan2002/Technology-&-Investments-Foreign-investments-in-India.htm> (last visited Mar. 31, 2004) (discussing the extent of foreign investments in software technology in India).

332. See TRIPS, *supra* note 3, pmb1.

333. See generally MASKUS, *supra* note 324, at 122–39, 158–91, 204–33.

334. *Id.*

335. *Id.*

## VII. CONCLUSION

Adam Smith remarked, “[w]hat is prudence in the conduct of every private family, can scarce be folly in that of a great kingdom.”<sup>336</sup> Similarly, what is prudence in the context of a nation cannot become folly in international context. International economic stability cannot, by definition, be enhanced from trade by depleting individual nations of welfare. The economic case for encouraging developing nations to respect their commitments under trade agreements cannot be made without a corresponding quid pro quo from developing nations.<sup>337</sup> The long-term costs of the poverty penalty in ignoring welfare could undermine the quid pro quo. It is an individual, as well as global interest, to ensure that the WTO mechanism does not selectively flex only for problems within developed nations. The uniform functioning of the WTO mechanism to problems across the globe could eventually be the factor that determines the survival of the mechanism in the long run.

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336. TODD G. BUCHHOLZ, *NEW IDEAS FROM DEAD ECONOMISTS* 37 (1999) (quoting ADAM SMITH, 1 *WEALTH OF NATIONS* 457 (1776)). Smith used the argument against merchants who lobbied for protective tariffs and quotas from foreign goods.

337. See Sykes, *supra* note 17, at 60.

The economic case for encouraging nations to respect their commitments under trade agreements has no quarrel with behavior that is consistent with those commitments. But to the extent that what developing countries propose to do with pharmaceutical patents is in tension with their TRIPS commitments, deviation comes at the cost of undermining the credibility of commitments, now and in the future.