The International Drug Industry: What the Future Holds for South Africa's HIV/AIDS Patients

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Lack of access to HIV/AIDS drugs is an internationally recognized problem. There has been growing attention to this issue since the Trade Related Agreement on Intellectual Property Rights (TRIPs) strengthened patent protection laws, causing drug prices worldwide to increase. Poor, developing nations have been most affected by the patent protection laws and resulting high drug prices, yet these nations also harbor the highest number of HIV-positive people. Consequently, the vast majority of people in need of HIV/AIDS medicines simply cannot afford them.

South Africa's future with regard to its access to HIV/AIDS medicines will be influenced by international law, economics, and politics. TRIPs provides for increased patent protection, culminating in 2006 when all nations, including the least-developed, must comply with its provisions. The agreement sets the patent standards that all nations' laws and national policies relating to affordable drugs must meet.

Enforcement of these standards comes by way of a worldwide crusade led by the brand-name pharmaceutical industry. The brand-name drug industry has an enormous financial interest in profiting from the high prices of their patented drugs. Weaker patent laws mean competition from producers of generic drugs and lower drug prices for brand-name companies. Thus, the industry often pressures many countries to strengthen their patent laws, sometimes beyond the minimum international standards. Stronger patent protection means higher drug

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prices, and developing countries will ultimately suffer.

Access to HIV/AIDS medicines is becoming an intensely debated international problem while simultaneously becoming a recognized necessity. South Africa, as the nation with the highest number of people living with HIV and AIDS, is the focus of international attention. Despite the international furor, South Africa faces barriers that threaten to block its access to affordable drugs, including emerging international law, economic pressure by the pharmaceutical industry, and political strong-arming by developed nations. Yet, there are other political measures that provide safeguards for South Africa in its pursuit of affordable medicines.

This Note examines South Africa's future in accessing affordable HIV/AIDS drugs. The central thesis is that South Africa's future in accessing HIV/AIDS drugs is optimistic because of legal, political, and general public policy concerns. Part I details the AIDS crisis, the problem of access to affordable medicines, the generic drugs used to combat HIV/AIDS, TRIPs, and South Africa's patent-protection laws. Section A of the analysis in Part II argues that South Africa's laws are valid under international law and, therefore, safe from legal challenge. Section B of the analysis in Part II argues that South Africa is further protected from legal action because of international public policy concerns. Section B also explains how public relations expand the pool of potential drug sources for South Africa. Finally, Section C of Part II describes how global political influence acts to increase leverage and improve South Africa's access to essential medicines. This analysis will show that the future of South Africa looks more promising in terms of obtaining affordable HIV/AIDS drugs.

I. AN INTERNATIONAL THREAT: COMBATTING THE DEVASTATING AIDS VIRUS AND THE PHARMACEUTICAL INDUSTRY

A. THE GLOBAL AIDS CRISIS

Over thirty-six million people are infected and live with the HIV/AIDS virus.[1] Ninety-five percent of these people, or 34.3

1. See Special Session of the General Assembly on HIV/AIDS: Report of the Secretary-General, U.N. GAOR, 55th Sess., Agenda Item 179, ¶ 4, U.N. Doc. A/55/779 (2001) [hereinafter Special Session].

million individuals, live in developing countries.[2] The majority of these people live in sub-Saharan Africa, South and Southeast Asia, and Latin America.[3] Globally, sub-Saharan Africa is the most impacted region, facing four million new HIV infections in 1999 alone.[4] South Africa has the largest number of HIV/AIDS-infected people in the world with 4.2 million.[5]

The impact of AIDS on human life is profound. In 2000, there were 5.3 million new HIV infections and three million deaths from AIDS worldwide.[6] Sub-Saharan Africa is at the center of the crisis, accounting for 3.8 million of the 5.3 million infections[7] and 2.4 million of the three million deaths.[8] As a result, life expectancy in southern Africa is expected to decline by fourteen years between 2005 and 2010.[9] South Africa suffers an extremely high morbidity rate as a result of AIDS, with up to 6000 South Africans dying each day.[10]

Proper drug treatment can help prolong lifespan and reduce morbidity. There are several different types of drugs on the market to help combat AIDS and AIDS-related illnesses. The drugs most beneficial to people living with HIV/AIDS include: "antiretrovirals (ARVs) to limit the damage that HIV does to the immune system and to prevent mother-to-child transmission;"[11] "anti-infective agents to treat or prevent opportunistic infections (OIs);"[12] and "palliative drugs to relieve pain, physical and men-

2. See Carmen Pérez-Casas et al., *Setting Objectives: Is There a Political Will?*, CAMPAIGN FOR ACCESS TO EFFECTIVE MEDICINES (Médecins Sans Frontiéres, Brussels, Belgium), July 6, 2000, at 5. See also Special Session, supra note 1, ¶ 99.

3. *See Report on the Global HIV/AIDS Epidemic,* UNAIDS, at 6, U.N. Doc. UNAIDS/00.13E (2000), *available at* www.unaids.org/epidemic_update/report/ [hereinafter *Report*]. 24.5 million people infected with HIV/AIDS live in Sub-Saharan Africa, 5.6 million live in South and Southeast Asia, 1.3 million live in Latin America, 520,000 live in Western Europe, and 900,000 live in North America. *See id.*

4. *See id.* at 8.

5. *See id.* at 9. India has the second highest number at 3.7 million people. *See id.* at 12.

6. *See Special Session, supra* note 1, ¶ 4.

7. *See id.* ¶ 5.

8. *See id.* ¶¶ 4, 5.

9. *See Statement of the Joint United Nations Programme on HIV/AIDS (UNAIDS) at the Third WTO Ministerial Conference,* UNAIDS, ¶ 2, (1999), *at* http//:www.unaids.org/publications/documents/health/access/wtostatement.html. The life expectancy in southern Africa is expected to decline from fifty-nine to forty-five years of age. *See id.*

10. *See* 147 CONG. REC. H995, H995-01 (daily ed. Mar. 20, 2001) (statement of Rep. Lee).

11. Pérez-Casas, *supra* note 2.

12. *Id.*

tal discomfort."[13] Antiretrovirals are the most important drugs of the three categories because of their overall success in combating the virus. They reduce the viral load in the bloodstream to nearly undetectable levels, reduce OIs, prolong life, and transform HIV/AIDS into a chronic infection requiring only outpatient care.[14] Antiretrovirals have also been successful in reducing mother-to-child transmission of HIV infection by nearly seventy percent.[15] One study found that highly active antiretroviral therapy reduced AIDS-related mortality in the United States by seventy-five percent and morbidity by seventy-three percent.[16] Triple therapy, a combination of three different antiretrovirals, has been the most promising treatment for reducing levels of mortality among people with AIDS.[17] Triple therapy's effect of suppressing the replication of the virus results in decreased OIs, fewer hospitalizations, and most importantly, an ability to return to the ordinary functions of daily living.[18]

These wonder drugs have the potential to increase the longevity and health of millions, but they are beyond the reach of the majority of people who need them. The high costs of the pharmaceuticals allow only a small number of people in Africa to have access to antiretroviral drugs.[19] Although palliative and anti-infective drugs have limited generic versions or no price-related access problems,[20] most antiretroviral patents are still valid in the original country and generic versions are difficult to procure.[21] Patent-protected antiretrovirals are exorbitantly priced, which makes them effectively inaccessible to those in need until their patents expire and generics can be produced.

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13. *Id.*

14. *See Antiretroviral Treatments for HIV/AIDS*, WHO, (1997), *at* http://www.who.int/inf-fs/en/fact163.html.

15. *See id.*

16. *See* B. Hirschel & P. Franciolo, *Progress and Problems in the Fight Against AIDS*, 338 NEW ENG. J. MED. 906, 906 (1998).

17. *See id.* Triple therapy of two Nuclesoside Reverse Transcriptase Inhibitors (NRTI) + one Protease inhibitors or two NRTIs + one Non Nucleoside Reverse Transcriptase Inhibitor showed reduced mortality among people living with AIDS. *See id.* Triple therapy is commonly known as a drug "cocktail."

18. *See Guidance Modules on Antiretroviral Treatments: Module 1, Introduction to Antiretroviral Treatments*, UNAIDS & WHO, at 11, U.N. Doc. WHO/ASD/98.1 (1998), *available at http://www.who.int/HIV_AIDS/antiretroviral_*modules/mod1.doc.

19. *See AIDS in Africa*, THE NATION, Aug. 7, 2000, at 4.

20. *See* Pérez-Casas, *supra* note 2, at T.1.

21. *See id.* These antiretrovirals include didanosine (ddI), efavirenz, lamivudine (3TC), nevirapine (NVP), stavudine (d4T), zifovudine (AZT), and AZT/3TC combination. *Id.*

As a result, impoverished nations face price-related problems of access to these vital medicines under patent protection.

The cost of HIV/AIDS drugs varies widely from country to country.[22] In some cases, the standard United States price for a drug may be discounted by as much as ninety-eight percent in other countries.[23] The most important determinant of these different prices between countries is the existence of market monopolies.[24] Market monopolies are created, in part, by national and international patent laws.[25] Patents are the driving force that encourage the creation of new products and processes in the market, which benefit the public and stimulate economic growth.[26] Once a nation grants a patent, the patentee has the "negative" right to prohibit others from "using, offering for sale, selling, or importing" the invention without the patentee's consent.[27] However, no international patent system exists for inventions. Consequently, the inventor must file a patent application in every country where protection is desired.[28]

The patent compensates pharmaceutical companies for their research and development (R&D) costs. Drug development is a risky and expensive process. Synthesizing a drug may take ten to twelve years,[29] and only one out of 5000 synthesized compounds will make it to the market.[30] Since so few drugs advance to the profit-bearing market, this places more investment burden on the successful drug, in some cases increasing costs by $350 million.[31] Without the protection of patents, pharmaceutical companies risk losing millions of dollars as companies that did not have to undertake the costly research and development produce and sell the same drug at lower costs.[32] Thus, patent

22. *See id.* at 9. For example, Lamivudine ranges from $0.80, $1.70, $2.40, $0.50, $1.10, $2.50, $1.60, and $4.50 for Brazil, Colombia, Guatemala, India, South Africa, Thailand, Uganda and the United States, respectively. *Id.* at T.2.

23. *See* Pérez-Casas, *supra* note 2, at T.2.

24. *See id.*

25. Other factors include tariffs, taxes, price controls, government price negotiations, and price mark-ups. *See id.*

26. *See* MICHAEL P. RYAN, KNOWLEDGE DIPLOMACY 26 (1998).

27. P. Boulet et al., *Patent Situation of HIV/AIDS-related Drugs in 80 Countries,* UNAIDS & WHO, Jan. 2000, ¶ 10, *at* http://www.unaids.org/publications/documents/health/access/patsit.doc.

28. *See id.* ¶ 8.

29. *See* RYAN, *supra* note 26, at 30.

30. *See* R.G. Halliday, et al., *R & D Philosophy and Management in the World's Leading Pharmaceutical Companies*, 2 J. PHARM. MED. 139 (1992).

31. *See* RYAN, *supra* note 26, at 30.

32. U.S. pharmaceutical companies' sales to Brazil were $27 million, while unauthorized sales by Brazilian pharmaceutical companies of the same drugs were $12

protection serves as a barrier to market entry, providing guaranteed profits in the billions of dollars for pharmaceutical companies.

The threat of generic competition still plagues the pharmaceutical companies. For example, Brazil can offer some of the lowest prices for generic products. In Brazil, a generic version of zidovine sells for one-fourteenth of its price in the United States.[33] Poorer countries buy these drugs from cheaper sources, such as Brazil, and import them back into their country, circumventing any national patent laws. Pharmaceutical companies encounter substantial profit losses on patented drugs when generic drug producers provide an effective substitute worldwide. Problems such as this led to the political push for a new international agreement on intellectual property rights.

B. TRADE-RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS ASSIGNMENT

1. In General

The Trade Related Aspects of Intellectual Property Rights Agreement (TRIPs) is the broadest international intellectual property agreement because of its expansive coverage and enforcement mechanisms.[34] Under TRIPs, Member States must make patents available for all inventions specifically defined in TRIPs.[35] Patents are valid for twenty years from the filing

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million. *See* Gerald J. Mossinghoff, *Research-Based Pharmaceutical Companies: The Need for Improved Patent Protection Worldwide*, 2 J.L. & TECH. 307, 309 n.6 (1987). If these drugs had been protected by a Brazilian patent law in 1985, U.S. pharmaceutical companies' sales would have increased by nearly 50 percent. *See* Christopher S. Mayer, *The Brazilian Pharmaceutical Industry Goes Walking from Ipanema to Prosperity: Will the New Intellectual Property Law Spur Domestic Investment?*, 12 TEMPLE INT'L & COMP. L.J. 377, 396 (1998).

33. *See* Pérez-Casas, *supra* note 2, at 10.

34. *See* DANIEL GERVAIS, THE TRIPS AGREEMENT: DRAFTING HISTORY AND ANALYSIS 3 (1998). TRIPs builds upon the legal foundations of four international instruments: the Paris Convention protecting industrial property; the Berne Convention protecting literary and artistic works; the Rome Convention protecting performers, broadcasting, and musical works, and; the Treaty on Intellectual Property protecting integrated circuits. *See id.* at 26.

35. *See* Agreement on Trade-Related Aspects of Intellectual Property Rights, Dec. 15, 1993, 33 I.L.M. 81 (1994) [hereinafter TRIPs]. Members must make patents available for any inventions that are new, involve an inventive step, and are capable of industrial application. *Id.* at art. 27, ¶ 1.

date.[36] Article 28 describes the rights conferred on the patentee and gives patent owners the "exclusive rights . . . to prevent third parties, not having the owner's consent from the acts of: making, using, offering for sale, selling or importing" products and processes.[37]

The major purpose of the agreement was to induce developing countries to enact legislation compliant with minimum intellectual property standards.[38] Unfortunately, the implications of patent protection mean developing countries will experience significantly higher drug prices.[39] The disparate impact that drug patents will have on developing nations and the pharmaceutical industry is enormous. The welfare loss suffered by developing countries is estimated to be between $3.5 billion and $10.8 billion, while the gain by foreign patentees is estimated to fall between $2.1 billion and $14.4 billion.[40]

2. *Treaty-Created Exceptions*

TRIPs does provide exceptions for developing countries to obtain drugs at cheaper prices. Parallel importation, or exhaustion, permits a party to buy a patented drug in one country and re-sell it in a second country at a lower price than the patentee. Article 6 of TRIPs states, "For the purposes of dispute settlement under this Agreement, subject to the provisions of Articles 3 and 4 above, nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights."[41] Under international law, once a legal reproduction of a product has been distributed anywhere in the world, the rights of that reproduction are exhausted.[42]

Compulsory licensing also assists countries in increasing access to cheaper drugs. Compulsory licensing permits a coun-

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36. *See id.* at art. 33.

37. *Id.* at art. 28, ¶ 1(a).

38. *See* Ruth L. Gana, *Prospects for Developing Countries Under the TRIPs Agreement*, 29 VAND. J. TRANSNAT'L L. 735, 740 (1996). *See also* John E. Giust, *Noncompliance with TRIPs by Developed and Developing Countries: Is TRIPs Working?*, IND. INT'L. & COMP. L. REV. 69, 70 (1997).

39. *See* CARLOS M. CORREAS, INTELLECTUAL PROPERTY RIGHTS, THE WTO AND DEVELOPING COUNTRIES 36 (2000).

40. *See id.* at 35 (citing Nogués).

41. TRIPs, *supra* note 35. Articles 3 and 4 address national treatment and most-favoured nation treatment. *See id.* at art. 3, 4.

42. *See* Vincent Chiapetta, *The Desirability of Agreeing to Disagree: The WTO, TRIPs, International IPR Exhaustion and a Few Other Things*, 21 MICH. J. INT'L L. 333, 341 (2000).

try to manufacture a patented drug itself if it pays a royalty to the patentee.[43] This has the effect of cutting the cost of drugs by as much as ninety-five percent.[44] TRIPs permits the use of compulsory licensing: (1) against any crises in public safety or health; and (2) to promote public interest in the areas of socio-economics and development.[45]

Article 8 allows Member States to adopt legislative or regulatory measures "necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic . . . development . . . provided that such measures are consistent with the provisions of this Agreement."[46] Article 8 acts as a policy statement for Articles 30, 31, and 40.[47] It suggests that a Member State cannot be prevented from considering general public policy or public welfare when enacting post-TRIPs patent laws.[48]

Article 27 provides exceptions to patents when necessary to prevent abusive commercial exploitation of the invention and to protect *ordre public*, morality, and human life or health.[49] There is no generally recognized definition of *ordre public*,[50] but the risk must arise from the invention's commercial exploitation rather than the invention itself.[51] Thus, if a country can prove its actions are "necessary" to protect public health, it could refuse to grant a patent on a drug and produce and sell the drug through a non-commercial body.[52]

Article 31 permits Members to determine the basis for

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43. *See What is the United States' Role in Combating the Global HIV/AIDS Epidemic?: Hearing Before the Subcomm. on Criminal Justice, Drug Policy, and Human Resources*, 106th Cong. 152 (1999) (statement of James Love, Director, Consumer Project on Technology).

44. *See id.*

45. *See* TRIPs, *supra* note 35, at art. 8.

46. *Id.* at art. 8, ¶ 1.

47. *See* GERVAIS, *supra* note 34, at 68. Article 30 permits parties to provide limited exceptions to the rights conferred by a patent; Article 31 states the required conditions for States to implement legislation allowing the use of a patent without the authorization of the patentee; Article 40 addresses control of anti-competitive practices in contractual licenses. See TRIPs, *supra* note 35.

48. *See* CORREAS, *supra* note 39, at 7.

49. TRIPs, *supra* note 35, at art. 27, ¶ 2. *See also Overview: The TRIPs Agreement*, World Trade Organization, *at* http://www.wto.org/english/tratop_e/trips_e/intel2_e.htm#patents (last visited January 13, 2001).

50. *See* CORREAS, *supra* note 39, at 62.

51. *See* GERVAIS, *supra* note 34, at 148.

52. *See* Robert Weissman, *A Long Strange TRIPs: The Pharmaceutical Industry Drive to Harmonize Global Intellectual Property Rules, and the Remaining WTO Legal Alternatives Available to Third World Countries*, 17 U. PA. J. INT'L ECON. L. 1069, 1109-10 (1996).

granting compulsory licenses,[53] and limits any compulsory license issued by restricting it to the purpose for which it was granted, mandating that the license is non-exclusive, and making it non-assignable.[54] A country may grant a compulsory license if the "user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and . . . such efforts have not been successful within a reasonable period of time" and also if the patentee will be adequately remunerated.[55] Some developing nations believe that compulsory licenses should be granted when drugs exist that are capable of curing or hindering the disease, valuing the right to receive health treatment above potential economic damages to the company.[56] Public health advocates and many developing nations claim the treaty permits them to produce or import generic drugs to avert the national disaster of the AIDS epidemic.[57] Pharmaceutical companies disfavor compulsory licensing and claim the policy removes any incentive for research and development in drugs subject to compulsory licensing.[58]

Signatory nations to TRIPs must comply with or exceed the minimum standards set by TRIPs. The agreement gives developing nations extra time to comply with its provisions. Developing member nations must comply with TRIPs starting in 2000.[59] Least-developed countries are not bound by TRIPs until 2006,[60] with possible extensions by the TRIPs Council.[61] Despite these

53. TRIPs, *supra* note 35, at art. 31.

54. TRIPs, *supra* note 35, at art. 31(c)-(e).

55. *Id.* at art. 3(b) and (h).

56. *See* Sara M. Ford, Note, *Compulsory Licensing Provisions Under the TRIPs Agreement: Balancing Pills and Patents*, 15 AM. U. INT'L L. REV. 941, 964 (2000).

57. *See* Donald G. McNeil Jr., *As Devastating Epidemics Increase, Nations Take on Drug Companies*, N.Y.TIMES, July 9, 2000, at 8.

58. *See* Patrick Bond, *Globalization, Pharmaceutical Pricing, and South African Health Policy: Managing Confrontation with U.S. Firms and Politicians*, 29 INT'L J. HEALTH SERVICES 765, 779 (1999) (quoting Harvey Bale, Director-General of the International Federation of Pharmaceutical Manufacturers in Geneva).

59. TRIPs, *supra* note 35, at art. 65 (providing developing countries with a grace period of five years to apply the provisions of the Agreement).

60. *Id.* at art. 66, ¶ 1 (providing these countries with a grace period of 11 years). The justification for providing the least developed country members with a longer grace period is explained in Article 66: "In view of the special needs and requirements of least-developed country Members, their economic, financial and administrative constraints, and their need for flexibility to create a technological base, such Members shall not be required to apply the provisions of this Agreement. . .for a period of 10 years. . ." *Id.* The delay does not include provisions regarding national treatment and Most Favored Nation (MFN) status. *Id.* at art. 66, ¶ 1.

61. *See id.* Article 66, ¶ 1 of TRIPs explains that the "needs and requirements of least-developed country Members, their economic, financial, and administrative

extensions, both developing and least-developed nations must make certain patent services available to patent-seekers.[62]

In case of non-compliance, TRIPs provides for World Trade Organization (WTO) dispute resolution.[63] Member States contesting the patent laws of another Member may bring a complaint against that State before a Dispute Settlement Panel. If the State is unhappy with the Panel's decision, it may appeal to the Appellate Body for review of the panel decision. In addition, TRIPs requires that Member states provide national processes and solutions for patentees to enforce their rights effectively.[64]

3. Drawbacks of the Exceptions

Public health groups believe that impoverished nations are deterred from utilizing parallel importation or compulsory licensing for fear of trade sanctions or legal challenge.[65] International pressure by the pharmaceutical industry on developing countries to strengthen their intellectual property laws is high. Such pressure may be brought directly by the pharmaceutical company against the offending nation in national court systems, through the WTO dispute resolution system, or by unilateral threats of trade sanctions.

The United States has been conspicuously active in pressuring other countries to strengthen their patent laws through the threat of trade sanctions and WTO dispute settlement actions. The 1988 amendments to the United States Trade Act implemented "Special 301," a statutory provision that allows the United States to employ trade sanction measures.[66] Special 301, as a means of putting pressure on countries with weak intellec-

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constraints, and their need for flexibility to create a viable technological base." *Id.* *See also* GERVAIS, *supra* note 34, at 257.

62. TRIPs, *supra* note 35, at art. 70, ¶ 8. This article requires patent services include a "mailbox" available for pharmaceutical patent applications. This "mailbox" began accepting filed applications as of January 1, 1995. *Id.* Also, if a patent and marketing approval has been granted for a product in one country, the second country is required to grant an "exclusive marketing right" for that product. *Id.* at art. 70, ¶ 9. *See also* U.N. CONF. ON TRADE & DEV., THE TRIPS AGREEMENT AND DEVELOPING COUNTRIES, at 11, para. 6, U.N. Doc. UNCTAD/ITE/1, U.N. Sales No. 96.II.D.10 (1996).

63. TRIPs, *supra* note 35, at art. 64, 68.

64. *Id.* at art. 42-49.

65. *See Activists Highlight AIDS Toll During Annual Observance*, MED. INDUSTRY TODAY, Dec. 2, 1999, at 1.

66. *See* JOHN H. JACKSON ET AL., LEGAL PROBLEMS OF INTERNATIONAL ECONOMIC RELATIONS 818 (3d ed. 1995).

tual property protection laws, permits the United States Trade Representative (USTR) to begin investigations upon citizen petition or its own initiative.[67] Under the Generalized System of Preferences (GSP), the United States may threaten trade sanctions against any trading country that does not provide "adequate and effective protection of intellectual property rights" or denies "fair and equitable market access to U.S. persons who rely upon intellectual property protection."[68] Furthermore, the USTR may list suspect countries as "Priority Foreign Countries," "Priority Watch List Countries," or "Watch List Countries."[69] This listing may lead to negotiations or trade sanctions if the country fails to change its patent laws to satisfy the United States.[70]

Thailand is one example of a country where the United States successfully tightened patent laws by threatening trade sanctions. In 1992, Thailand amended its Patent Act of 1979 to allow compulsory licensing and parallel importing.[71] This legislation directly conflicted with United States interests when Thailand began producing a generic version of the HIV antiretroviral didanosine (ddI).[72] After threats of trade sanctions, Thailand halted its generic ddI production.[73] Responding to pressure from the United States, Thailand again amended the Patent Act in 1999, effectively eradicating parallel importing and restricting compulsory licensing.[74]

If the AIDS crisis in Thailand is a "national emergency," ar-

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67. *See id.*

68. 19 U.S.C. §§ 2461-67 (1998).

69. *See* Judith H. Bello & Alan F. Holmer, *"Special 301": Its Requirements, Implementation, and Significance,* 13 FORDHAM INT'L L.J. 259, 266-67 (1990) (Titles are in order of decreasing perceived violations).

70. *See id.* at 262-63.

71. *See* Rosemary Sweeney, *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 445, 451 (2000).

72. *See* Bond, *supra* note 58, at 775.

73. *See id.*

74. *See* Sweeney, *supra* note 71, at 449 (citing Thailand Patent Act (No. 3) B.E. 2542 (1999) Art. 36(7)). The 1999 Amendments explicitly prohibit parallel importing without the patentee's permission. *See id.* As a result, it is illegal to import generic drugs into Thailand, even from countries where drugs are unprotected by patents and generic production is legal. *See id.* By specifically addressing parallel importation, Thailand's 1999 Act gives more protection against parallel importation than TRIPs. *Compare* TRIPs, *supra* note 35, at art. 6 *with* Thailand Patent Act (No. 3) B.E. 2542 (1999) Art. 36(7) (cited in Sweeney, *supra* note 71, at 449). The Amendments also limit the Thai government's ability to grant compulsory licenses. *See* Sweeney, *supra* note 71, at 452.

guably Thailand should be able to grant compulsory licenses legally under TRIPs and its 1999 Act. The threat of United States sanctions has made pursuing this route undesirable.[75] The United States is Thailand's biggest export market, totaling $12.65 billion in 1999.[76] Moreover, because the United States market promises great economic benefit, Thailand will be reluctant to risk losing the United States as a commercial partner.[77] Currently, Thailand is on the United States "Regular Watch List."[78] Between the benefits of compulsory licensing and the possibility of trade sanctions, it is likely that Thailand will avoid sanctions and renounce compulsory licensing.

C. SOUTH AFRICA

South Africa's current patent laws are codified in the Medicines and Related Substances Amendment Act. South Africa amended its Medicines and Related Substances Act 101 in 1997 to give its Minister of Health discretion over when to grant compulsory licenses for the production of generic medicines.[79] Specifically, the amendment grants the Minister of Health the power to allow for compulsory licensing, provided the drug was initially marketed by the patentee or with the patentee's consent and the drug does not have other expressed restrictions.[80] Some feel that Article 15(C)(a) of the South African Act ends patent rights by stating that pharmaceutical patent rights "shall not extend to acts in respect of such medicine which has been put onto the market."[81] Interpreted broadly, this provision could deny patentee protection once they begin to sell their

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75. *See* Sweeney, *supra* note 71, at 463-64.

76. *Thailand's Exports Increase Seven Percent in 1999*, XINHUA, Feb. 28, 2000, *at* 2000 WL 14191093. Thailand's total exports in 1999 amounted to $58.49 billion. *Id.*

77. For example, Thai exports to the United States increased 17.7% in the first seven months of 2000. *See Commerce Ministry Says Climate Right for Further Export Growth*, BUS. DAY (THAIL.), Sept. 5, 2000, *at* 2000 WL 6317728.

78. *See* Sweeney, *supra* note 71, at 462. From 1989, the USTR moved Thailand through a series of watch lists, from "priority watch list" (1989), to "priority foreign country" (1991) to "priority watch list" (1993) to "regular watch list" (1994) in response to moves by Thailand to strengthen intellectual property laws. *See id.* at 460-62 (citations omitted).

79. *See* Duane Nash, *South Africa's Medicines and Related Substances Control Amendment Act of 1997*, 15 BERKELEY TECH. L. J. 485, 492 (2000).

80. Medicines and Related Substances Control Amendment Act, No. 90, § 10 (1997) (S. Afr.) [hereinafter Medicines] (referring back to Medicines and Related Substances Control Amendment Act, No. 101, § 15(C) (1965)).

81. *Id.*

drugs.[82] The Act also weakens patent protection under 15(C) by permitting parallel importation under 15(C)(b).[83]

The international response to Article 15(C) was swift. United States government officials proposed bilateral trade sanctions to pressure South Africa to repeal the amendment. The USTR placed South Africa on the "Watch List," and the White House tentatively withheld preferential tariff treatment for four South African exports.[84] The Pharmaceutical Manufacturers' Association (PMA) of South Africa, on behalf of forty domestic and international pharmaceutical companies, brought a lawsuit against the South African government upon the enactment of the Act.[85] After the suit was filed, the South African government passed the South African Medicines and Medical Devices Regulated Authority Act (SAMMDRA), which rescinded the Medicines and Related Substances Amendment Act and the amendment. Due to various failings of SAMMDRA, President Mandela repealed it. In response, the courts ruled that President Mandela acted outside of his executive power when he rescinded SAMMDRA.[86] The PMA put its lawsuit on hold while the Minister of Health agreed to consider legislation that would better comply with TRIPs.[87] In April 2001, the PMA made a startling move announcing that it would drop the lawsuit entirely.[88] Since then, no other drug industry has challenged

82. *See id.*

83. *See id. See also* David Benjamin Snyder, *South Africa's Medicines and Related Substances Control Act: A Spoonful of Sugar or a Bitter Pill to Swallow?* 18 DICK. J. INT'L L. 175, 186 (1999).

84. *See* Bond, *supra* note 58, at 771, 774. The State Department reported that it would ". . .continue our unflagging efforts to convince the South African Government to either repeal Article 15(C) or make it consistent with the TRIPs agreement, and thus eliminate the possibility that any abrogation of U.S. pharmaceutical patent rights in South Africa. Should there be an actual violation of any U.S. pharmaceutical patent right (e.g. patent abrogation) this Administration will respond forcefully in accordance with appropriate trade remedy legislation." *Id.* at 774 (citations omitted).

85. *See* Lynn Woods, *Government AIDS Efforts To Target Drug Makers: Pharmaceuticals Act to Stop Backlash Against their IP Rights*, BUS. WITHOUT BORDERS, Aug. 2000, at 18, in CORP. LEGAL TIMES (Aug. 2000). The lawsuit was later put on hold. *See also* McNeil, *supra* note 57 (describing when South Africa attempted to pass legislation permitting the health minister to disregard TRIPs in health crises, the U.S. pressured South Africa with threats of trade sanctions).

86. *See* Woods, *supra* note 85.

87. *See Drug Patents: Clash Averted for Now*, FIN. MAIL (S. Afr.), Sept. 24, 1999, at 14, *available at* 1999 WL 16764741. *See also* Gumisai Mutume, *Trade: U.S. Drug Companies Ease Up on South Africa*, INTER PRESS SERVICE, Sept. 12, 1999, *available at* 1999 WL 27373954.

88. *See Campaign Accomplishments for 2001*, CAMPAIGN FOR ACCESS TO

South Africa's laws within the South African court system.

In response to growing international pressure by AIDS activists and public health groups[89] over the growing problem of access to drugs, President Clinton issued an executive order to promote access to HIV/AIDS medicines on May 10, 2000.[90] The order permits sub-Saharan Africa to regulate privately patented pharmaceuticals,[91] provided the legislation still complies with TRIPs. The order also permits United States government officials to evaluate and take action if a law or policy is inconsistent with the TRIPs agreement.[92] The order protects South Africa from United States trade retaliation or WTO dispute settlement in regard to its patent laws.

Following President Clinton's executive order, the five largest pharmaceutical companies promptly signed an agreement with the United Nations to cut the price of HIV/AIDS drugs up to eighty percent for impoverished countries.[93] Bristol-Myers Squibb, Roche, Boehringer Ingelheim, Glaxo-Wellcome, and Merck & Company offered lower prices for various HIV/AIDS drugs.[94] The impact of this gesture is diminished by the existence of cheaper generics in Thailand, India, and Brazil.[95] The eighty percent reduction is inadequate to make the drugs affordable to most Africans.

Fortunately, the HIV/AIDS problem is a crisis recognized by the world. Nations, nongovernmental organizations (NGOs), and intergovernmental organizations (IGOs) have donated mil-

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EFFECTIVE MEDICINES (Médecins Sans Frontiéres, Brussels, Belgium), Apr. 23, 2001.

89. *See generally Activists Highlight AIDS Toll During Annual Observance*, *supra* note 65.

90. Exec. Order No. 13155, 3 C.F.R. 268-70 (2000). "This order prohibits the United States Government from taking 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.*

91. *See id. See also* Neeraj Kaushal, *EcoScope: Not by Aid Alone*, ECON. TIMES, May 16, 2000, *at* 2000 WL 16892773.

92. *See* Exec. Order 13155, *supra* note 90.

93. *See* Kaushal, *supra* note 91.

94. *See Companies Agree to Cut Prices of HIV Drugs in Poor Nations*, MED. INDUSTRY TODAY, May 12, 2000, at 1. Glaxo-Wellcome (UK) will offer Combivir (AZT and 3TC) at a cost of $2, compared with $16.50 in the United States. *See id.* Bristol-Myers Squibb (US) intends to increase access to antiretroviral drugs, Videx, Zerit, Megace, and Fungizone. *See id.* Roche (Switzerland) will offer developing countries better rates. *See id.*

95. *See* Kaushal, *supra* note 91.

lions of dollars in drugs, services, and assistance to combat this disease. Yet, these efforts still fall short of supplying the majority of the thirty-six million people with the medication they desperately need. One promising alternative for South Africa is to seek affordable drugs through the generic drug sector.

D. GENERIC DRUGS

The generic drug industry is a viable solution for increasing the affordability of essential medicines. By producing copied versions, generic companies are able to provide cheaper versions of otherwise unaffordable drugs. The average price of HIV/AIDS drugs in South Africa was eighty-two percent less than prices in the United States because of the availability of generic drugs.[96] The international organization Doctors Without Borders found that in most cases, even if brand-name prices were reduced eighty-five percent, the prices would still not drop as low as generic copies.[97]

Brazil provides one example of how access to generic drugs can revolutionize the fight against AIDS. In 1971, Brazil took steps to make medicines available to impoverished Brazilians and created Central de Medicamentos (CEME).[98] CEME proposed assisting state-owned laboratories and giving preferential treatment to domestic companies. In short, CEME promoted the domestic production of most AIDS drugs.[99] From 1969 to 1994, there was no Brazilian patent protection available for international pharmaceutical products or procedures.[100] Instead, Brazil's pharmaceutical companies produced generic drugs with astounding success.[101] In fact, Brazil's pharmaceutical market is now the fourth largest in the world, grossing over $8 billion.[102] By producing generic drugs, Brazil forced prices of imported drugs down through domestic competition and lowered its AIDS-related death rate.[103] In 1996, Brazil used compulsory li-

96. *See* Pérez-Casas, *supra* note 2, at 9.

97. *See id.*

98. *See* Mayer, *supra* note 32, at 379. Despite the lack of protection for drugs, foreign investment in Brazil's pharmaceutical industry increased from $113 million in 1971 to $646 million in 1979. *See* id. at 380 (citations omitted).

99. *See id.* at 379 (citations omitted).

100. *See* Gary Gereffi, THE PHARMACEUTICAL INDUSTRY AND DEPENDENCY IN THE THIRD WORLD 229 (1983).

101. *See* Mayer, *supra* note 32, at 380; *see also* GEREFFI, *supra* note 100.

102. *See e.g., New Intellectual Property Law in Brazil*, 8 J. PROPRIETARY RTS. 34 (1996).

103. *See AIDS in Africa*, *supra* note 19.

censing to make antiretrovirals available to all persons infected with HIV/AIDS.[104] Brazil's public health system can administer antiretroviral therapy to 1000 people living with HIV/AIDS for the same cost that the Ugandan government spends to treat two hundred twenty-eight people living with HIV/AIDS.[105] As a result, AIDS mortality in Brazil plummeted by half of its projected rate by the end of 1999.[106]

Yet, even the generic drug sector is not immune to legal challenge and skirmishes. India, a major producer of generic drugs, is one example of the legal battle that confronts the generic industry. Indian companies are among the largest generic drug manufacturers and control eighty-five percent of the Indian pharmaceutical market.[107] The Indian generic drug industry earns $900 million annually from domestic sales alone.[108] This extensive market control by the generic sector is due to India's weak patent laws, which did not provide patents for pharmaceutical products.[109] As a result, Indian-owned companies could copy an existing drug without paying a patent fee.[110] Furthermore, Indian generic companies reduced their need to invest in research and development by simply copying the drugs, which enabled them to keep their drug prices low.[111]

The United States placed India on its "Priority Watch List" in 1996 for its lack of protection for patented pharmaceutical drugs.[112] It claimed its pharmaceutical industry lost $450 million due to India's weak patent protection laws.[113] India and the

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104. *See* Claire Bisseker, *The Turning of the Tide*, FIN. MAIL, July 21, 2000, *at* 2000 WL 8448820.

105. *See* Pérez-Casas, *supra* note 2, at 12. Antiretroviral therapy of ddI 400mg + d4T 80 mg daily costs $78 per month in Brazil, where it is manufactured locally as generics. *See id.* In Uganda, the cost is $342 per month, as there are no generics available. *See id.*

106. *See* Bisseker, *supra* note 104.

107. *See* David K. Tomar, *A Look Into the WTO Pharmaceutical Patent Dispute Between the United States and India*, 17 WIS. INT'L. L. J. 579, 592 (1999). *See also India's Lax Patent Regime Hits U.S. Pharmaceutical Companies*, MARKETLETTER, Jan. 19, 1998, *available at* 1998 WL 9220214.

108. *See* George K. Foster, *Opposing Forces in a Revolution in International Patent Protection: The U.S. and India in the Uruguay Round and Its Aftermath*, 3 UCLA J. INT'L L. & FOR. AFF. 283, 307 (1998).

109. *See* Tomar, *supra* note 107, at 583-84.

110. *See id.* at 584.

111. *See* J.H. Reichman, *Compliance with the TRIPs Agreement: Introduction to a Scholarly Debate*, 29 VAND. J. TRANSNAT'L L. 363, 379 (1996).

112. *See U.S. Opens Investigation into Protection of Intellectual Property Rights in India*, 13 INT'L TRADE REP. (BNA) 1117, July 10, 1996.

113. According to the USTR, India neither provided a permanent mailbox system nor did it have a system to grant exclusive marketing rights to inventors. *See*

United States were unable to resolve their differences, so they presented the issue to the WTO Dispute Settlement Panel.[114] The United States prevailed on its claim, and India appealed.[115] The WTO Appellate Body held that India had not complied with TRIPs and ordered India to do so.[116] Meanwhile, the United States continues to battle the generic industry, and it recently began proceedings in the WTO dispute settlement system to determine possible violations of TRIPs by Brazil. The United States claims that Article 68 of Brazil's 1996 Industrial Property Law discriminates against U.S. patented products that are imported into, but not produced within, Brazil.[117]

Based on the experiences of Thailand, Brazil, and India, it would appear likely that South Africa faces similar threats of trade sanctions or dispute settlement in the WTO. Yet, as the analysis will argue, such a fate for South Africa is improbable due to international law, public relations, and increasing global HIV/AIDS awareness.

II. ATTEMPTS TO INCREASE DRUG AVAILABILITY IN SOUTH AFRICA

A. TRIPs

"We need life-saving action, not litigation, not lawsuits."[118] The words of Representative Barbara Lee reflect the growing sentiment by the international community, the NGO sector, governments, and even the pharmaceutical industry that the battle against AIDS cannot be hampered by legal fights. Yet, in spite of these valiant words, pharmaceutical companies and developed nations often use TRIPs to challenge patent laws in de-

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USTR to Investigate India's Protection of Intellectual Property Rights, 8 J. PROPRIETARY RIGHTS 10, Oct. 1996.

114. *See U.S.-India Patent Dispute Continues*, 9 J. PROPRIETARY RIGHTS 6, at 33, June 1997.

115. *See Report of the Panel, India-Patent Protection for Pharmaceutical and Agricultural Chemical Products*, at 63, WTO Doc. WT/DS50/6 (1997). The WTO Dispute Panel originally found that India failed to comply with art. 70(8)(a) of TRIPs, or, in the alternative, article 63(1) and (2). Id.

116. *See Report of the Appellate Body, India-Patent Protection for Pharmaceutical and Agricultural Chemical Products*, at 33-34, WTO Doc. WT/DS50/AB/R (1997).

117. *See* Sarah Boseley, *Opinion: Pharmaceuticals Move Their Battleground to Brazil to Stem the Tide of Cheaper Drugs-Drug Companies are now Focusing on South America to Prevent Cheap Generic AIDS Drugs from Reaching the United States*, IRISH TIMES, Apr. 20, 2001, at 14.

118. *See* 147 CONG. REC. H995, *supra* note 10 (statement of Rep. Lee).

veloping countries. The international community has already encountered litigation over TRIPs between the United States and India. After a prolonged dispute, India was ordered to strengthen its patent laws to conform to TRIPs.[119] Currently, the world is witnessing a "re-play" of the United States-India dispute, as the United States takes Brazil before the WTO panel, challenging its patent laws under Articles 27.1 and 28.1 of TRIPs.[120] This leads to the question of how international law affects South Africa's access to medicines and whether South Africa's laws can stand up to legal challenge.

South Africa's circumstances resemble those of India and Brazil, making it appear prone to the same legal challenges. Like India and Brazil, South Africa has a high number of people living with HIV/AIDS. In fact, South Africa has the highest in the world.[121] Like these countries, South Africa is a developing country seeking to improve its access to affordable drugs through legislation.[122] Unlike India and Brazil, South Africa has successfully evaded legal challenge and retaliation over its patent legislation.

One possible legal conclusion that explains why South Africa has not been haled before the WTO panel is because Article 15 simply does not violate any provision of TRIPs. Representative Lee remarked, "everyone from international patent experts to the World Health Organizations agrees that the South African Medicine Act is perfectly legally sound."[123] This appears to be somewhat of an overstatement; forty drug companies disagreed.[124] Specifically, the pharmaceutical industry found fault with South Africa's provisions on parallel importation and compulsory licensing.[125]

1. Parallel Importation

South Africa permits parallel importation under Article

119. *See Report of the Appellate Body*, *supra* note 116, at 64.

120. *See South Africa's Moral Victory*, LANCET, Apr. 28, 2001, *at* 2001 WL 10158573.

121. *See Report*, *supra* note 3.

122. *See* Bess-Carolina Dolmo, *Examining Global Access to Essential Pharmaceuticals in the Face of Patent Protection Rights: The South African Example*, 7 BUFF. HUM. RTS. L. REV. 137, 140-41 (2001).

123. *See* 147 CONG. REC. H995, *supra* note 10 (statement of Rep. Lee).

124. *See* Woods, *supra* note 85.

125. *See* Marina Jimenez, *Companies Fight Law Allowing Cheap, Generic AIDS Drugs: Test Case in South Africa*, *NAT'L. POST*, (Mar. 6, 2001), *available at* 2001 WL 14438143.

15(C)(b) of its Medicines and Related Substances Control Amendment Act. Article 15(C)(b) states that a drug that "meets the same quality standards and is intended to have the same proprietary name as that of another medicine already registered in the Republic, but which is imported by a person other than the person who is the holder of the registration certificate . . . may be imported."[126] It is debatable whether TRIPs prohibits parallel importation. Barfield and Groombridge argue that the parties to TRIPs "agreed to disagree" over the parallel importation issue.[127] They set forth several arguments for parallel trade, including reduced impetus for research and development and serious health and safety concerns over counterfeit drugs. However, Article 6 clearly states, "nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights."[128] Many scholars feel that because TRIPs fails to address parallel importation, it does not prohibit it.[129] Thus, a WTO Member should be free to import the cheapest drug available from another nation where the drug is legally sold to re-sell within its own territory. Presumably, an opposing Member State cannot argue international exhaustion as a violation of TRIPs.[130] Another common argument against a prohibition construction is that construing TRIPs to restrict parallel imports would conflict with the fundamental principles of free trade upon which the WTO rests.[131] Arguably, parallel importation is a domestic legal issue about which the South African government is free to decide.[132]

Recognizing the questionable quality of drugs produced in other developing countries and Kenya's recent experience in parallel importation, South Africa may be deterred from using parallel importation to get less expensive medicines. Developing countries often lack the technological capability to develop and dispense generic drugs safely.[133] In Kenya's experience

126. *See* Medicines, *supra* note 80.

127. *See* Claude E. Barfield & Mark A. Groombridge, *Parallel Trade in the Pharmaceutical Industry: Implications for Innovation, Consumer Welfare, and Health Policy*, 10 FORDHAM I.P., MEDIA & ENT. L.J. 185, 191 (1999).

128. *See id.*

129. *See e.g.*, Nash, *supra* note 79, at 490 (citations omitted); *see also* Snyder, *supra* note 83, at 188.

130. *See* Snyder, *supra* note 83, at 188.

131. *See* Barfield, *supra* note 127, at 191.

132. *See* Nash, *supra* note 79, at 494.

133. *See* Bisseker, *supra* note 104. This ineptitude can result in drug resistance or inactive ingredients. *See also Compulsory Licensing: Activists Demonstrate at WTO*, AM. HEALTH LINE, Nov. 1999.

with parallel importation, it found "alarming evidence" of substandard and counterfeit drugs, faced difficulties in recalling unsafe products, and dealt with consumer confusion over multiple brands of the same drug.[134] Ultimately, Kenya proscribed the parallel importation of drugs due to safety concerns.[135]

Despite such problems, South Africa has chosen to import generic drugs from India for HIV/AIDS treatment. Cipla, an Indian generic drug manufacturer, recently offered to sell its triple-combination therapy for $350 per year per patient and to governments for $600 per year.[136] The $350 price is ninety-six percent lower than the United States price.[137] Shortly following this announcement, a second Indian generic drug producer offered to sell the triple-combination therapy for $347 per year per patient to a South African generic drug firm.[138] In sum, parallel importation offers a legal and economically attractive option that South Africa is willing to accept.

2. Compulsory Licensing

Although the circumstances are limited, TRIPs leaves loopholes in the patent drug market for the generic manufacture of HIV/AIDS medicines. Under Articles 27 and 31, TRIPs permits compulsory licensing, subject to conditions that limit the domestic manufacturer's production of generic copies to certain circumstances. The relevant provisions require that compulsory licensing can be necessary to protect human life and health or to address a national emergency.[139] Some trade experts argue that Article 27.1 allows patents to be enjoyed without discrimination and therefore, any program for compulsory licensing based on public health is discriminatory.[140] However, most trade experts view this interpretation as absurd and cite the broad scope of TRIPs to permit compulsory licensing on nearly all public health

134. *See* Claire Bisseker, *Beware of Counterfeit Medicines, Kenya Warns South Africa Medicines Control*, 40 FIN. MAIL, Oct. 24, 1997, at 40.

135. *See id.*

136. *See* Press Release, Médecins Sans Frontiéres Campaign for Access to Essential Medicines, AIDS Triple-Therapy for Less Than $1/Day, Feb. 7, 2001, *at* http://www.accessmed-msf.org/ (last visited Oct. 14, 2001).

137. *See id.*

138. *See Inside the Industry Merck: Lowers AIDS Drugs Prices for Africa*, 6 AM. HEALTH LINE 9, ¶ 2 (Mar. 8, 2001). Hetero Drugs, Ltd. entered into an agreement with Aspen Pharmacare, Ltd., a South African generic drug firm, to distribute generic drugs. *See id.*

139. *See* TRIPs, *supra* note 35, at art. 27, 31.

140. *See* Bond, *supra* note 58, at 777 (citations omitted).

grounds.[141]

Under Article 27, the issue of whether compulsory licensing is necessary to protect human life or health in South Africa has two counter-arguments.[142] First, the standard is "necessary," suggesting that no alternatives exist.[143] While supplying antiretrovirals is an important follow-up treatment for post-HIV diagnosis, pharmaceutical companies, the health care sector, and activists recognize that education, prevention, diagnosis, and counseling are also vital measures to preserve human life and health amidst the AIDS crisis. In fact, South Africa has follow-up support and established care procedures for HIV-positive patients.[144] Moreover, it provides programs that educate and prevent the spread of HIV, including HIV-specific testing. Alongside the array of preventative programs available, drug treatment is not the only means of protecting life and health of South Africans during the AIDS crisis. As the Special Session of the United Nations General Assembly noted, antiretroviral therapy is not a cure for people dying of AIDS;[145] it merely reduces the presence of the virus.

The terminal progress of AIDS and staggering number of AIDS-related deaths is highly persuasive evidence that compulsory licensing is necessary to protect human life or health. A death from AIDS is a premature death. Most people who acquired HIV from unprotected sex are in their twenties or thirties.[146] A majority of these people can expect to die within ten years.[147] If these people had triple combination therapy, the mortality rates would be dramatically lowered. Despite the existence of effective therapy, several thousand South Africans continue to die each day from AIDS because of the unaffordable price of drugs.[148]

Moreover, the number of children left orphaned as a result of AIDS is overwhelming. Already, AIDS has orphaned 13.2 million children, and twenty to twenty-five percent of homes in

141. *See id.*; *see also* TRIPs, *supra* note 35, at art. 31.

142. *See* TRIPs, *supra* note 35.

143. *See* Gervais, *supra* note 34, at 150.

144. *See Epidemiological Fact Sheet-South Africa-2000 Update: On HIV/AIDS and Sexually Transmitted Infections*, UNAIDS, at 8, *available at* http://www.unaids.org/hivaidsinfo/statistics/june00/fact_sheets/pdfs/southafrica.pdf (last visited Sept. 15, 2001).

145. *See Special Session*, *supra* note 1, ¶ 98.

146. *See id.*

147. *See id.* Ten years is the average number of years for these people to live. *See id.*

148. *See* 147 CONG. REC. H995, *supra* note 10 (statement of Rep. Lee).

Africa have orphans.[149] These children face a difficult life, not only because of the loss of their parents, but also because children orphaned by AIDS face a higher risk of malnutrition, illness, abuse, and sexual exploitation than other orphans.[150] UNAIDS projects that by 2010, approximately forty million African children will be orphans due to AIDS.[151] In light of these factors, it follows that education, prevention, testing, and follow-up care do not constitute alternative measures for those who already have AIDS or are orphaned as a result of AIDS. In fact, increasing access to essential drugs seems vital to reducing the effects of this disease, elongating lives, and protecting the health and well-being of children. By increasing the affordability of drugs, the availability could stem mortality and reduce the numbers of children orphaned by AIDS-related deaths.

The impact of AIDS on the development, social, and economic infrastructure is another reason justifying South Africa's legislation. Article 8 permits legislation that is necessary to protect public health and to promote public sectors of importance to South Africa's socio-economic development.[152] South Africa's situation certainly meets the level of a socio-economic disaster in terms of development and education. The UN Programme Coordinating Board has declared the HIV/AIDS situation in sub-Saharan Africa a development crisis.[153] AIDS is "reversing decades of development" in the worst hit areas.[154] In fact, if the AIDS pandemic continues at its present rate, these areas can expect to lose approximately twenty-five percent of their economic growth over the next twenty years.[155] Also, its destructive impact on education is startling. AIDS diminishes the availability of qualified teachers, financial resources and the quality of education. It also forces numerous children to drop out of school to assist at home.[156] A review of the problem of HIV/AIDS by the UN Secretary General succinctly describes the socio-economic development crisis created by AIDS:

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149. *See Special Session*, *supra* note 1, ¶ 31.

150. *See id.*

151. *Framework for the International Partnership Against AIDS in Africa*, UNAIDS Programme Coordinating Board, Provisional Agenda Item 7, UNAIDS/PCB(9)/00.4, (May 2000), *available at* http://www.unaids.org/about/governance/files/pcb9-00.4-e.doc [hereinafter *Framework*].

152. *See* TRIPs, *supra* note 35, at art. 8

153. *See* Framework, *supra* note 151, at 1.

154. *Special Session*, *supra* note 1, ¶ 23.

155. *See id.* ¶ 1.

156. *See id.* ¶ 29.

> It changes family composition and the way communities operate, affecting food security and destabilizing traditional support systems. By eroding the knowledge base of society and weakening production sectors, it destroys social capital. By inhibiting public and private sector development and cutting across all sectors of society, it weakens national institutions. By eventually impairing economic growth, the epidemic has an impact on investment, trade and national security, leading to still more widespread and extreme poverty. In short, AIDS has become a major challenge for human security.[157]

The HIV/AIDS epidemic constitutes an Article 31 "national emergency" for South Africa. Furthermore, recognition by the international community of the magnitude of South Africa's situation is intensifying. In an effort to combat the spread of HIV and decrease its impact on human suffering, UNAIDS has created an International Partnership against AIDS in Africa.[158] If the HIV/AIDS situation in South Africa does not constitute a national emergency for purposes of compulsory licensing, then it is difficult to imagine what mass epidemic would.

B. PUBLIC RELATIONS

In addition to the legal arguments for the validity of South Africa's laws under TRIPs, there are compelling political factors that safeguard South Africa from challenge. It is doubtful that any country or drug company will challenge South Africa in any legal forum over its drug laws and policies due to other factors, including public relations and government policies.

Public relations is a factor that promises to shield South Africa from legal challenges and expand its pool of drug sources. The drug industry depends on public relations to increase consumption of its products.[159] Yet disapproval of developed countries' policies regarding access to drugs, especially toward the

157. *Id.* ¶ 23.
158. *See id.* ¶ 56.
159. *See* Bond, *supra* note 58, at 782.

United States and other governments, is highly visible.[160] Condemnation of restrictive United States policies is evident from frequent public demonstrations that express concern about the United States impeding developing countries from gaining access to essential drugs.[161]

The recent withdrawal of the lawsuit against South Africa by 40 pharmaceutical companies demonstrates the potential of public relations to change South Africa's future in medicines.[162] Although no country has taken South Africa before a WTO dispute resolution panel, the pharmaceutical industry attempted to challenge South Africa in its national court system. The pharmaceutical companies questioned three portions of South Africa's laws: the legality of parallel importation, the applicability of the compulsory licensing, and the discretion granted to the Minister of Health when deciding to grant compulsory licenses.[163] The pharmaceutical companies chose to drop the lawsuit, citing the need to cooperate and collaborate, not litigate.[164] Despite this explanation, it was becoming increasingly clear that the HIV/AIDS epidemic in South Africa probably qualified under the compulsory licensing exception because of the public health crisis. More importantly, the lawsuit was rapidly turning into a public relations disaster.[165] People worldwide opposed the lawsuit. For example, 300,000 individuals and 140 groups across 130 nations signed a worldwide petition to pressure the PMA to withdraw its suit.[166] Had the pharmaceutical industry pursued litigation, it may have been required to reveal sensitive information about its research and development costs, profit margins, and marketing costs. This information would likely have caused public disapproval.[167] The withdrawal probably benefits other developing nations seeking cheaper drugs. In

160. *See generally* Woods, *supra* note 85; *See also* Dzulkifli Abdul Razak, *Let's Give Hope to AIDS Victims*, N. STRAITS TIMES, July 16, 2000, at 27, *available at* 2000 WL 22840920.

161. *See Activists Highlight AIDS Toll During Annual Observance, supra* note 65.

162. *See Campaign Accomplishments for 2001, supra* note 88.

163. The pharmaceutical companies challenged the constitutionality of the discretion granted to the Minister of Health under South Africa's constitution. *See* Adele Baleta, *Drug Firms Take South Africa's Government to* Court, THE LANCET, (Mar. 10, 2001), *available at* 2001 WL 10158293.

164. *See South Africa Settles Patent Dispute with Drug Industry*, ANDREWS PHARM. LITIG. REP., May 2001, at 13.

165. *See South Africa's Moral Victory, supra* note 120.

166. *See Campaign Accomplishments for 2001, supra* note 88.

167. *See South Africa's Moral Victory*, supra note 120.

light of the ill-fated lawsuit and disastrous public relations effect, Ellen 't Hoen of Doctors Without Borders remarked that it was unlikely the drug companies would challenge another developing country in court in the near future.[168]

In addition to shielding South Africa from legal challenges, public relations also expand the pool of affordable drugs available to South Africa. For example, many pharmaceutical companies are touting their humanitarian efforts to increase access to HIV/AIDS drugs. In general, altruistic efforts have not been the foremost consideration of the pharmaceutical industry. As one spokesman for a pharmaceutical company stated, "The industry has never been philanthropic. It has always made products with an aim of getting a return on investment."[169] Yet, as the HIV/AIDS crisis grows, so do the humanitarian efforts by pharmaceutical companies. The recent offer of discounted HIV/AIDS drugs by the five largest pharmaceutical companies demonstrates this growing realization that they must improve their public image.[170]

The effect discounted prices will have on increasing access to drugs is questionable. Many sub-Saharan citizens would not be able to afford the drugs even if they were available at an eighty percent discount.[171] Triple drug therapy would still cost $2,000 per year, and considering the per capita income in Africa is less than fifty dollars per month,[172] that is a price beyond the reach of most South Africans.[173] The pharmaceutical companies have recognized this conundrum and announced further reductions this year. Last March, Merck & Company declared it would lower prices of its two AIDS drugs for certain developing nations.[174] One week following this announcement, Bristol-

168. *See* Press Release, Médecins Sans Frontiéres Campaign for Access to Essential Medicines, Drug Companies in South Africa Capitulate Under Barrage of Public Pressure, (Apr. 19, 2001), *available at* http://www.accessmed-msf.org/prod/publications.asp?scntid=218200141159&contenttype=PARA& (last visited Oct. 14, 2001).

169. *See* Razak, *supra* note 160.

170. *See Companies Agree to Cut Prices of HIV/AIDS Drugs in Poor Nations*, *supra* note 94.

171. *See AIDS in Africa*, *supra* note 19. "Even with price reductions of up to 80%, most Sub-Saharan nations will not be able to provide long-term drug treatment for 20-30% of their citizens." *Id.*

172. *See* Woods, *supra* note 85.

173. *See* Joel Lexchin, *Patents on AIDS Drugs Are Patently Unnecessary*, GLOBE & MAIL, Sept. 4, 2000, at A13.

174. *See* Karen DeYoung & Bill Brubaker, *Another Firm Cuts HIV Drug Price: Sub-Saharan Africa Is the Focus of Bristol-Myers Move*, WASH. POST, March 15, 2001, at A1.

Myers Squibb Company declared it would sell two AIDS drugs at "below cost" to sub-Saharan African countries.[175] Despite these reductions, prices for these drugs will not fall as low as generic prices.[176] Although Videx will now sell for $0.85 in South Africa, the same drug is still available in Thailand for $0.36.[177]

Other companies have taken price reduction a step further by donating the drugs. The German company Boehringer-Ingelheim offered Viramune, its version of Nevirapine, free for five years.[178] Recently, South Africa accepted a fifty million dollar donation of fluconazole from Pfizer.[179] Yet, even donations by pharmaceutical companies are viewed critically by drug consumers as ineffective and transparent public relations efforts. After Bristol-Myers Squibb donated drugs totaling one hundred million dollars, some observers viewed the donation critically, stating that the donation amounted to only three to four dollars per HIV-positive African.[180] By itself, the humanitarian factor is not enough to pave the way to vital medicines for all of South Africa's needy, but these gestures do expand South Africa's access to drugs.

C. POLITICAL INFLUENCE

A second factor that influences South Africa's access to drugs is political influence. Awareness in the international community and the United States is escalating due to coverage by the media and the responsive agendas of NGOs and IGOs. General public sentiment favoring increased access to medicines

175. *See id.* Bristol-Myers will charge $1 per day per patient for its drugs Zerit and Videx. *See id.*

176. *See id.* Merck will charge $600 per year per patient for Crixivan, a protease inhibitor. *See id.*

177. *See id.*

178. *See* Andrew Stawicki, *Africa Waits as Drug Firms Work It Out*, TORONTO STAR, Aug. 29, 2000, ¶ 3, *available at* 2000 WL 2539294. Viramune is a drug that prevents mother-to-child transmission of the AIDS virus. *See id.*

179. *See Albright Spotlights AIDS Fight*, HOUS. CHRON., Dec. 9, 2000, at 30, *available at* 2000 WL 24533258. Flucanozole is used to treat meningitis and throat inflammation of AIDS patients. *See id.*

180. *See* Bond, *supra* note 58, at 780 (quoting Love, J. Gore & Mbeki Commission and Compulsory Licensing Disputes with South Africa. Personal communication, Washington, D.C., April, 2, 1999). Critics also observed that the donation was less than the $146 million paycheck of the company's CEO and that the announcement came just two weeks before the World Health Assembly meeting in Geneva. *See* id.

is clear from grassroots efforts, NGO campaigns, and IGO initiatives.[181]

Numerous efforts by IGOs and NGOs have been prominent in the fight against AIDS. High-profile organizations, including UNAIDS and Nobel Peace Prize winner Doctors Without Borders, bring international and scientific attention to the problem.[182] The United Nations Commission on Human Rights approved a resolution submitted by Brazil stating that access to HIV/AIDS treatment is a fundamental aspect of the right to physical and mental health.[183] Recently, the United Nations Special Session on HIV/AIDS issued a Declaration of Commitment on HIV/AIDS, calling for national strategies and international cooperation to disseminate AIDS awareness and prevention.[184] The degree and intensity of attention from the international community has given the AIDS crisis a place on the agenda of nearly every nation.

The United States has a conflicted history when it comes to protecting patent laws and promoting access to medicines. The United States has already brought two developing nations before the WTO panel to seek stronger national patent laws and compliance with TRIPs.[185] It has effectively used the threat of trade sanctions to cow other nations into strengthening national patent laws.[186] In addition, the United States was the sole country out of fifty-three nations to veto the UN Human Rights Commission's declaration on access to HIV/AIDS treatment as a fundamental right.[187] Despite this seemingly anti-access behavior, the United States government appears increasingly interested in protecting and improving South Africa's access to drugs. In the 106th Congress, Senators Feinstein and Feingold introduced an amendment to the Africa Growth and Opportu-

181. *See, e.g., Activists Highlight AIDS Toll During Annual Observance*, *supra* note 65; Razak, *supra* note 160; Woods, *supra* note 85.

182. *See generally Accelerating Access to Care, Support, and Treatment*, UNAIDS, *available at http://www.unaids.org/acc_access/acc_care_support/news_bulletin2.html* (last visited on Sept. 15, 2001).

183. *See* Gustavo Capdevila, *Health: U.N. Rights Panel Favors Free Access to AIDS Drugs*, INTER PRESS SERVICE, Apr. 23, 2001, *at* 2001 WL 4803632.

184. *See* United Nations, *Declaration of Commitment on HIV/AIDS*, United Nations Special Session on HIV/AIDS, ¶¶ 37-57, (June 2001), *available at* http://www.unaids.org/whatsnew/others/un_special/Declaration2706_en.htm (last visited Aug. 2, 2001).

185. *See supra* notes 107-116 and accompanying text.

186. *See supra* notes 66-78 and accompanying text.

187. *See* Capdevila, *supra* note 183. The resolution was submitted by Brazil and approved by fifty-two of fifty-three countries. *See id.*

nity Act to increase access to generic AIDS drugs.[188] This amendment was later struck from the final Africa Trade Conference Report.[189] However, the growing crisis and international attention has changed attitudes over the course of just one year. President Clinton's Executive Order protecting access to drugs soon followed the deleted amendment.[190] The order protects the developing nations from retaliation and is a powerful shield for South Africa because it broadens its options considerably. Unlike Thailand, which was coerced into enacting stronger patent laws, South Africa no longer has the threat of trade sanctions looming over its shoulder. Likewise, South Africa is safe from India and Brazil's fate before the WTO dispute panel. The Executive Order clears the air of any Special 301 or WTO threats.[191] Thus, South Africa is free to enact affordable medicine legislation, develop access-friendly policies, and make decisions like the one to buy generic drugs from Cipla.

Legislators have continued their efforts to promote access to vital medicines. Senators Dianne Feinstein from California and Russ Feingold from Wisconsin continued their efforts to increase access to medicines by introducing the Access to AIDS Treatment Act of 2001, which would: 1) require World Health Organization and USAIDS to take the lead in the international organization of producing and distributing HIV/AIDS drugs; 2) permit developing countries suffering an HIV/AIDS health care crisis to use compulsory licensing or parallel importation consistent with TRIPs; 3) authorize $25 million per year in grants to developing countries to create and execute programs for improving health care systems and the distribution of HIV/AIDS drugs; 4) create a global database of HIV/AIDS drugs, including their price, quality, and patent status; and 5) authorize $1 million per year for loan repayment and deferment program for various health professionals who provide HIV/AIDS treatment and care in developing nations.[192]

The Affordable HIV/AIDS Medicines for Poor Countries Act was introduced in the House of Representatives last March. It

188. *See HIV/AIDS Drug Database*, 44 BLUE SHEET, Mar. 21, 2001, *at* 2001 WL 7811097.

189. *See id.*

190. *See* Exec. Order 13155, *supra* note 90.

191. *See id.*

192. *See* Dianne Feinstein, *Senators Feinstein and Feingold Introduce Legislation to Increase Access to HIV/AIDS Treatment in Developing Countries,* Government Press Release, Federal Document Clearing House (March 6, 2001), *at* 2001 WL 5420413.

recognizes pricing policies and pricing practices of drug companies and also prohibits the USTR from challenging a country in the WTO over its policies on access to HIV/AIDS drugs.[193] Representatives Barbara Lee and Jan Shakowsky introduced H.R. 1185, the Global Access to HIV/AIDS Medicines Act of 2001, which codifies President Clinton's Executive Order 13155.[194] Representative Joseph Crowley introduced the Global Health Act of 2001, which earmarks an additional $1 billion to global health programs, including a $275 million budget increase for HIV/AIDS, calls for greater coordination between the government health agencies, and increases funding for programs combating infectious disease.[195] Other legislators are using economic means to protect access to drugs. In May of 2001, Representatives Waters and Sanders introduced H.R. 1690 to amend the Export-Import Bank Act of 1945. This amendment would prohibit the U.S. Export-Import Bank from assisting the export of any good or service to or by a company challenging a patent law or policy of a developing country that promotes access to HIV/AIDS drugs.[196] Based on these actions, it seems that South Africa has the ironic support of the United States in its efforts to increase affordability and accessibility of HIV/AIDS medicines.

CONCLUSION

South Africa's outlook for accessing affordable medicines is fairly positive. South Africa's patent legislation should be safe from trade retaliation or litigation because its provisions on parallel importation and compulsory licensing are legal under TRIPs. The provision providing for parallel importation is permissible under TRIPs because the agreement does not prohibit this type of trade. Also, provisions that allow compulsory licensing are legitimate under TRIPs exceptions provided for in the agreement. South Africa should be able to follow through and

193. *See* Affordable HIV/AIDS Medicines for Poor Countries Act, H.R. 933, 107th Cong. § 2 (2001).

194. *See* Barbara Lee, *Decision to Drop Lawsuit Against South Africa Stresses Importance of Legislation to Improve Access to Life Medication,* Government Press Release, Federal Document Clearing House (Apr. 19, 2001), *available at* 2001 WL 5421088.

195. *See* 147 CONG. REC. E476-05, (daily ed. Mar. 28, 2001) (statement of Rep. Crowley).

196. *See* Export-Import Bank HIV/AIDS Medicines Access Promotion Act, H.R. 1690, 107th Cong. § 2 (2001).

freely grant compulsory licenses because the HIV/AIDS crisis is a national emergency, compulsory licenses are necessary to protect human life or health, and HIV/AIDS is seriously eroding development in South Africa. Public relations guarantees that South Africa will be protected from legal challenge over its patent laws; companies and governments are well aware of the public condemnation that would swiftly follow such action. Public relations also improve South Africa's situation by expanding its pool of affordable drugs through discounted drug offers and donations. Finally, international political and non-governmental bodies are strongly supportive of opening up South Africa's access to HIV/AIDS medicines. This support has even filtered through to the United States government, where legislators are making efforts to pass friendlier drug-access legislation. In light of these factors, access to affordable medicines will likely increase for the South African government, as well as for the thousands of South African citizens waiting for medicines.