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The Bolar Amendment Abroad: Preserving the Integrity of American Patents Overseas After the South African Medicines Act

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The Bolar Amendment Abroad: Preserving the Integrity of American Patents Overseas After the South African Medicines Act

Recent advancements by the U.S. pharmaceutical industry have been nothing short of amazing. Perhaps more than any other development, the current generation of AIDS therapies is an example of the benefits delivered by this industry. By relegating HIV and AIDS to the status of a controllable disease, millions of people will be able to live productive lives where just a decade earlier they would have been facing almost certain death. "Drug cocktails" of the latest and most innovative medicines can save lives, but at a cost; these regimens can run as much as $12,000 per year per patient.[1] With the average African nation spending as little as $10 per person on health care each year, any hope of securing new, more effective HIV/AIDS drugs does not exist.[2]

In response to the growing AIDS crisis in the country, the South African Parliament introduced legislation that provides their country with opportunities to obtain lower cost versions of the latest U.S. drugs and make them widely available. The 1997 South African Medicines and Related Substances Control Act Amendments ("Medicines Act")—specifically section 15C—gave the Health Minister power to ensure that international patent rights over any medicine did not stop the South African government from issuing licenses to produce that same medicine locally.[3] The legislation also provides for the parallel importation of drugs from other countries that produce them inexpensively, such as India.[4]

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1. Ralph Nader, *In the Public Interest,* HEALTH LETTER, June 1, 1999, *available at* 1999 WL 13846869.

2. Gumisai Mutume, *Trade: U.S. Drug Companies Ease Up On South Africa,* Inter Press Service, Sept. 12, 1999, *available at* 1999 WL 27373954.

3. *Id.*

4. *Id.*

Claiming that their patent rights, as protected by the Trade Related Aspects of Intellectual Property ("TRIPS") agreement of the World Trade Organization ("WTO") treaty, were violated, the U.S. and European pharmaceutical industries erupted in protest.[5] The Pharmaceutical Research and Manufacturers of America ("PhRMA") brought suit against South Africa to have these new laws struck down, and asked the WTO to intervene and compel South Africa to honor its TRIPS agreements.[6]

This comment traces the origins of the WTO and TRIPS agreements and the Hatch-Waxman Act, also known as the "Bolar Amendment" in the U.S., that deals with modifying pharmaceutical patents. Applying those legal constructs to the AIDS crisis in South Africa and the recent Medicines Act intellectual property dispute, the author proposes a way of applying patent exceptions that have been developed in the United States to international trade agreements. Some observers have recommended introducing a version of the U.S. Orphan Drugs Act to the WTO, but this would not address many of the widespread diseases that affect millions of people in South Africa and around the world.[7]

Pitting the economic and political might of the United States and Europe against the impoverished, suffering population of South Africa exposes several fundamental flaws in the current world trading system. Much of the criticism the WTO and GATT attracted in the past was the inability of humanitarian interests to rival economic concerns at the negotiating table in situations like South Africa. Less developed countries ("LDCs") often point to situations like the current AIDS crisis as examples of why they should not be required to adhere to conventions like the WTO.

In the end, free-trade and Western style capitalism seem destined to be the most effective method of improving lifestyles and encouraging innovation, but in the short term many barriers

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5. Marcus Marby, *Give Us This Day Our Daily Meds,* Newsweek International, July 5, 1999, *available at* 1999 WL 8074144.

6. Mutume, *supra* note 2.

7. Jeremy Lovell, *Drug Firms Refuse to Yield in SA Patent Row at* http://www.woza.co.za/reuters/nov98/patento.html (last modified Nov. 13, 1998). The Orphan Drug Act provides up to seven years of exclusivity for medicines developed to treat diseases that affect less than 200,000 people. This was designed to encourage the pharmaceutical industry to research diseases that otherwise would not have a large enough potential market to warrant a costly research program. Often, the populations of less developed countries suffer greatly from diseases not prevalent in the industrialized West (like malaria), and have benefited from drugs developed under the Orphan Drug Act.

remain to be overcome, especially in the LDCs. By ignoring the potential backlash that strict patent enforcement may unleash in situations like South Africa, the Western industrial nations are failing to address an essential component of effective trade management. The future of the WTO as a capable instrument for managing world trade is jeopardized when nations are forced into unpopular and potentially harmful positions. Only when the people and governments of all nations involved in international trade feel they are treated fairly will there be long-term stability in the system.

Even within the United States and other affluent Western nations there is widespread opposition to trade. As the recent violence at the WTO meeting in Seattle demonstrated, people of even the most prosperous countries feel threatened by supra-national, non-elected governmental bodies. Whether it is the supposed lack of accountability of organizations like the WTO or opposition to policy goals of treaties like TRIPS, the Seattle experience illustrated how fragile international trade institutions can be. Defending these establishments should be a priority for the U.S.

Protectionist forces and special interests have been able to force the U.S. government into unilateral trade actions that have often rankled our trading partners.[8] The coming years will require a harmonization of U.S. trade policy with the demands of established international trade bodies to ensure both the survival of these bodies as effective governing entities and an American ability to address concerns like the environment and human rights abroad. Without legitimate, neutral bodies like the WTO, political pressures may force more states to turn to harmful unilateral actions like the South African Medicines Act without fear of a unified punitive response from the international community. The United States needs to lead in this instance to

8. *See generally* Marcus Noland, *Learning to Love the WTO,* Foreign Affairs, Sept./Nov. 1999, at 78. Arguing that the United States needs to accept a greater leadership role within the WTO specifically, the author describes the current state of American trade policy as a "road to nowhere." Protectionist tendencies in the United States need to be held at bay, and the article implies that strengthening international trade bodies will accomplish this by providing a legitimate and internationally recognized vehicle for American policy goals and by preventing the American government from being able to unilaterally alter trading policies based on internal politics. A strong trade system where all participants—especially the United States—is in our best interest as it will deter unilateral actions by other countries that may be harmful to trade. In the long run, an "anarchic" trade policy by the United States will benefit no one.

prevent others from following the route South Africa has taken. This comment suggests steps towards demonstrating that leadership while simultaneously removing a threat to the organized trading system that provides many benefits around the world.

While there are many aspects of international trade and its social impacts that are beyond the scope of this limited examination, the South African AIDS crisis illustrates where there is a need for a reevaluation of the human impact of trade. The United States in particular has acted to provide quick, inexpensive access to generic drugs for its citizens, but has denied comparable access to citizens of other nations. This must change to ensure the long-term stability of an international trading system. Only by giving all of the signatories of the WTO a stake in the continued success of the trading system can we expect to make progress in defending aspects of trade like intellectual property. A modification of the TRIPS treaty to allow easier access by LDCs and other poor nations, like South Africa, to essential medicines will solidify support for the WTO and intellectual property rights across the board.

Beginning with the emergence of the current generation of trade treaties and the situation that has developed in South Africa, this comment will illustrate the possibilities for change that exist in the WTO/TRIPS regime. This complex problem contains economic, political and moral elements, and this comment will address all of these aspects. Perhaps no other current humanitarian crisis in the world today has the long-term destabilizing potential that the AIDS epidemic does, and as a result must be dealt with soon.

I. Origins and Background of TRIPS

A. History of GATT, the World Trade Organization and TRIPS

When examining General Agreement on Tariff and Trade ("GATT"), the forerunner of the WTO and TRIPS agreements, it is important to consider the economic and political climate in which the treaties developed. Essentially an outgrowth of the Bretton Woods agreements of 1944 that established a framework of international economic cooperation,[9] GATT emerged in 1947 as the agreement on international tariffs, a primary consideration in

9. JOHN H. JACKSON, THE WORLD TRADING SYSTEM 36 (1997).

any trading system.[10] The goal of this treaty was to promote international free trade while protecting the interests of both developed and developing nations. Many of the leaders involved in forming the post-war international economic system viewed the breakdown of international trade during the Great Depression as one of the key contributors of instability that lead to the Second World War.[11] Despite being established by many countries to protect their local industries from competition as the world economy collapsed, retaliatory trade barriers were seen as having contributed to the severity of the depression.[12] The economic blunders of the inter-war period (1920 to 1939), especially the highly protectionist U.S. tariff act in 1930, were seen as mistakes not be repeated again.[13] The importance that was attached to reforming the world economy to avoid similar catastrophes cannot be underestimated.

It is interesting to recognize that the notion of free trade and patent protection as they exist today is a relatively new phenomenon. The patent is, inherently, a limited monopoly, and the idea of strict government enforcement of such an idea would have seemed outrageous to many of the American Founding Fathers.[14] It has only been in the last half of the twentieth century, since World War II, that the push for more secure and stable international trading systems, and the emergence of the hyper-connected international economy, have necessitated strict intellectual property protections.

1. GATT and WTO—Trade regulation today traces its roots back centuries, with the Treaty of Utrecht of 1713 being described as the a "forerunner" of GATT.[15] However, it was not until World War II that we see the emergence of modern trade policies.

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10. *Id.*

11. *Id.* at 38.

12. *Id.* at 36.

13. JACKSON, *supra* note 9, at 37.

14. *See generally*, A. Samuel Oddi, *TRIPS—Natural Rights and a Polite Form of Imperialism*, 29 VAND. J. TRANSNAT'L L. 415 (1996) (quoting the Supreme Court holding in *Graham v. John Deere Co*, 383 U.S. 1, 8-9 (1982), in which the Court described the ideas of Thomas Jefferson as: "reject[ing] a natural rights theory in intellectual property rights and clearly recognized the social and economic rationale of the patent system. The patent monopoly was not designed to secure to the inventor[s] . . . natural right[s] in [their] discoveries. Rather it was a reward, an inducement, to bring forth new knowledge.").

15. WOLFGANG FRIEDMAN, THE CHANGING STRUCTURE OF INTERNATIONAL LAW, 40-45 (1964).

Along with the United Kingdom, the United States took the lead working to establish a secure world economy following the war.[16] After the signing of the GATT in October of 1947, one of the first developments to emerge from these economic summits (now commonly referred to as "rounds") was the creation of the International Trade Organization ("ITO") in 1948.[17] While the GATT was not intended to be a physical organization, the ITO was to be the vehicle for stimulating the world economy and trade.[18] As the ITO was never ratified by the U.S. Congress (and ultimately doomed by this rejection), GATT served as the main vehicle for addressing issues of international trade.[19]

As the decades progressed and international trade grew, becoming more complex, several attempts were made to establish a successor organization to GATT that could deal with the new intricacies of modern commerce. The push for a new trade organization became increasingly strong after the Tokyo Round of GATT conferences in 1979, when it became clear that the trade regulations needed to be revamped.[20]

Finally, when the Uruguay Round began in 1986, there was movement towards the creation of an international body designed to effectively regulate trade.[21] The United States, under the leadership of an actively pro-trade Clinton administration, finally signed the GATT in 1994, and then accepted the WTO agreement that emerged a year later.[22] A product of perhaps the most complex international treaty ever produced, the WTO (whose charter incorporates much of the text from the earlier GATT

16. *Id.*

17. JACKSON, *supra* note 9, at 39.

18. *Id.* at 38.

19. Ned Milenkovich, Note, *Deleting the Bolar Amendment to the Hatch-Waxman Act—Harmonizing Pharmaceutical Patent Protection in a Global Village,* 32 J. MARSHALL L. REV. 751, N. 35 (quoting MICHAEL BLAKENEY, TRADE RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS: A CONCISE GUIDE TO THE TRIPS AGREEMENT 31-33 (1996).)

20. JACKSON, *supra* note 9, at 44.

21. *Id.*

22. *Id.* at 46. This period of intense activity surprised many observers and was the result of intense efforts, by both the GATT organization and the leaders of the various nations that ratified the new treaties. Different factions within the international trade community lobbied for slightly different versions of what would become the WTO. The Uruguay round did not begin with the explicit purpose of creating a new regulatory body. After enactment of the WTO in 1994, it had a year of overlap with the GATT, which effectively expired at the end of 1995, despite the "de facto" application of many of its provisions to trade regulation even today.

agreements) is a dispute resolution forum for international trade conflicts.[23] Importantly, the WTO operates independently of other governmental bodies, and establishes its laws and regulations at regular ministerial conferences (such as the recent, ill-fated Seattle conference).[24] As a truly international body capable of policing itself and imposing regulations that can supercede the laws of sovereign states, the WTO has developed into the leading international trade organization in the world.[25]

2. TRIPS—One of the most important features to emerge out of the Uruguay Round was the TRIPS agreement. A sweeping intellectual property agreement, TRIPS is the section of the GATT that outlines international patent rights.[26] Section 5, Articles 27-34, outlines the member states' responsibilities regarding international patents and the protections afforded them.[27] Interestingly, the TRIPS agreement contains, in Article 31, an exception for countries to violate international patent rights in times of national emergency.[28] Aside from this exception, the TRIPS treaty holds member states to a very high level of patent protection. The treaty currently mandates a patent protection period of twenty years, longer than the similar time required by the U.S. at the time of the Uruguay Round.[29] The Agreement enumerates the following rights for patent holders:

Rights Conferred

1. A patent shall confer on its owner the following exclusive rights:
   (a) where the subject matter of a patent is a product, to prevent third parties not having [the owner's] consent from the acts of: making, using, offering for sale, selling, or importing for these purposes that product;
   (b) where the subject matter of a patent is a process, to prevent third parties not having [the owner's] consent from the act of using the process, and from the acts of: using, offering for sale, selling, or

23. *Id.* at 15.

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

25. *Id.*

26. *Id.*

27. *Id.* at 93-97.

28. *Id.* at 95(b).

29. JACKSON, *supra* note 9, at 313.

importing for these purposes at least the product obtained directly by that process.

2. Patent owners shall also have the right to assign, or transfer by succession, the patent and to conclude licensing contracts.[30]

One of the reasons intellectual property rights were pushed into the GATT framework (and later the WTO inherited this responsibility) was the need for an effective dispute resolution mechanism.[31] In the recent South African Medicines Act altercation, one of the first responses by the U.S. government, on behalf of the pharmaceutical industry, was to request that the WTO intervene in the controversy to resolve the conflict.[32]

3. Technical aspects of TRIPS Relating to Pharmaceutical Patents—Building on the earlier cornerstones of international patent law, TRIPS places several more layers of obligations on the member states than did the Paris and Berne Conventions that protected industrial and literary/artistic patents, respectively.[33] All of the substantive aspects of the previous conventions are included in the TRIPS accord.[34] The agreement is a "minimum standards" treaty, defining the base of acceptable intellectual patent protection that any WTO member state may provide.[35]

The basis for international patent protection under TRIPS is the requirement that all products and processes, in all fields of technology and industry, be afforded full patent protection by all member states, regardless of which country developed it.[36] There are certain exceptions to this rule. They include preventing the issuance of a patent if doing so world result in severe environmental damage, allowing access to new surgical advancements and other, albeit limited, exceptions where it would offend the *order public* to insist on patent protection.[37]

For the entire twenty-year period of protection, the owners have the exclusive right to assign, transfer, and license their

30. *TRIPS Treaty, supra* note 24, at 94 (footnote omitted).

31. *Id.* at 311.

32. Gumisai Mutume, *TRADE: U.S. Companies Ease Up on South Africa,* Inter Press Service, Sept. 12, 1999, *available at* 1999 WL 27373954.

33. World Trade Organization, *An Overview of the Agreement on Trade-Related Aspects of Intellectual Property Rights* [hereinafter *TRIPS Overview*], http://www.wto.org/wto/intellec/intell2.htm.

34. *Id.*

35. *Id.*

36. *TRIPS Treaty, supra* note 24, at 93-94.

37. *Id.*, art. 27.2.

patent.[38] Member states of the WTO are bound by TRIPS not to interfere with the rights of a patent holder, unless such action would not prejudice the rights of and prevent the reasonable exploitation of the patent by its owner.[39] It is difficult to see how the patent nullification aspects of the South African Medicines Act would not violate this clause of the treaty.[40]

The South African Act also provided for compulsory licensing (forcing a patent holder to provide licenses for production to local producers before the expiration of a patent), which is permitted by TRIPS, but subject to certain restrictions.[41] Any patent holder subject to these licensing requirements should be compensated according to the economic value of the license, and there must also be an attempt made to agree to reasonable terms for a voluntary licensing agreement.[42] South Africa made none of these allowances.

One of the areas where the U.S. pharmaceutical industry claimed the South Africans violated TRIPS was Articles 39.3 and 41 *et seq.*[43] These provisions of the treaty require that the patent holder's trade secrets and other undisclosed information be protected by member states (Article 39.3) and that effective remedies must be available to combat patent infringement (Article 41).[44]

Interestingly, there are provisions in the TRIPS treaty for a transitional period for LDCs.[45] Recognizing the need for these generally poorer nations to ease into heightened patent protection rather than cutting themselves off from certain technologies immediately, the treaty allows a five year transition period ending on January 1, 2000.[46] Even after this transition period has ended, certain LDCs may petition for an additional five-year extension in certain essential fields, such as pharmaceuticals due to the overwhelming need for many medicines.[47] However, these

38. *Id.*, art 28.

39. *Id.*

40. PhRMA, *National Trade Estimate Report on Foreign Trade Barriers (NTE) at* http://www.searchforcures.com/issues/intl/safrica.html (last modified Nov. 16, 1999).

41. *TRIPS Treaty, supra* note 24, art. 31.

42. *Id.*

43. PhRMA, *National Trade Estimate Report On Foreign Trade Barriers (NTE), supra* note 40.

44. *TRIPS Treaty, supra* note 24, art. 39.3, 41 *et seq.*

45. *Id.*, arts. 65, 66 *et seq.*

46. *Id.*

47. *Id.*

extension provisions have not modified South Africa's treaty responsibilities.[48]

II. The Hatch-Waxman Act ("The Bolar Amendment")

Despite the hard-line position that the U.S. government has taken in regards to enforcing its citizen's patent rights abroad, it maintains a very different position at home—at least in regards to pharmaceuticals. The Hatch-Waxman Act, otherwise known as the "Bolar Amendment," has been criticized both in the U.S. and abroad, but its impact on the drug market has been undeniable. This section examines the history and application of the Bolar Amendment to U.S. pharmaceuticals.

A. Background of the Bolar Amendment

According to federal law in place since the early 1960s, generic drug companies were forced to conduct their own research and development into a drug that had previously been developed and marketed by a leading research company.[49] Because of the original manufacturer's patent on the drug, the generic company was required to wait until the expiration of the first patent held by the creator of the drug, and then duplicate all of the research.[50] This federally mandated redevelopment of an existing drug could delay by years the amount of time it would take for a less expensive generic version to become available on the market.

In 1983, Roche Products, Inc, one of the largest primary research drug companies in the world, sued a generic drug producer, Bolar Pharmaceutical Company, in federal court for patent infringement.[51] At issue was research being conducted by Bolar to analyze a sleeping pill patented by Roche in order to allow the rapid development of a generic version by Bolar after

48. PhRMA, *National Trade Estimate Report on Foreign Trade Barriers (NTE), supra* note 40 (describing the Medicines Act as violating South Africa's obligations under the TRIPS agreement and advocating punitive action by the United States and the WTO).

49. Federal Food and Drug Act, 21 *U.S.C.* § 355 (1999). This statute describes patent infringements as any research done for the purposes of "manufacture, use, or sale" of a drug before the expiration of a current patent, subject to penalties to be ascribed by law. This allowed no exception for generic manufacturers to test a drug in order to allow preparation for FDA approval and marketing after the expiration of the original patent.

50. Roche Prods., Inc. v. Bolar Pharm. Co., 572 F. Supp. 255 (E.D.N.Y. 1983).

51. *Id.*

the expiration of the existing patent.[52] Essentially admitting that their actions constituted patent infringement under the letter of the law, Bolar contended that their research should be permitted because no profit will result from it until after the expiration of the Roche patent.[53] The district court agreed, holding that any other conclusion would be to grant a de facto extension of the patent held by Roche (which, in 1983, ran for seventeen years).[54] Despite the subsequent reversal of this decision on appeal,[55] the stage had been set for action by the federal government.

B. Federal Action and the Creation of the Bolar Amendment

Recognizing the potential benefits of allowing generic drug companies to conduct research before the expiration of a patent to allow for expedited FDA market approval of their drug, Congress enacted the Hatch-Waxman Act.[56] This legislative act reversed the ruling by the Federal Circuit Court and extended an exception to the U.S. generic pharmaceutical industry in patent law that no other industry enjoys.[57] In a speech supporting the amendment, Representative Henry Waxman of California, one of the bill's co-sponsors, stated "it provides low-cost generic drugs for millions of Americans, saving maybe a billion dollars over a several year period . . . ."[58]

C. International Implications of the Bolar Amendment

The European reaction to the Bolar Amendment has been overwhelmingly negative. The European Court of Justice has held that actions like those allowed under the Amendment are patent

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52. *Id. at 257.*

53. *Id.*

54. *Roche, supra* note 50, at 258. The district court also determined that the infringement was *de minimus* and would not result in any financial harm to Roche. Limiting its holding to research only, the court held open the possibility of damages to Roche if they could show any financial harm before the expiration of the patent.

55. Roche Prods., Inc. v. Bolar Pharm. Co., 733 F.2d 858, 863 (Fed. Cir. 1984) (holding that the research conducted by Bolar was a "violation of the patent laws in the guise of 'scientific inquiry,'" and had substantial "commercial purposes.").

56. 35 *U.S.C.* § 271(e)(1) (providing that it "shall not be an act of infringement to make, use, offer to sell within the United States or import into the United States a patented invention. . .solely for uses reasonably related to the development and submission of information under a federal law which regulates the manufacture, use, or sale of drugs. . . .")

57. Milenkoich, *supra* note 19, n.78.

58. H.R. Rep. No. 98-857 at 14 (1984).

infringement.[59] The main concern arising from Bolar is whether this is an infringement of the TRIPS agreements, of which the U.S. is arguably the key signatory and supporter. The inconsistencies that the Bolar Amendment creates in global patent policy make it more difficult to enforce international protection of intellectual property, not only for pharmaceuticals, but also other industries such as computer software.[60]

U.S. trade policy should act to prevent unilateral actions by other nations that could threaten the security of American patents; the most effective way for the U.S. to accomplish this goal is by leading by example.[61] A main goal of the WTO and its member states should be the maintenance of the intellectual property provisions currently available.

III. The Current AIDS Crisis in South Africa and the Medicines Act

Unilateral steps such as the abrogation of intellectual property agreements have occurred before. Faced with a humanitarian crisis, many countries feel compelled to act expeditiously, in ways that harm them and their trading partners in the long run. However, the scale of the suffering in South Africa is incredible, and the situation continues to deteriorate every day. Currently one of every eight South Africans is infected with HIV, with that number continuing to rise.[62] The inability for a country like South Africa to cope with these numbers of infected persons can be politically, socially and economically destabilizing. The traditional dispute resolution mechanisms of the WTO that resolve any TRIPS disputes may take months or years to complete, and in the meantime, understandably, South African government has felt compelled to act.

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59. IPL Newsletter, *Judgment of EU Court on Generic Medicines and Patent Rights*, Summer 1998, at 47.

60. J.H. Reichman, *Compliance with the TRIPS Agreement: Introduction to a Scholarly Debate*, 29 VAND. J. TRANSNAT'L L. 363 (1996) (describing actions by the U.S. that undermine the agreement while demanding strict adherence to the agreement by other nations).

61. Marcus Noland, *Learning to Love the WTO,* Foreign Affairs, Sept./Oct. 1999, at 79.

62. Africa Policy Information Center, *AIDS Drug Policy*, Africa News Service, Sept. 7, 1999, *available at* 1999 WL 25944377.

A. HIV/AIDS in South Africa

With a population of roughly 26 million people, South Africa is also home to approximately three million reported cases of HIV/AIDS.[63] With 1,500 new cases emerging every day, by the year 2005, almost 20% of the workforce is predicted to be infected with the virus.[64] These numbers are staggering, and the burden this will place on the already strained health care system in South Africa may destroy it. Simple and generally inexpensive drugs, such as AZT, which can halt the transmission of AIDS from mothers to their unborn children, are priced out for reach of many people in South Africa.[65] Doctors often do not even tell their patients about the medicines that exist, because few of the infected South Africans can afford them.[66] U.S. Surgeon General David Sacher has compared the current African AIDS crisis to the Black Death that swept Europe five hundred years ago.[67]

B. The Medicines Act

In response to the incredible need for medical treatments to its population, the South African Parliament passed in 1997 the Medicines and Related Substances Control Act Amendments.[68] Included in this bill, specifically section 15C, were provisions for parallel importing, compulsory licensing, and a clause that overrules patent rights that prevent South African companies from developing local versions of effective treatments.[69]

This legislation was met by strong opposition from the U.S. and European pharmaceuticals industries and their governments.[70] The U.S. government went to the WTO on behalf of its pharmaceutical industry to try to enforce U.S patent rights, and even imposed sanctions on some South African goods to further emphasize U.S. displeasure with the Medicines Act.[71] Additionally, the U.S. government places South Africa on the "Special 301"

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63. *AIDS Crisis Predicted for South African Work Force*, BALTIMORE SUN, Jan. 28, 1999 at 17A.
64. *Id.*
65. Africa Policy Information Center, *supra* note 62.
66. *Id.*
67. *Id.*
68. Mutume, *supra* note 6.
69. Marby, *supra* note 4.
70. *Id.*
71. *Id.*

watch list, which imposes increased governmental scrutiny regarding trading practices.[72]

Under pressure from the WTO and lobbying from Vice-President Gore and the rest of the U.S. Government, the South Africans agreed to rework the offending sections of their Medicines Act early in the year 2000.[73] In exchange, the U.S. pharmaceutical industry plans to withdraw a suit they had filed in the Constitutional Court in South Africa.[74] Although the exact details of what the new South African law will contain have not emerged, the Parliament has promised to honor its intellectual property obligations as put forward under TRIPS.[75] It remains unclear what actions South Africa will take in the year 2000 in order to modify the Medicines Act, especially in light of the Seattle WTO meeting in late 1999, the details of which remain unavailable at the time this comment was published. It is possible that the South African government will not put forward another version of the Act in light of the pressure exerted by the U.S. government.

IV. Applying Bolar to TRIPS

Writing a Bolar-type amendment into the TRIPS Treaty could accomplish several goals; First, pharmaceutical drugs could be made available to South African HIV and AIDS patients years earlier than would otherwise be the case. Second, international opposition could be muted about the TRIPS-legality of the American Bolar Amendment. Finally, the corrosive influence of

72. Africa Policy Information Center, *supra* note 62. "Special 301" is a section of the U.S. Trade Act of 1974 which requires the United States Trade Representative to monitor the actions of a targeted country carefully to ensure full compliance with trade regulations. This is a punitive act that demonstrates U.S. displeasure with the actions of a country and may be the precursor to trade sanctions. Cf. PhRMA, *Issues and Policies at* http://www.phrma.org/issues/nte/nte_pub.html (last modified Feb. 16, 1999).

73. Africa Policy Information Center, *supra* note 62; *see also* Mutume, *supra* note 6.

74. Africa Policy Information Center, *supra* note 62; *see also* Amy Stilwell, Tom Tripp, Helaine Klasky, *U.S. South Africa Understanding on Intellectual Property at* http://www.ustr.gov/releases/1999/09/99-76.html (last modified Sept. 17, 1999) This press release from the U.S. Trade Representative announces an agreement between the U.S. and South Africa to recognize the TRIPS agreement while working towards providing health care for HIV infected South Africans. Little detail was included in the article that may explain how this will be accomplished except to say that the Medicines act will be implemented in a manner consistent with international intellectual property obligations.

75. *Id.*

many countries unilaterally violating the TRIPS treaty could be avoided, and the integrity of the agreement as an effective mechanism for intellectual property rights enforcement can be preserved.

Applying the Bolar Amendment to the TRIPS treaty is based on the premise that current intellectual property protections systems are, in the long term, beneficial to developing and less developed countries. Many people do not feel, however, that poorer nations should be obliged to recognize the same level of patent protection as developed nations.[76] Proponents of this view reject the notion that LDCs need "strong, nineteenth-century-type patent protection."[77] Those who have advocated relaxing patent restrictions on LDCs and poorer countries envision an economic benefit for them by influencing industries to produce low cost versions of products they need.[78]

While this approach seems to ignore the possibility of harm to industries in developed nations, the need to maintain the integrity of international patent systems and harmonize the patent protection regimes of many nations under TRIPS is paramount. Even disregarding the social pressures, the domestic economic and political incentives for LDCs to flout international patents and build viable domestic industries may become difficult to discount. Action now can prevent counties like South Africa from feeling the need to abrogate patent protections in the future.

One of the goals of global patent protection is the harmonization of the intellectual property laws around the world. The root of this movement came directly from an international conference in Los Angeles in 1989, when the importance of establishing a worldwide framework was examined.[79]

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76. J.H. Reichman, *Compliance With The TRIPS Agreement: Introduction to a Scholarly Debate, supra* note 60 (introducing a panel of lecturers at an international intellectual property symposium at the Annual Meeting of the Intellectual Property Section, American Association of Law Schools (AALS), San Antonio, Texas, on January 4, 1996. Several of the lecturers discussed the inherent unfairness of requiring LDCs to essentially forego developing their own industries in fields like pharmaceuticals because of strong international patents that keep them out of the market) (hereinafter *Compliance with TRIPS).*

77. *Id.*

78. *Id.*

79. Harold C. Wegner, *TRIPS Boomerang—Obligations for Domestic Reform,* 29 VAND. J. TRANSNAT'L L. 535, 540 (1996) (describing a meeting of the American Intellectual Property Association, in which the Association produced many ideas that have since been passed into law, most notably the twenty year patent period that is a cornerstone of the TRIPS agreement).

A. The Indian Model

For many less developed parts of the world, including South Africa, the path followed by India has been a model for establishing patent protection systems responsive to the needs of developing countries. Although based on the English patent system, the Indians have developed their own patent system that has been modified to suit the needs of their population.[80] India is comparable to South Africa for the purposes of comment due to the presence in both countries of stratified social structures, large numbers of uninsured poor and a highly educated, technologically advanced elite. Like South Africa, India has struggled with the problem of providing medicines to their populations while maintaining patent systems acceptable to their trading partners.[81]

Since Independence in 1947 from British rule, India has seen its pharmaceutical industry explode, growing into a multibillion-dollar enterprise.[82] The local companies have evolved from basic, low-tech operations into some of the world's leading, most highly competitive pharmaceutical powerhouses.[83] Most analysts credit this, in large part, to the almost complete absence of pharmaceutical patent protection for many years.[84]

As recently as the 1960s, the Indian drug market, much like the South African market today, was almost completely dominated by foreign companies.[85] However, by refusing to join the Paris Convention (protecting industrial designs and processes) and designing patent laws that rejected protection for pharmaceutical products, India changed their country into a hotbed of domestic production.[86]

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80. B.K. Keayla, *Patent Protection and the Pharmaceutical Industry,* Intellectual Property Rights, 151 (1994).

81. *See generally, Compliance with TRIPS, supra* note 76.

82. Shivlanand Kanavi, *Leaders in Technology,* Bus. India, July 1994.

83. Martin J. Adelman, *Prospects and Limits of the Patent Provision in the TRIPS Agreement: The Case of India,* 29 VAND. J. TRANSNAT'L L. 507, 526 (1996) (discussing the impacts that the lack of Indian pharmaceutical patent protection has had on the development of Indian drug companies, noting that they have grown and become competitive, but have failed to innovate) (hereinafter "*India*").

84. *Id.*

85. *Id.* (describing ninety percent of the Indian pharmaceutical market as being controlled by foreign companies who dominate both the retail and bulk markets).

86. *Id.* at 520 (describing the Indian patent system that gave preference to domestic patent applications).

Enacting legislation similar to the South African Medicines Act, the Indian government passed the Drug Price Control Order.[87] This act placed both price and production controls on drugs, and required local production of life-saving drugs.[88] This protection by the government gave the Indians an opportunity to focus their industry on diseases affecting their population, rather than on those diseases that affect Western nations. By the mid-1990s, the Indian pharmaceutical industry had become a net exporter of drugs, focusing on lower margin markets such as the former Soviet states, developing nations and, not surprisingly, South Africa.[89]

This model of self-sufficiency must be appealing to a country like South Africa, which is struggling as it tries to find drugs to combat a growing AIDS crisis. However, it is important to note that India was able to develop its pharmaceutical industry by abstaining from international patent and trade agreements. India is now a member of the WTO and a signatory nation to TRIPS, which will compel changes in its patent protections.[90]

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87. Martin J. Adelman, *India*, *supra* note 83, at 526. The Drug Price Control Order was designed to protect consumers from high prices. It divided all drugs into four categories:

1. life saving (i.e. treatments for malaria, tuberculosis and leprosy—all required by the National Health Program)
2. essential
3. less-essential
4. non-essential

Price controls were imposed for the first three categories, with production incentives provided for local producers.

88. *Id.*

89. *India, supra* note 83, at 527. India has focused on mass production of generic drugs, which are ideally suited for these markets. India's contribution to the international drug market has come in the form of increases in process efficiency, not from the development of new medicines.

90. TRIPS Treaty, *supra* note 22, art 27, "Patentable Subject Matter", in pertinent part:

1. Subject to the provisions of paragraphs 2 and 3 below, patents shall be available for any invention, whether products or processes, in all fields of technology, provided they are new, involve an inventive step and are capable of industrial application. Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.
2. Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the

B. Enhancing Generic and Local Drug Availability

Applying a Bolar-type amendment to the TRIPS treaty would bring affordable drugs to the people of South Africa at least two years before they would be available under the current scheme.[91] The savings, especially to cash starved states like South Africa, would be tremendous. Considering the expected numbers of patients in the coming decades, the savings could reach into the tens of millions of dollars.

C. Preserving the Integrity of TRIPS

A key aspect of the Bolar Amendment in the United States is that it is only applicable to the pharmaceutical industry. The expansion of the Bolar Amendment to TRIPS would in effect limit the pressure on the treaty as a whole that the South African Medicines Act has placed on it. Many developing countries have felt that they have been unfairly burdened by the terms of the TRIPS agreement and often have done little to prevent widespread violation of international patent laws within their borders. An expansion of Bolar to TRIPS would carve out exceptions for the most pressing humanitarian and health concerns, while removing the incentive to abrogate the treaty in part or in its entirety by poorer nations. Removing an important and politically volatile incentive to exercise the national emergency exception built into TRIPS will also help ensure that many nations will comply with the treaty that otherwise would not.

A reduction in the years that a pharmaceutical patent is protected by TRIPS could also play an important part in restoring

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environment, provided that such exclusion is not made merely because the exploitation is prohibited by domestic law.

3. Members may also exclude from patentability:
   (a) diagnostic, therapeutic and surgical methods for the treatment of humans and animals;
   (b) plants and animals other than microorganisms. . .However, Members shall provide for the protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof. The provisions of this sub-paragraph shall be reviewed four years after the entry into force of the agreement. . . .

91. *See Roche Prods., v. Bolar Pharm. Co., supra* note 55 (describing the time needed by generic drug companies to fully develop a new drug as two years) While this holding reffered to the time needed to complete research required by the FDA, and no doubt this process would be expedited in places like South Africa, the incredible complexity of the new generation of AIDS therapies will likely take years to master absent licensing.

confidence and compliance to this part of the TRIPS Agreement. A twenty-year term of pharmaceutical patent protection under TRIPS could be reduced for to twelve or fifteen years. The shorter the patent, the greater the number of lives that would be able to be saved in the poorer parts of the world. A reduced patent protection period would still ensure that drug companies receive sufficient returns on their investments (through ten or fifteen year limited monopolies) that they will continue to support the capital-intensive research which produces innovative medicines like the new AIDS drugs.

With a Bolar amendment to the TRIPS treaty and a twelve year patent period, infected patients in South Africa would have access to affordable medicines approximately ten years earlier than they do now (assuming the two year development period for generics). Additionally, the South African population would provide another market for the pharmaceutical industry where there currently is none. By denying the South African population medicines at prices they can afford, the pharmaceutical industry is foregoing possible profits and risking another round of unilateral action by the South African Parliament in coming years.

D. Eliminating International Opposition to Bolar Amendment

Since its introduction, the Bolar amendment has been attacked abroad for being hypocritical and violating the TRIPS agreement. Criticism has focused on American demands for strict compliance by all WTO nations to the TRIPS agreement yet, at home, the U.S. modifies pharmaceutical patents to save money and increase drug availability. This criticism has taken on new meaning in light of the South African situation. The inclusion of a Bolar Amendment in the TRIPS treaty will silence much of this opposition, while preserving the massive savings that the American public and government reaps by the widespread and early availability of generic drugs.

D. Eliminating the Freerider Problem

The economic concept of the freerider describes the ability of some participants in the marketplace to benefit from the actions of others without having to contribute to the production of that benefit. Critics of countries that refuse to enforce patent rights have often focused on this premise, arguing that actions like South

Africa's Medicines Act will ultimately harm the world community.[92]

Critics of the Medicines Act can point to the lack of patent protection and the likelihood of reduced drug prices as disincentives to further invest in pharmaceutical research.[93] Unilateral actions, like those in South Africa, expose the international patent protection system to destabilizing forces that it could do well to avoid. By extending a Bolar-type amendment to TRIPS, it would be possible to avoid one of the most politically popular reasons for abrogating trade obligations. The experiences in India show that there was little innovation made by their drug companies, and that the low prices created by the Indians may have discouraged foreign pharmaceutical interests from paying to research diseases that were prevalent in India.[94]

While it is true that the Bolar Amendment has caused decreased research spending to a certain extent in the United States, the negative effects have been minimal and have not affected the advancement of pharmaceutical science. The key to the effectiveness of a Bolar-type amendment would be that it is limited to pharmaceuticals; poorer nations would thus not be able to use a medical crisis as a reason to leave the WTO and impose protectionist policies. In this sense, the pharmaceutical industry can act as a lynchpin for the TRIPS treaty by either ensuring stability of the whole by providing flexibility or by allowing the whole structure to collapse, as countries like South Africa may pull out to provide ample medicines to their ailing populations.

Patent laws have historically been territorial, having legal effects only within the borders of the country that creates them. But the new system of trade, embodied in the WTO and TRIPS Agreement, is inherently international and hyper-territorial. Only by protecting a nation's ability to safely include their products in trade and recognizing that their patents will be honored will the system work correctly.

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92. *E.g. India, supra* note 83, at 510-511.

93. *Id.*

94. *Id.* at 527, 528 (illustrating how government mandated research programs have produced little discovery of new medicines. However, as foreign markets become more important to Indian pharmaceutical manufacturers, change I occurring as more capital has become available and the Indian companies are no longer prohibited from importing technology to aid in their research. This indicates that a free marketplace, with appropriate patent protection, will produce better scientific results than government regulated research and development).

V. Conclusion

The need to protect the pharmaceutical industry is important. The capital-intensive research they undertake is made possible by the huge rewards the development of a successful drug guarantees. That interest must be balanced, however, with the need to make available life-saving medicines to countries like South Africa who are suffering massive public health crises. In order to continue to promote the stability of the world trading system and the integrity of intellectual property rights around the world, basic human needs must be addressed. Few nations will adhere to a trading system that is potentially killing millions of its citizens.

Recognizing the moral responsibility to protect human life does not completely blind us to the benefits of trade—nor should it. The ability of industries to produce (at great expense) the innovative medicines that save millions of lives must also be protected. Redefining the TRIPS treaty in this one area, pharmaceuticals, can add both the stability and integrity to the trading system that the West desires and the reasonable access to new medicines that the people of South Africa and elsewhere need. The long-term benefits of modifying TRIPS with a Bolar-style amendment would accrue to people around the world for years to come.

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