Promoting Access to HIV/AIDS Pharmaceuticals in Sub-Saharan Africa Within the Framework of International Intellectual Property Law

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Introduction

Approximately thirty-four million people in the world are infected with the HIV/AIDS virus.[1] Cases are growing fastest in the developing world, with the African continent being hit the hardest by the pandemic.[2] Exacerbating the effects of HIV/AIDS, one-third of the world population and fifty percent of the population in parts of sub-Saharan Africa do not have access to essential medicines.[3] Furthermore, ninety-five percent of people

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1. *See* Press Release, UNAIDS, AIDS is Key Issue for New Century, On Par with Globalization, Peace, Environment, http://www.unaids.org/whatsnew/press/eng/london040900.html (Sept. 4, 2000) (reporting that 34.3 million people globally are living with HIV/AIDS); *see also Estimates of Cumulative HIV/AIDS Infections and AIDS Deaths and Number of Reported AIDS Cases*, 1996 Stat. Y.B. 43, U.N. Sales No. E/F.98.XVII.1 [hereinafter *Estimates of Cumulative HIV/AIDS Infections*] (stating that the estimated cumulative number of HIV/AIDS infections, AIDS deaths, and people newly infected with HIV in 1997 was approximately 30.6 million people worldwide). HIV is an acronym for the human immuno virus. AIDS is an acronym for acquired immunodeficiency syndrome.

2. *See Estimates of Cumulative HIV/AIDS Infections*, *supra* note 1 (reporting that, of the estimated 126,191 new cases reported to the World Health Organization in 1997, approximately half (61,232) were in Africa); *see also* Anne-Valerie Kaninda, Remarks at the World AIDS Day Teleconference, http://www.doctorswithoutborders.org/news/wad2000_transcript.htm (Nov. 28, 2000) (noting that of the approximately thirty-six million people infected with AIDS worldwide, twenty-five million live in sub-Saharan Africa).

3. *See* World Health Org., *Drug Management and Supply Strategies*, http://www.who.int/medicines/teams/par/drug_management_and_supply_strat.html (last visited Mar. 4, 2001); *see also* Medecins Sans Frontieres Campaign for Access to Essential Medicines, *Improving Access to Medicines: Rising to the Challenge*, http://www.accessmed-msf.org (June 2000) [hereinafter *Improving Access to Medicines*] (stating that disadvantaged patients without access to health care often

with AIDS worldwide do not have access to any HIV/AIDS treatment.[4] The devastation to sub-Saharan Africa has begun.[5] The resultant situation will affect not only sub-Saharan Africa, but also the entire world.[6]

To address the crisis, the U.N. Security Council conducted a session in January 2000 on AIDS in Africa.[7] Of the 4086 times the Council has met, this was the first time the topic of the meeting was a health issue, reflecting the magnitude of the crisis.[8] Former Vice President Al Gore spoke at the meeting and noted that AIDS "is a security crisis—because it threatens not just individual citizens, but the very institutions that define and defend the character of a society."[9] He described the dramatic impact of AIDS on sub-Saharan Africa: it "weakens workforces and saps economic strength. AIDS strikes at teachers, and denies education to their students. It strikes at the military, and subverts the forces of order and peacekeeping."[10]

Many factors contribute to the lack of availability of pharmaceuticals in the developing world. Of these factors, absence of production, lack of research, and prohibitive prices play significant roles.[11] U.S. patent law and the World Trade Organization's (WTO) Agreement on Trade Related Aspects of

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receive a death sentence as a result of the high cost and lack of availability of medicines).

4. *See Improving Access to Medicines*, *supra* note 3.

5. *See* Sarah Boseley, *Call to Africans: Fight to Free the Young from AIDS*, GUARDIAN (England), July 13, 2000, at 14 (stating that one in three women and one in seven men aged fifteen to twenty-four in Botswana are HIV positive and that six people under the age of twenty-four are infected every minute).

6. *See id.* (quoting Carol Bellany, Unicef's Executive Director, as stating that AIDS in Africa "is very dangerously eroding already very fragile social structures"); *see also Permitting Patent Infringements to Combat AIDS*, 94 AM. J. INT'L L. 541, 542 (Sean D. Murphy ed., 2000) (stating that it is in the interest of the United States to take all reasonable steps to prevent the further spread of infectious diseases, especially HIV/AIDS).

7. *See* Richard C. Holbrooke, U.S. Ambassador to the U.N., Statement for the Record Submitted to the House Committee on Banking and Financial Services, http://www.state.gov/ww/policy_remarks/2000/000308_holbrooke_hiv-aids.html (Mar. 8, 2000).

8. *See id.*

9. Al Gore, Vice President of the United States, Remarks as Prepared for Delivery to the United Nations Security Council Session on AIDS in Africa, http://www.state.gov/www/global/oes/health/000110_gore_hiv-aids.html (Jan. 10, 2000).

10. *Id.*

11. *See Improving Access to Medicines*, *supra* note 3 (adding that a lack of infrastructure and logistics, a lack of good quality production, and irrational drug choice also impact accessibility).

Intellectual Property Rights (TRIPS Agreement)[12] function to keep the prices of drugs high and require countries to respect intellectual property rights, often at the expense of promoting access to essential pharmaceuticals.[13] Former President Bill Clinton took a new stance on the situation in May 2000 when he issued Executive Order 13,155.[14] The Executive Order provides that the United States will not seek to revoke or revise any intellectual property law or policy of a beneficiary sub-Saharan African country that regulates HIV/AIDS pharmaceuticals or medical technologies.[15] However, it is unclear whether Executive Order 13,155 has promoted access to these drugs in a meaningful way.[16] The World Health Organization (WHO) has also offered possible solutions to the problem, stating that providing adequate financing, affordable pricing, and a reliable supply system are all critical to making pharmaceuticals available.[17] To effectively combat the disease, the United States, the pharmaceutical companies, the governments of developing nations, and financial institutions must make a concerted effort to make essential

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12. *See* Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, LEGAL INSTRUMENTS-RESULTS OF THE URUGUAY ROUND vol. 31, 33 I.L.M. 81 (1994) [hereinafter TRIPS Agreement].

13. *See AIDS Drugs: Activists March on White House*, NAT'L. J. GROUP, INC., Dec. 1, 1999, LEXIS, American Health Line (reporting that activists allege U.S. policy puts the concerns of drug companies ahead of the public health by prohibiting compulsory licensing that would allow developing countries to manufacture their own, less-costly HIV treatments); *see also* Integrated Reg'l Info. Network, *Africa-AIDS: IRIN Focus on Drug Debate*, http://www.aegis.com/news/irin/2000/IR000705.html (July 11, 2000) (arguing that drug companies have used international intellectual property law to maintain "their stranglehold on the development, manufacture, distribution, and pricing of AIDS drugs," but also noting that allowing infringement of intellectual property rights in the developing world would undermine companies' ability to fund research).

14. *See* Exec. Order No. 13,155, 65 Fed. Reg. 30, 521 (May 10, 2000).

15. *See id.* § 1(a)(1)-(2) (providing further that such revocations or revisions of any intellectual property law or policy of a beneficiary sub-Saharan African country will not be sought as long as the policies promote access to HIV/AIDS pharmaceuticals for affected populations of a sub-Saharan African country and provide adequate and effective intellectual property protection consistent with the TRIPS Agreement).

16. *See id.* § 3(b) ("This order is intended only to improve the internal management of the executive branch and is not intended to, and does not create, any right or benefit, substantive or procedural, enforceable at law or equity by a party against the United States . . . .").

17. *See* Michael Scholtz, Executive Director Health Technology and Pharmaceuticals World Health Organization, International Trade Agreements and Public Health: WHO's Role, Address at the Conference on Increasing Access to Essential Drugs in a Globalized Economy, http://www.who.int.medicines.docs/wto_public.health_amsterdam_ms.html (Nov. 25-26, 1999).

medicines and medical technology available to persons affected by the HIV/AIDS virus.[18]

This Note focuses on how HIV/AIDS virus is affecting sub-Saharan Africa and argues that the United States, in collaboration with the pharmaceutical industry and various international organizations, must take affirmative steps toward promoting access to essential medicines.[19] Part I gives an overview of the complex issues involved in approaching this subject. It identifies the population affected and the severity of the AIDS crisis, and describes the recent medical advances that have greatly increased the chances of survival for persons living with the HIV/AIDS virus.[20] It also examines laws that are involved, including the TRIPS Agreement, U.S. patent law, and Executive Order 13,155.[21] Finally, Part I looks at the role of the WHO, the U.N., and the World Bank in breaking down the barriers that inhibit access to essential medicines.[22]

Part II seeks to offer a practical solution to the current situation. It addresses the possible measures that can be taken while still adequately protecting intellectual property rights.[23] It argues that pharmaceutical companies and those who regulate them owe a greater duty to society to promote the general welfare.[24] Thus, the pharmaceutical industry should not inhibit access to medical treatment and pharmaceuticals for millions of suffering people.[25]

This Note concludes that affirmative steps can and must be taken to provide access to medications in the area of the world most affected by the HIV/AIDS crisis. These steps include compulsory and voluntary licensing, parallel importing, and generic manufacturing within the framework of international intellectual property law.[26] Promoting access to essential

18. *See* Gro Harlem Brundtland, Director-General World Health Organization, Remarks at the WHO/Public Interest NGO Pharmaceuticals Roundtable, 3d Meeting, http://www.who.int/director-general/speeches/2000/20000501_ngo.html (May 1, 2000); *see also* Gore, *supra* note 9 (calling for an initiative for an expanded public-private partnership in the battle against AIDS).

19. *See Improving Access to Medicines*, *supra* note 3 (stating that action must be coordinated with three entities: the WHO, the pharmaceutical industry, and patient groups and doctors).

20. *See* discussion *infra* Parts I.A-B.

21. *See* discussion *infra* Part I.C.

22. *See* discussion *infra* Part I.D.

23. *See* discussion *infra* Part II.A.

24. *See* discussion *infra* Parts II.B, III.

25. *See* discussion *infra* Part II.B.

26. *See* discussion *infra* Parts II.A, III.

pharmaceuticals requires cooperation between various groups, industries, and governments.[27] Although all of these entities have different goals, it is indisputable that the political, social, and economic instability of sub-Saharan Africa, which is certain to accompany the HIV/AIDS crisis, will impact the entire world.[28]

I. Background

Understanding the HIV/AIDS crisis and its possible solutions requires background information in various and complex areas. Increasing access to essential medicines requires the initiative of the pharmaceutical industry,[29] cooperation between the governments of the developed and the developing world,[30] and an understanding of international law and its treatment of intellectual property rights.[31]

A. The HIV/AIDS Crisis and Its Impact on Africa

The HIV/AIDS virus has become a leading health concern in sub-Saharan Africa.[32] Rates of infection and death in this region are three times what was projected ten years ago.[33] It is currently estimated that twenty-five million people in sub-Saharan Africa are infected with the virus.[34] Almost three million people died of AIDS in 1999, marking the highest death rate since the explosion of the epidemic fifteen years ago.[35]

The dramatic rates of infection are attributed partially to ignorance surrounding how HIV/AIDS is transmitted and the

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27. *See* discussion *infra* Part III.

28. *See* discussion *infra* Part III.

29. *See* Brundtland, *supra* note 18 (stating that pharmaceutical companies are important partners).

30. *See id.* (stating that in order to promote access, governments of industrialized countries must lead the way, but governments of developing countries must do their share by facilitating access to financing, importation, purchasing, and distribution).

31. *See id.*

32. *See Providing HIV Drugs to Developing Countries; Hope on the Horizon?*, MARKETLETTER, July 24, 2000, LEXIS, Marketletter Publications Ltd. [hereinafter *Providing HIV Drugs*] (noting that there are sixteen African countries in which more than ten percent of the adult population aged fifteen to forty-nine is infected with the HIV virus).

33. *See id.*

34. *See* Kaninda, *supra* note 2; Medecins Sans Frontieres, *HIV/AIDS: World AIDS Day Fact Sheet*, http://www.doctorswithoutborders.org/news/wad2000.htm (last visited Mar. 4, 2001).

35. *See Interpreter of Maladies - AIDS in the Developing World*, HINDU, July 20, 2000, 2000 WL 23317621.

nature of the disease.[36] Young people are most vulnerable to infection, due in part to these myths.[37] In some cultures, young girls lack the negotiating skills to ensure condom usage and are often prey to older men offering gifts for sex.[38] Moreover, many young people, particularly girls, do not believe they are at risk and do not know that someone who looks healthy could be infected with the virus.[39] Furthermore, some men appear to believe that having sex with a virgin can rid them of the HIV infection.[40]

The HIV/AIDS virus exacerbates the problems that many developing countries face[41] because of the substantial negative impact on economic growth.[42] Young adults are a driving force in the economies of developing nations. However, a staggering number have died prematurely from AIDS,[43] causing a devastating economic effect on the countries.[44] As a result, the stability of the

36. *See* Boseley, *supra* note 5, at 14; *see also Foreign AIDS Crisis*, HARPER'S, Dec. 2000, at 23, 23-26 (transcript of a September 5, 2000 interview on South Africa's Radio 702 with South African Health Minister, Manto Tshabalala-Msimang) (relaying how Tshabalala-Msimang refuses to acknowledge or accept the proposition that HIV causes AIDS).

37. *See* Boseley, *supra* note 5, at 14.

38. *See id.*

39. *See id.*

40. *See* Kate Stanley, *Where Shame Would Silence Others, She Speaks Out*, STAR TRIB. (Minneapolis), Oct. 8, 2000, at A35 (noting that the "virgin cure" tale is to blame for the rape and infection of the very young and that curbing the spread of AIDS requires dispelling the myth).

41. *See* Todd M. Rowe, *Global Technology Protection: Moving Past the Treaty*, 4 MARQ. INTELL. PROP. L. REV. 107, 131 (2000) ("Presently, countries considered to be underdeveloped lack sufficient resources to provide their citizens with necessities, including health care, education, food, and clothing.").

42. *See* World Bank, *Africa-Multi-Sector HIV/AIDS Program*, Report No. PID9365, http://www-wds.worldbank.org/cgi-bin/cqc (July 27, 2000) (estimating that twenty African countries pay an annual cost in per capita growth of at least 0.4 percentage points because of AIDS).

43. *See* Carmen Perez-Cases et al., *Setting Objectives: Is There a Political Will?*, Campaign for Access to Essential Medicines HIV/AIDS Medicines Pricing Report, http://www.accessmed-msf.org Medecins Sans Frontieres (July 6, 2000) (estimating that thirteen million children around the world have lost their mother or both parents to AIDS); *see also* Tina Rosenberg, *Look at Brazil*, N.Y. TIMES, Jan. 28, 2001 (Magazine), at 26, 26 (noting that a fifteen-year-old in South Africa has more than a fifty percent chance of dying of AIDS); World Bank, *supra* note 42 (estimating that eleven million African children have been orphaned by AIDS).

44. *See* World Bank, *supra* note 42 ("AIDS dismantles the very foundations of development. Because it weakens and kills adults in the prime of their lives as workers and parents, it erodes productivity, decimates the workforce, depletes the skills base, consumes savings, orphans children, and radically changes the structure of households.").

sub-Saharan African region is greatly jeopardized.[45] "As they lose their productive citizens, the nations themselves face collapse."[46]

Finally, global trade in general will suffer if the HIV/AIDS crisis causes the collapse of the African market.[47] The developed world insisted upon the strengthening of intellectual property rights under the TRIPS Agreement.[48] For example, the United States forced the developing countries to acquiesce in the establishment of higher intellectual property standards by conditioning access to the U.S. market on acceptance of the higher standards.[49] Thus, the developing countries were coerced to take into account what they could gain through exports of other products by offering concessions on intellectual property rights.[50] Relaxing the TRIPS Agreement in the area of HIV/AIDS pharmaceuticals could help protect the basic framework of global trade by preventing the economic collapse of developing nations, including those in sub-Saharan Africa.

B. Recent Medical Advances

There is no cure for AIDS; nonetheless, recent medical developments have demonstrated a prolongation of life by the use of certain antiviral therapies.[51] Although patients are not considered cured of AIDS, two to three years of viral suppression may rid the body of HIV.[52] This treatment plan has reduced AIDS-related mortality by over seventy percent in developed countries.[53] However, unlike in most industrialized countries, up to ninety percent of the medicines are "out-of-pocket" expenses for individuals in the developing world.[54] Because the cost of drug

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45. *See id.*

46. Rosenberg, *supra* note 43, at 26.

47. *See* Abdulqawi A. Yusuf, *TRIPS: Background, Principles and General Provisions, in* INTELLECTUAL PROPERTY AND INTERNATIONAL TRADE, THE TRIPS AGREEMENT 3, 8 (Carlos M. Correa & Abdulqawi A. Yusuf eds., 1998) [hereinafter INTELLECTUAL PROPERTY AND INTERNATIONAL TRADE] (explaining that developing nations had to agree upon the enforcement of intellectual property standards under the TRIPS Agreement to maintain global trade relations).

48. *See id.*

49. *See id.* at 8-9.

50. *See id.*

51. *See* Alexander Scriabine, *Discovery and Development of Major Drugs Currently in Use, in* PHARMACEUTICAL INNOVATION; REVOLUTIONIZING HUMAN HEALTH 148, 175-76 (Ralph Landau et al. eds., 1999) (identifying a combination of drugs and protease inhibitors that is capable of reducing, often to nondetectable levels, the virus levels in the blood).

52. *See id.*

53. *See* Perez-Cases et al., *supra* note 43.

54. *See* Scholtz, *supra* note 17; *see also* Robyn Tamblyn et al., *Adverse Events*

therapy is staggering to an individual living in sub-Saharan Africa, the majority of those infected with HIV/AIDS go untreated.[55] For example, Kenya's per capita gross national product is $360 per year.[56] The average price for an annual course of anti-AIDS triple therapy is $15,000.[57] Thus, the cost of the triple antiretroviral therapy is about thirty times the average monthly salary of a Kenyan.[58] Because the cost prohibits access to treatment, the recent advancements in antiviral therapy have done little to retard the course of the disease in developing nations. Recognizing this, the WHO has left certain drugs that treat HIV off of its Model List of Essential Drugs.[59]

C. The Role of Law in Access to Medication

1. The TRIPS Agreement

The purpose of the TRIPS Agreement is "to narrow the gaps in the way [intellectual property rights] are protected internationally, and to bring them under common international rules."[60] Through the TRIPS Agreement, the WTO requires countries to give protection to intellectual property.[61] The Agreement requires that patent protection for inventions be available for at least twenty years,[62] and establishes jurisdiction over international enforcement of intellectual property rights.[63]

Associated with Prescription Drug Cost-Sharing Among Poor and Elderly Persons, 285 JAMA 421, 422 (2001) (noting that in 1996 the Canadian province of Quebec attempted to enhance equity of access to prescription drugs by passing legislation making drug insurance mandatory for all residents).

55. *See* Integrated Reg'l Info. Network, *supra* note 13 (recognizing that the drug therapy is beyond the reach of most Africans because the majority of people earn less than one U.S. dollar per day); *see also* discussion *supra* Part I.A (describing the devastating impact of HIV/AIDS in sub-Saharan Africa).

56. *See* Medecins Sans Frontieres, *supra* note 34.

57. *See id.*; Integrated Reg'l Info. Network, *supra* note 13.

58. *See* Medecins Sans Frontieres, *supra* note 34.

59. *See* Perez-Cases et al., *supra* note 43 (stating that one criteria for the WHO's Model List of Essential Drugs is reasonable price, which HIV drugs do not meet).

60. World Trade Org., *Trading into the Future: The Introduction to the WTO, The Agreements, Intellectual Property: Protection and Enforcement*, http://www.wto.org/english/thewto_e/whatis_e/tif_e/agrm6_e.htm (last visited Mar. 4, 2001) (recognizing that, as intellectual property became more important in trade, differences in the protection and enforcement of intellectual property rights became a source of tension in international economic relations).

61. *See* TRIPS Agreement, *supra* note 12.

62. *See* World Trade Org., *supra* note 60.

63. *See* Sarah M. Ford, *Compulsory Licensing Provisions Under the TRIPS Agreement: Balancing Pills and Patents*, 15 AM. U. INT'L. L. REV. 941, 946-47

Although proponents of the TRIPS Agreement predicted that it would also benefit developing countries in the long run,[64] developed countries clearly are the primary beneficiaries.[65] Specifically, the U.S. pharmaceutical industry greatly benefits from the Agreement.[66] It uses the Agreement to enforce the protection of U.S. drug patents abroad, thereby yielding greater profits.[67] Moreover, the pharmaceutical industry is very influential on U.S. policy by substantially supporting and lobbying both Republicans and Democrats.[68]

The traditional rationale for a patent system is that society benefits from innovations, and the best way to promote research and development is to grant exclusive rights to patent holders.[69] Applying this rationale, the pharmaceutical companies contend that exclusive rights are necessary to protect their substantial investment in research and development.[70] However, money for research and development often comes from sources outside the pharmaceutical company itself.[71] For example, a study of new

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(2000).

64. *See* Ford, *supra* note 63, at 946 (noting that although TRIPS would initially cost developing countries money, it speculatively would have long-term benefits which include promoting the emergence of pharmaceutical industries in developing countries and ultimately reducing the cost of pharmaceuticals).

65. *See* U.N. CONFERENCE ON TRADE & DEV., THE TRIPS AGREEMENT AND DEVELOPING COUNTRIES at 4, U.N. Sales No. 96.II.D.10 (1996).

66. *See* Integrated Reg'l Info. Network, *supra* note 13 (stating that the drug companies "have used international intellectual property law to maintain their stranglehold on the development, manufacture, distribution and pricing of AIDS drugs"); *see also* Rosenberg, *supra* note 43, at 28 (noting that under the TRIPS Agreement, manufacturers receive a twenty-year monopoly to sell the patented drug in nations at whatever price they choose).

67. *See* Integrated Reg'l Info. Network, *supra* note 13; *see also* Rosenberg, *supra* note 43, at 28.

68. *See* Rosenberg, *supra* note 43, at 58 (noting that the industry spends about $75 million in lobbying every year). The industry closely monitored and influenced the negotiations for the TRIPS Agreement. *See* Integrated Reg'l Info. Network, *supra* note 13.

69. *See* David Benjamin Snyder, *South Africa's Medicines and Related Substances Control Amendment Act: A Spoonful of Sugar or a Bitter Pill to Swallow?*, 18 DICK. J. INT'L L. 175, 188-89 (1999).

70. *See Intellectual Property: UN-Backed Group Says TRIPS Agreement Puts Company Profits Above Human Rights*, BNA INT'L TRADE DAILY, Aug. 22, 2000, WL 8/22/2000 BTD d3 [hereinafter *Intellectual Property*]; Integrated Reg'l Info. Network, *supra* note 13; *see also* Sabra Chatrand, *Patents: In Health Emergencies, Brazil Allows Copying of Drugs, to the Dismay of American Companies*, N.Y. TIMES, Feb. 19, 2001, at C8 (stating that the pharmaceutical industry claims that the cost of research for a new drug is $500 million).

71. *See* Integrated Reg'l Info. Network, *supra* note 13; *see also* Trans Atl. Consumer Dialogue, *Recommendations on Health Care and Intellectual Property*, http://www.tacd.org/pharmf.html (last updated Mar. 8, 2000) (recommending that U.S. consumers and policy makers obtain better information about pharmaceutical

antiretroviral drugs studied by the international organization, Medecins Sans Frontieres (Doctors Without Borders), found that five of the six drug companies involved received public funding.[72] By receiving public funds for research and development, the pharmaceutical companies' argument that they need exclusive patent protection to recover their investment in research and development is tenuous.

Although patents are highly profitable to many groups in the developed world, the developing world views them quite differently.[73] Because the pharmaceutical industry sets its own research and development priorities, marketing forces are a deciding factor in how resources are allocated.[74] The development of medicines is motivated by corporate profit in the developed world and consequently neglects global public health concerns, particularly those of the developing world.[75] Recognizing this reality, some developing countries have determined that their citizens will benefit more from not patenting certain essential inventions, especially medicines.[76]

2. Impact of the Enforcement of the TRIPS Agreement

Enforcing a patent abroad has the practical effect of prohibiting four mechanisms which lower prices of pharmaceuticals in developing countries: compulsory licensing, voluntary licensing, parallel importing, and generic manufacturing.[77] The difficulty in using these mechanisms is

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economics to ensure that the drug companies can truly justify their argument that protecting research and development is necessary to promote innovation; this can be done by obtaining data on global revenues, cost of clinical trials, and the role of government in the development of the drug).

72. *See* Integrated Reg'l Info. Network, *supra* note 13; *see also* Rosenberg, *supra* note 43, at 31 (stating that some pharmaceutical companies manufacturing AIDS drugs did not invent the drug or discover its use in AIDS therapy, and that some of the drugs were developed using grants from the U.S. government); *see also* Trans Atl. Consumer Dialogue, *supra* note 71.

73. *See Intellectual Property*, supra note 70 (reporting that a U.N. body criticized the TRIPS Agreement for giving exclusive rights to pharmaceutical companies, which allows the companies to set high prices for new drugs, thus making the drugs unaffordable and inaccessible for the poor).

74. *See* Integrated Reg'l Info. Network, *supra* note 13.

75. *See id.*

76. *See* Snyder, *supra* note 69, at 180 (noting that some developing countries refuse to allow patents for newly developed medicines because they believe that the cost to their economies would be too great or the prices of important discoveries would be prohibitive for their citizens).

77. *See* Rosenberg, *supra* note 43, at 28 (stating that enforcing a patent abroad functions to keep the prices of pharmaceuticals high and arguing that the pharmaceutical companies' solution is ineffective).

that, depending on the circumstances in which they are used, they may be considered a violation of patent protection pursuant to the TRIPS Agreement.[78]

Compulsory licensing has been used to try to lower prices. "Compulsory licensing would involve the government of a developing country issuing licenses to local firms to manufacture lower cost, generic versions of expensive, patented HIV/AIDS drugs."[79] Before a government can grant a compulsory license, the TRIPS Agreement requires that it must attempt to acquire a voluntary license from the patent holder.[80] A request for a voluntary license must be made on reasonable terms, within a reasonable time, and include an offer to pay adequate remuneration in the circumstances of each case, taking into account the economic value of the license.[81]

Parallel importing can also provide medications at lower prices.[82] Also known as gray market goods, parallel imports are "goods which are bought in a foreign market by an independent third party, and then resold in [another] market to compete with authorized distributors."[83] This system decreases prices by forcing the original manufacturer that sells a product abroad to compete with its own product; the product is imported directly from the manufacturer, as well as from wholesalers in other countries who

78. *See* David P. Fidler, *Neither Science Nor Shamans: Globalization of Markets and Health in the Developing World*, 7 IND. J. GLOBAL LEGAL STUD. 191, 210 (1999) (reporting that the TRIPS Agreement allows compulsory licensing of patents in certain situations); *see also* U.N. CONFERENCE ON TRADE & DEV., *supra* note 65, at 30 (providing that compulsory licenses are available under the TRIPS Agreement subject to their detailed conditions set forth in the Agreement (Article 31)); Trans Atl. Consumer Dialogue, *supra* note 70 (recommending that governments of the United States and the European Union (EU) should neither bring trade sanctions against poor countries who use parallel imports to obtain cheaper access to pharmaceuticals nor prohibit the use of compulsory licenses when they are issued in compliance with Article 31 of the TRIPS Agreement).

79. Fidler, *supra* note 78, at 210-11.

80. *See* TRIPS Agreement, *supra* note 12, art. XXXI para. (b); *see also* World Trade Org., *Overview: The TRIPS Agreement*, http://www.wto.org/english/tratop_e/TRIPS_e/ intel2_e.htm (last visited Mar. 4, 2001); Rosenberg, *supra* note 43, at 52 (indicating that the United States has recently issued compulsory licenses in situations that are far less dire than the AIDS crisis, including tow trucks, stainless-steel wheels, and corn seeds, and that compulsory licenses are also common in antitrust cases).

81. *See* TRIPS Agreement, *supra* note 12, art. XXXI, para. (b); *see also* World Trade Org., *supra* note 80.

82. *See* Snyder, *supra* note 69, at 181, 196 (noting that parallel imports may drastically lower prices of drugs by increasing competition and pressuring companies to lower prices).

83. *Id.* at 180 (quoting Hillary A. Kremen, *Caveat Venditor: International Application of the First Sale Doctrine*, 23 SYRACUSE J. INT'L L. & COM. 161 (1997)).

pay less for the product initially.[84] Because parallel imports decrease prices through increased competition, they have obvious potential benefits for consumers.[85]

Finally, generic manufacturing of pharmaceuticals lowers prices by allowing a different manufacturer to make the exact pharmaceutical and introduce it into the market, thereby increasing competition.[86] However, it can only legally take place after a patent expires or when the drug is not under patent protection.[87] Implementation of initiatives to manufacture generic AIDS drugs has proven successful in Brazil.[88] The price of AIDS drugs has fallen eighty percent since the Brazilian government authorized production of generic drugs.[89] The price of the same drugs fell only nine percent between 1996 and 2000 before Brazil undertook the manufacturing of the generic versions.[90]

Not surprisingly, the pharmaceutical industry rejects the implementation of these measures and favors a strict interpretation of the TRIPS Agreement that limits or even prohibits the use of compulsory or voluntary licensing, parallel importing, and generic manufacturing.[91] It maintains that the

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84. *See id.* at 180-81 (noting that parallel importing is possible because companies often discriminate in pricing between countries for reasons such as money spent on advertising and on product support for their goods). Furthermore, unauthorized dealers exploit currency fluctuations such as buying in a country where the currency is weak and selling in a country where that currency is strong. *See id.*

85. *See id.*

86. *See* Rosenberg, *supra* note 43, at 31 (noting that in Brazil, generic manufacturing was undertaken by enlisting a chemist to analyze and copy the world's major AIDS drugs).

87. *See* Snyder, *supra* note 69, at 178 (stating that a patent is essentially the government granting the inventor a monopoly on his or her invention); *see also* U.N. CONFERENCE ON TRADE & DEV., *supra* note 65, at 30 (providing that a domestic patent is for a minimum of twenty years after filing).

88. *See* Rosenberg, *supra* note 43, at 31 (describing the success of Brazil's government-initiated program, which produces non-patented protected drugs that Brazil has the infrastructure to manufacture); *see also* Integrated Reg'l Info. Network, *supra* note 13 (reporting that the price of AIDS drugs has fallen by eighty percent in Brazil since the government allowed the production of generic drugs).

89. *See supra* note 88.

90. *See supra* note 88.

91. *See Intellectual Property*, *supra* note 70; *see also* Sarah Boseley, *At the Mercy of Drug Giants: Millions Struggle with Disease as Pharmaceutical Firms Go to Court to Protect Profits*, GUARDIAN (England), Feb. 12, 2001, http://www.guardian.co.uk/Archive/Article/0,4273,4134799,00.htlm (reporting that forty-two pharmaceutical companies have taken action in South Africa to block the South African government from importing cheap medicines). Drug companies have spent several years and millions of dollars preparing the case. *See id.*

development of new drugs costs hundreds of millions of dollars and that higher prices are necessary to recover their investments.[92]

The pharmaceutical companies' arguments can be repudiated on several grounds. First, much of the research and development costs associated with the development of drugs is subsidized by public funding.[93] Second, the improvement of access to AIDS drugs will not have a large adverse effect on the current structure of the pharmaceutical industry or its profits.[94] The industry has a projected worth of $406 billion in 2002.[95] Of that amount, Africa will represent just over one percent of the market.[96] Thus, the pharmaceutical industry will make hundreds of billions of dollars without relying on the African market. Third, pharmaceutical companies spend enormous amounts of money marketing their products, often exceeding dollars spent on research and development.[97] Marketing in this context is wholly unnecessary.[98] Finally, and most alarming, only two-tenths of a percent of the total research budget is devoted to those diseases responsible for eighteen percent of the deaths worldwide.[99] Little research is required in the context of HIV/AIDS because the triple therapy course has already been developed.[100] Therefore, promoting access is the primary task at hand, and it does not involve the expenditure of large amounts of money for research and development or marketing.

The United States has traditionally interpreted the TRIPS Agreement strictly and has considered certain practices of developing countries relating to pharmaceuticals as violations of

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92. *See supra* note 70.

93. *See supra* notes 64-72 and accompanying text (arguing that the pharmaceutical industry's argument that patents are needed to protect its investment on research and development is dubious).

94. *See Providing HIV Drugs*, *supra* note 32.

95. *See id.*

96. *See id.*; *see also* Integrated Reg'l Info. Network, *supra* note 13 (quoting Daniel Berman, coordinator of Doctors Without Borders Access to Essential Medicines Campaign, "Africa currently only represents one percent of the world-wide drug market . . . . Companies can survive and prosper if prices are lower in poor countries. More importantly, millions of lives can be saved.").

97. *See AIDS Drugs: Activists March on White House*, *supra* note 13 (citing Bristol-Myers's 1998 annual report, which stated that the company spent more than sixty-seven billion on marketing compared to sixteen billion on research).

98. *See* Scriabine, *supra* note 51, at 176.

99. *See Improving Access to Medicines*, *supra* note 3 (stating that only 0.2% of the global pharmaceutical research budget, estimated between fifty to sixty billion dollars, is devoted to acute respiratory infections, tuberculosis, and diarrhoeal diseases).

100. *See* Scriabine, *supra* note 51, at 176.

the Agreement.[101] For example, several developing countries have used the issuance of compulsory licenses as a way of reducing the costs of pharmaceuticals in order to protect the health of their citizens.[102] The TRIPS Agreement allows compulsory licensing of patents in certain situations, but the pharmaceutical companies and developed countries such as the United States have generally opposed compulsory licensing of pharmaceutical patents.[103]

In May 2000 the stance of the U.S. government changed, however, when President Clinton issued Executive Order 13,155.[104] The Order provides a more liberal approach to patent enforcement in sub-Saharan African countries, where policies that promote access to HIV/AIDS medications have been created.[105] The Order followed the President's declaration that AIDS in sub-Saharan Africa is a threat to U.S. national security.[106] Fortunately, the Bush Administration has committed to maintaining the Clinton Administration's generous policy concerning AIDS drugs for Africa.[107]

This new perspective by the U.S. executive branch has had some practical effect. Shortly after the issuance of the Order,

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101. *See* Ford, *supra* note 63, at 952 (discussing a dispute in 1997 between the United States and South Africa over South Africa's proposed Medicines and Related Substances Control Amendment Act, which would allow the South African Health Minister to override patent rights and allow compulsory licensing and parallel imports); *see also AIDS Drugs: Activists March on White House*, *supra* note 13 (noting that President Clinton was criticized at the 1999 WTO meeting for putting the interests of drug companies ahead of the public health, both in international trade agreements and WTO negotiations, by threatening sanctions if manufacture continued under compulsory licenses).

102. *See* Fidler, *supra* note 78, at 210-11 ("Compulsory licensing would involve the government of a developing country issuing licenses to local firms to manufacture lower cost, generic versions of expensive, patented HIV/AIDS drugs."): Ford, *supra* note 63, at 959-60 (noting that the TRIPS Agreement authorizes the issuance of compulsory licenses in times of national emergency or extreme urgency, but is ambiguous as to when such a situation arises).

103. *See* Fidler, *supra* note 78, at 211.

104. *See* Exec. Order No. 13,155, 65 Fed. Reg. 30,521 (May 20, 2000).

105. *See id.* (alluding to the possibility that the U.S. government's stance on compulsory licenses has changed in relation to the situation in sub-Saharan Africa; it may no longer be a violation of the TRIPS Agreement to grant compulsory licenses in ways that promote access to HIV/AIDS medications for persons in this region).

106. *See Improving Access to Medicines*, *supra* note 3. A threat to public health and security occurs when effective medicines are unaffordable because it prevents an appropriate response to public health needs. This problem, in turn, results in irrational drug use leading to the emergence of drug-resistant micro-organisms that can spread across the globe as populations move. *See id.*; *see also* Gore, *supra* note 9 and accompanying text.

107. *See* Donald G. McNeil Jr., *Bush Keeps Clinton Policy on Poor Lands' Need for AIDS Drugs*, N.Y. TIMES, Feb. 22, 2001, at A9.

multi-national pharmaceutical companies lowered prices of certain drugs, made donations to developing economies, and promised to slash prices on other HIV drugs for individuals living in developing countries.[108] These measures have not been well received by some African governments, however, because they overlook the real issue of lowering prices of pharmaceuticals permanently.[109] For example, the South African Development Community (SADC), an organization of fourteen southern African countries, disapproves of the proposal because it doubts that any of the drug donations and vague promises of price reduction will actually help patients.[110] Instead, the SADC remains committed to promoting drug access through parallel importing, compulsory licenses, and generic manufacturing in southern Africa because these measures could reduce the cost of the triple therapy treatment there from $15,000 to as little as $200 a year.[111]

In addition, the current structure of drug donations and price reductions also require each country to negotiate individually with each pharmaceutical company offering the donation for each drug being donated.[112] The country-by-country policy functions to inhibit the development of more sustainable ways to get medication to people in need.[113] Thus, little progress has been made since the promises to lower the prices of HIV drugs.[114]

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108. *See Providing HIV Drugs*, *supra* note 32 (noting that the multi-national company, Glaxo Wellcome, significantly reduced the price of zidovudine (an antiretroviral) and that multi-national company, Blehringer Ingelheim, said it would provide nevirapine (also an antiretroviral) free to developing economies for a period of five years).

109. *See* Bernard Pecoul, *Taking Our Own Pulse*, http://www.accessmed-msf.org (July 2000) (criticizing the efforts as "not convincing" and stating that "Brazil should be held up as a model, and its political choices should be promoted by international organizations that are supposed to be strategically guiding governments.").

110. *See Providing HIV Drugs*, *supra* note 32.

111. *See id.*

112. *See* Rosenberg, *supra* note 43, at 58.

113. *See id.*

114. *See* Medicins Sans Frontieres, *Six Months After Durban: Have AIDS Drug Prices for the Poor Been "Slashed?"*, http://www.doctorswithoutborders.org/pr/pr108/htm (Dec. 1, 2000). *But see* Donald G. McNeil Jr., *Indian Company Offers to Supply AIDS Drugs at Low Cost in Africa*, N.Y. TIMES, Feb. 7, 2001, at A9 (stating that the Indian drug manufacturer, Cipla Ltd., has offered to sell generic AIDS drugs to African governments for $600 per year per patient, which is $400 less than prices offered by the companies holding the patents).

D. The Key Players

1. The World Bank

The World Bank is responsible for funding $500 million of the long-term program to help AIDS patients in Africa.[115] The World Bank has recently asked African leaders, the private sector, and society to focus on the HIV/AIDS crisis in sub-Saharan Africa because AIDS is quickly undoing the development accomplished over the past thirty years.[116] Although significant, the monetary support the World Bank has committed is insufficient to address a problem of such magnitude. Further, it inadequately responded to the call by UNAIDS, the U.N.'s group dealing with the AIDS pandemic, for an additional three billion dollars in funding.[117]

2. The U.N. and the WHO

The U.N. and the WHO have been instrumental in bringing the HIV/AIDS crisis to the forefront of the international agenda and in promoting access to medication. In furthering its mission to promote peace, human rights, and social justice,[118] the U.N. created the WHO in 1948.[119] The goal of the WHO is for all people to attain a level of health that permits them to lead socially and economically productive lives.[120] The development of the WHO included a blueprint of health that emphasized making essential medical treatment universally accessible to people by acceptable means.[121] The blueprint aimed at having full participation at a cost affordable to each community and country by 2000.[122] All of the WHO's 191 Member States have agreed that health is a

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115. *See Providing HIV Drugs, supra* note 32.

116. *See* World Bank, *World Bank Intensifies Approach to HIV/AIDS Crisis in Africa*, http://www.worldbank.org/html/today/archives/html/sep13-17-99.htm (Sept. 14, 1999) (providing examples of how AIDS is destroying the human population and specifically noting that "[l]ife expectancy—the best overall measure of development—is now declining in a host of African countries, a reversal of the rapid progress in the years following independence").

117. *See Providing HIV Drugs, supra* note 32.

118. *See* Barbara Crossette, *Globalization Tops 3-Day U.N. Agenda for World Leaders*, N.Y. TIMES, Sept. 3, 2000, at A1 (quoting Debi Barker, deputy director of the International Forum on Globalization stating, "The U.N. . . . was really created to be a space to promote peace, human rights, the environment, social justice, livelihoods and democracy.").

119. *See* EDMUND JAN OSMANCZYK, ENCYCLOPEDIA OF UNITED NATIONS AND INTERNATIONAL AGREEMENTS 915 (1985).

120. *See id.*

121. *See id.*

122. *See id.*

human right, and are therefore committed to promoting access to essential drugs.[123]

Although the WHO has taken a leading role in promoting access to medication, their goal for universally accessible primary health care is far from being realized.[124] While globalization leads to increased access for some, this is not true for most of the developing world.[125] Therefore, bringing down prices is necessary to provide access to essential medicines. Because the WHO recognizes the TRIPS Agreement, any solution that the WHO promotes will balance intellectual property rights with the urgency of providing essential medicines to the developing world.[126]

II. Analysis

A. Solutions Within the Framework of the TRIPS Agreement

The current situation clearly shows that affirmative steps must be taken to promote access to essential medicines. Lowering the prices of these medicines is a crucial step in promoting access.[127] Measures such as compulsory and voluntary licensing, parallel importing, and generic manufacturing can be taken within the framework of the TRIPS Agreement to help reduce prices while still giving adequate protection to intellectual property law. The issuance of Executive Order 13,155 increases the possibility that such measures comply with the Agreement when taken by governments of sub-Saharan African countries to address the HIV/AIDS crisis. The manner in which the promotion of access to essential medicines affects protection of human rights must also be addressed. It is time to put aside the immediate benefits of

123. *See* Scholtz, *supra* note 17.

124. *See* Medecins Sans Frontieres Campaign for Access to Essential Medicines, *G8 Statement on Health*, http://www.accessmed-msf.org (last visited Mar. 4, 2001) (stating that "[i]nfectious and parasitic diseases, most notably HIV/AIDS, [tuberculosis], and malaria, as well as childhood diseases and common infections, threaten to reverse decades of development," and must therefore be combated).

125. *See id.*; *see also* Crossette, *supra* note 118 (noting that for the industrial world, globalization is a chance to expand international standards of law, social development, and human rights; however, for the developing world, it represents a troublesome prospect that the U.N. is further aligning itself with the power centers: big corporations and high technology).

126. *See* Brundtland, *supra* note 18.

127. *See* Joint UNAIDS-UNICEF SD-WHO/EDM Project, *Essential Drugs Used in the Care of People Living with HIV: Sources and Prices*, http://www.unaids.org/publications/documents/health/access/drugs1.doc (Feb. 2000) (stating that treatment for HIV/AIDS is limited in developing countries because of the high cost and inability to finance and purchase drugs).

strict enforcement of the TRIPS Agreement in the sub-Saharan African region and deal with the crisis at hand.

1. Current Position of the U.S. Government

Executive Order 13,155 issued by President Clinton on May 10, 2000, was a necessary response to the crisis in sub-Saharan Africa.[128] The Order states that the United States will not seek to revise the intellectual property laws of a sub-Saharan African country that uses its domestic law to promote access to HIV/AIDS pharmaceuticals for affected populations in its country.[129] However, this Order includes the condition that sub-Saharan African countries provide adequate and effective intellectual property protection consistent with the TRIPS Agreement.[130]

Executive Order 13,155 has positive implications for countries in sub-Saharan Africa if parallel importing, compulsory licensing, and generic manufacturing are used.[131] Although the language of the TRIPS Agreement is ambiguous as to whether these methods absolutely provide adequate protection for intellectual property, it is clear that the methods do so in many circumstances.[132] In light of this, sub-Saharan African countries will be able to use such practices without fear of repercussions in other areas of trade with the United States.[133]

2. Compulsory Licensing

Several provisions in article 31 of the TRIPS Agreement allow compulsory licensing.[134] Compulsory licensing involves use of the patent without the authorization of the right holder if

128. *See* Exec. Order No. 13,155, 65 Fed. Reg. 30,521, 30,523 (May 20, 2000).

129. *See id.* at 30,521.

130. *See id.*

131. *See* Integrated Reg'l Info. Network, *supra* note 13 (quoting Medecins Sans Frontieres: "When countries are barred from accessing low cost drugs due to the exclusive marketing rights of the patent holder, international organisations should actively support the efforts of developing countries to improve access through parallel imports, and voluntary and compulsory licenses.").

132. *See Improving Access to Medicines*, *supra* note 3 (noting that granting of voluntary licenses for limited use in poor countries and supporting compulsory licenses are both compliant with the TRIPS Agreement).

133. *See* Ford, *supra* note 63, at 954 (reporting that the United States strongly opposed South Africa's Medicines and Related Substances Control Amendment Act because it would allow the issuance of compulsory licenses and parallel importing by the South African Health Minister; the United States argued that this law would violate the TRIPS Agreement, which reflects the position of the U.S. government before Executive Order 13,155).

134. *See* TRIPS Agreement, *supra* note 12, art. XXXI; *see also* Ford, *supra* note 64, at 959.

certain conditions are met. For example, a country must first attempt to gain authorization from the right holder.[135] The attempt must be based on reasonable terms and must fail within a reasonable period of time.[136] If these conditions are met, the government of a country needing access to the patented product may grant a compulsory license by seizing the patent and manufacturing a generic copy of the drug while paying the patent holder a reasonable royalty.[137] The issuance of a compulsory license often results in a sharp decrease in prices because of the introduction of competition.[138]

The language of the TRIPS Agreement is equivocal regarding when compulsory licenses may be granted.[139] However, the Agreement clearly includes five grounds for granting compulsory licenses: refusal to deal, anti-competitive practices, non-commercial use, dependent patents, and situations of emergency and extreme urgency.[140] The HIV/AIDS crisis is undeniably a situation of emergency and extreme urgency.[141] It is estimated that as many as one in three young women and one in seven young men are infected with the HIV/AIDS virus in some areas.[142] Therefore, the crisis justifies the granting of compulsory licenses in sub-Saharan Africa.[143] Furthermore, article 31(b) makes this course of action more direct in situations of extreme urgency by waiving the usual requirements of attempting to gain a voluntary license.[144]

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135. *See* TRIPS Agreement, *supra* note 12, art. XXXI, para. (b); *see also* Carlos M. Correa, *Patent Rights*, *in* INTELLECTUAL PROPERTY AND INTERNATIONAL TRADE, *supra* note 47, at 189, 208-16. By doing so, the country seeks a voluntary license from the patent holder. *See* discussion *infra* Part II.A.3 (explaining voluntary licensing).

136. *See* TRIPS Agreement, *supra* note 12; *see also* Correa, *supra* note 135, at 208-16.

137. *See* Rosenberg, *supra* note 43, at 31.

138. *See* Ford, *supra* note 63, at 946.

139. *See id.* at 970-71.

140. *See* TRIPS Agreement, *supra* note 12, art. XXXI; Correa, *supra* note 135, at 212-13 (reporting that the grounds stated for granting compulsory licenses in the TRIPS Agreement are only illustrative and other grounds, including public health and nutrition, may be contemplated).

141. *See* discussion *supra* Part I.A (describing the devastating impact of HIV/AIDS in sub-Saharan Africa).

142. *See* Boseley, *supra* note 5, at 14.

143. *See* TRIPS Agreement, *supra* note 12, art. XXXI, para. (b); Correa, *supra* note 135, at 210 (listing emergency and extreme urgency as grounds for granting compulsory licenses under TRIPS).

144. *See* TRIPS Agreement, *supra* note 12, art. XXXI, para. (b).

Member countries use a case-by-case analysis to determine whether a compulsory license should be granted.[145] Among the factors considered, the countries examine the scope and duration of the license and give preference for the domestic market.[146] The extreme situation in sub-Saharan Africa lends support to these factors. The HIV/AIDS antiretrovirals would be used in the domestic market of sub-Saharan African countries where the rates of infection are staggering.[147] Furthermore, the scope and the duration of the compulsory licenses could be limited to the time it takes to curb the spread of the virus.

The pharmaceutical companies disagree with the granting of compulsory licenses, arguing that it takes profits away from research and development and therefore reduces incentives to create new pharmaceuticals.[148] The greatest loss of profits would result if the pharmaceuticals being manufactured under a compulsory license in sub-Saharan Africa were to drift back into the United States and other markets via the gray market, causing competition with the same drug being produced by the patent holder. However, the United States and other developed countries could enact strict penalties and a careful monitoring of pharmaceutical imports to discourage this practice. While the pharmaceutical industry is profit-oriented and HIV/AIDS drugs have been developed from these profits,[149] the time has come to put the welfare of the twenty-five million people in the sub-Saharan region suffering from AIDS ahead of the profits of the pharmaceutical industry.[150] Rather than accepting the argument that compulsory licensing should be prohibited because it leads to declining profits, the governments of developed nations should take proactive steps to protect the pharmaceutical industry by aggressively dealing with the problems compulsory licensing may cause.

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145. *See* Correa, *supra* note 135, at 210.

146. *See id.* (identifying other conditions, such as, prior request, non-exclusive, non-assignable, revocation, remuneration, and revision of decisions (validity of remuneration)).

147. *See* discussion *supra* Part I.A (describing the devastating impact of HIV/AIDS in sub-Saharan Africa).

148. *See supra* notes 70, 91-92 and accompanying text (stating that because the development of new pharmaceuticals costs hundreds of millions of dollars, the pharmaceutical companies favor charging high prices and oppose compulsory licensing).

149. *See supra* note 70, 92 and accompanying text.

150. *See AIDS Drugs: Activists March on White House*, *supra* note 13 (marking the release of documentation which showed several times where the U.S. government placed drug company concerns above public health concerns).

The sub-Saharan African national governments should make a case for compulsory licenses of essential medicines within the framework of the TRIPS Agreement.[151] At the same time, the United States and other countries that are home to multi-national drug companies must allow a broader reading of article 31 of the TRIPS Agreement when considering the issuance of compulsory licenses in this situation. Executive Order 13,155 shows an affirmative step in this direction by the U.S. government.[152] Finally, if countries grant compulsory licenses under the TRIPS Agreement, the extreme strain that the HIV/AIDS crisis is causing to the sub-Saharan countries' economies should be carefully considered in deciding what the appropriate remuneration required will be for the licenses.[153] Little or no remuneration seems appropriate due to the dire financial situation in the sub-Saharan region.[154]

3. Voluntary Licensing

A patent holder may directly allow a foreign manufacturer to use a patent by granting a voluntary license.[155] Voluntary licensing involves technology transfer and allows developing nations to boost their economies by manufacturing certain pharmaceuticals. Concomitantly, it allows the pharmaceutical companies, as the patent holders, to retain a degree of control.[156] Thus, under a voluntary license, the pharmaceutical industry could maintain control of the drug manufacturing and play a great role in promoting access.[157]

Sub-Saharan African countries may grant compulsory licenses if a voluntary license is refused.[158] The grounds and conditions considered by the pharmaceutical company in deciding

151. *See supra* note 140 (noting that the TRIPS Agreement allows compulsory licensing of patents in certain situations).

152. *See supra* notes 101-108 and accompanying text (noting that until May 2000, the United States strictly interpreted the TRIPS Agreement; however, shortly after the issuance of Order 13,155, multi-national pharmaceutical companies lowered prices for, and made donations of, certain drugs to developing countries).

153. *See* World Trade Org., *supra* note 80.

154. *See supra* notes 41-46 and accompanying text (describing the dire financial situation in sub-Saharan caused by HIV/AIDS).

155. *See* World Trade Org., *supra* note 80.

156. *See* Scholtz, *supra* note 17.

157. *See Improving Access to Medicines*, *supra* note 3 (stating that by granting voluntary licenses, the pharmaceutical industry can allow a transfer of technology that allows the developing nation to create industries capable of producing generic medicines).

158. *See* discussion *supra* Part II.A.2 (explaining compulsory licensing).

to grant the voluntary license would most likely be similar to that involved in the decision of whether to grant a compulsory license.[159] The terms of the decision include the appropriate remuneration and the scope and duration of the license.[160] Therefore, it is in the best interest of a pharmaceutical company to grant a voluntary license in order to retain greater control.

4. Parallel Imports

Parallel importing is another method that can be used to lower prices of pharmaceuticals.[161] Parallel imports introduce competition into the market and provide an incentive for pharmaceutical companies to lower the prices of such pharmaceuticals.[162] Similar to the issue of compulsory licensing, the TRIPS Agreement is ambiguous regarding the issue of parallel licensing.[163] Parallel importing appears to comply with the TRIPS Agreement in that article 6 states, "nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights."[164] The debatable issue is whether the patent holder's rights extend from the first sale of the product. Under the "first sale doctrine" or "doctrine of exhaustion," the owner of the property right benefits from the protection on the first sale of the product, thereby allowing the first-sale buyer to resell the product in competition with the patent holder without infringing on the patent holder's rights.[165] The text of the TRIPS Agreement purposely does not state that its protection extends beyond the first sale of the product.[166] Because parallel imports involve only

159. *See supra* notes 140, 145-146 and accompanying text (listing the grounds and conditions used to grant compulsory licenses).

160. *See supra* notes 145-146 and accompanying text (explaining that whether a compulsory license should be granted requires a case-by-case analysis).

161. *See supra* notes 82-85 and accompanying text (noting that parallel importing could lower the price of medicines).

162. *See supra* note 85 and accompanying text (noting that parallel importing increases competition, thereby lowering prices).

163. *See supra* note 132 and accompanying text (noting that the language of the TRIPS Agreement may be interpreted to allow parallel importing); *see also* Claude E. Barfield & Mark A. Groombridge, *Parallel Trade in the Pharmaceutical Industry: Implications for Innovation, Consumer Welfare, and Health Policy*, 10 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 185, 190-91 (noting that the TRIPS Agreement explicitly acknowledged a lack of consensus over the issue of exhaustion of patents).

164. TRIPS Agreement, *supra* note 12, art. VI.

165. *See* Snyder, *supra* note 69, at 181 (explaining the first sale doctrine); Barfield & Groombridge, *supra* note 163, at 190-93, 196-200 (explaining the doctrine of exhaustion and discussing the arguments about whether parallel imports comply with the TRIPS Agreement).

166. *See* Barfield & Groombridge, *supra* note 163, at 191; *see also* Snyder, *supra*

the importation of the drug from a country where the patent holder sells the drug for less–and not the manufacturing of a drug in violation of the patent–it is not in violation of the TRIPS Agreement.[167]

Arguments that the long-term detriment of prohibiting parallel imports will outweigh the short-term benefits of allowing them are based on patent law policy. This argument centers on exhaustive patents, which provide heightened incentives for pharmaceutical companies to engage in research and development.[168] If patents were exhaustive under the TRIPS Agreement, the patent would extend beyond the first sale of the drug and parallel importing would be a violation of the TRIPS Agreement. However, as noted above, the drafters of the Agreement purposely refrained from using language that would have this effect.[169] Therefore, the Agreement should be read to allow parallel importing, which should be vigorously utilized to introduce competition into foreign markets in order to lower prices of essential pharmaceuticals.

Admittedly, allowing parallel importing presents a dilemma because it may discourage differential pricing or price discrimination by the pharmaceutical industry, which in itself is beneficial to developing nations.[170] Unfortunately, there is a risk that allowing parallel imports would force pharmaceutical companies to raise prices in developing countries in order to make

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note 69, at 191, 197-98 (explaining the inconsistent positions countries take regarding parallel imports and stating that a law that allows patented drugs to be imported from other countries where the pharmaceutical companies sell them more cheaply is consistent with the TRIPS Agreement).

167. *See* Snyder, *supra* note 69, at 197.

168. *See* Barfield & Groombridge, *supra* note 163, at 197 (explaining that "under current U.S. law the patent owner has the right to exclude others from making, using, offering for sale, selling, or importing the patented invention[,]" and noting that "in general courts continue to uphold the territorial nature of the patent against claims of universal exhaustion").

169. *See supra* notes 163-166 and accompanying text (noting that the TRIPS Agreement explicitly acknowledges a lack of consensus over the issue of exhaustion of patents and that the issue of parallel imports remains unresolved).

170. *See* Brundtland, *supra* note 18 ("Equity pricing means that the poor would not have to pay the same price for life-saving drugs as those who are better off."); *see also* Barfield & Groombridge, *supra* note 163, at 251 (explaining that pharmaceutical companies may charge different prices to consumers based on their geographic region and finding that pharmaceutical companies have reduced the prices of HIV/AIDS drugs by fifty to seventy-five percent in developing countries). *But see* Snyder, *supra* note 69, at 182 (recognizing that nations have been "hesitant to apply the first sale doctrine internationally due to the fear that importers would re-direct goods from poorer countries to the countries where the price is higher, and as a result, economically disadvantaged countries would be denied sufficient supplies of goods and technology that are extremely beneficial").

parallel importing less profitable.[171] However, it is unlikely that the negative impacts of an altered differential pricing scheme would outweigh the positive effects of parallel importing because parallel importers rely greatly on the value of domestic currencies, a factor completely out of the control of the pharmaceutical industry.[172] Furthermore, raising prices in developing nations to prices equal to those in developed nations would most likely eliminate the market completely. Pharmaceutical companies simply cannot charge persons in sub-Saharan Africa, where the majority of the people earn less than a dollar a day, the same price as those in the developed world.[173]

In addition, the United States can enact laws regulating the importation of gray market goods. As in the context of compulsory licensing, this is a way to deal with the possible unintended consequences of parallel importing by protecting the interests of the pharmaceutical industry while allowing sub-Saharan African countries to undertake practices that will be effective in lowering the prices of pharmaceuticals.

5. Generic Manufacturing

Generic manufacturing of pharmaceuticals also introduces competition into the market and therefore lowers prices of essential medicines; however, it cannot take place until the patent has expired. A spokesperson for Medecins Sans Frontieres, Daniel Berman, noted the success of generic manufacturing: "The few developing countries that have achieved significant access for people with AIDS have done so by aggressively pursuing generic strategies."[174]

For example, generic manufacturing has been highly successful and has lowered the price of AIDS drugs by eighty

171. *Cf.* Barfield & Groombridge, *supra* note 163, at 251 ("Pharmaceutical companies 'have an incentive to set lower prices in low-income countries as long as parallel trade does not exit, so developing countries pay lower prices compared to high-income countries.'") (quoting Richard P. Rozek & Ruth Berkowitz, *The Effects of Patent Protection on the Prices of Pharmaceutical Products—Is Intellectual Property Protection Raising the Drug Bill in Developing Countries?*, 1 J. WORLD INTELL. PROP. 179, 215-16 (1998)).

172. *See supra* note 84 and accompanying text (noting that unauthorized dealers exploit currency fluctuations by buying in a country where the currency is weak and selling where that currency is strong).

173. *See supra* notes 56-59 and accompanying text (noting that the WHO has left certain HIV drugs off its Model List of Essential Drugs because they are unaffordable).

174. Press Release, Medecins Sans Frontieres, Access to Treatment–Should We Wait for Barcelona?, http://www.msf.org/advocacy/accessmed/reports/2000/07/aidsconference/pr-wait.htm (July 12, 2000).

percent in Brazil, where the government has allowed generic manufacturing of quality drugs no longer under patent.[175] Brazil's program implemented a policy of universal access to antiretroviral drugs; the policy halved the number of AIDS deaths between 1996 and 1999.[176] By government initiation, Brazil manufactured drugs that were not protected by patent and that required the infrastructure and knowledge that Brazil could develop.[177] Such a model could work in sub-Saharan Africa. The developing countries could create the appropriate infrastructure while the patent is still in effect so that the generic production could begin immediately upon expiration. Or, as in Brazil, the nations of sub-Saharan Africa could immediately produce drugs not under patent protection. Moreover, the TRIPS Agreement allows a concession for developing countries and allows them a grace period before requiring compliance with the Agreement.[178] Under this grace period, some of the AIDS drugs are not under patent in many sub-Saharan African countries and their generic manufacturing could be undertaken immediately.[179]

A final option is to use the "bolar exception" to patent laws, which permits a firm to test generic drugs in order to prepare for marketing approval prior to the expiration of the patent.[180] The process is useful because it ensures the timely introduction of competition into the market when the patent expires.[181] Sub-Saharan African countries could begin this immediately.

Compulsory and voluntary licensing, parallel importing, and generic manufacturing are all ways of introducing competition into the market and will therefore have the impact of lowering drug prices in the developing world.[182] Since the issuance of Executive Order 13,155, the United States is more willing to allow these practices and consider them in accord with the TRIPS

175. *See supra* note 90 and accompanying text (noting that the cost of such drugs fell only nine percent before the implementation of generic drugs).

176. *See supra* note 88.

177. *See supra* notes 88-89 and accompanying text (explaining how Brazil has used generic manufacturing of pharmaceuticals to increase competition and lower prices).

178. *See* Rosenberg, *supra* note 43, at 31.

179. *See supra* notes 101-107 and discussion *supra* Part II.A.1 (noting that the United States will not seek to revise intellectual property rules of sub-Saharan African countries that use their domestic law to promote access to HIV/AIDS medicines, though the United States wants those countries to abide by the TRIPS Agreement).

180. *See* Trans Atl. Consumer Dialogue, *supra* note 71.

181. *See id.*

182. *See* discussion *supra* Part II.A.2-5 (describing the methods to lower prices of drugs and arguing that the methods may fall within the TRIPS Agreement).

Agreement.[183] The developing world should act promptly in order to benefit from this policy.

B. Initiatives Recently Taken by World Organizations

The World Bank and the U.N. have been instrumental in developing programs to address the HIV/AIDS crisis.[184] The World Bank recently agreed to lend African governments money to implement a Multi-Sector HIV/AIDS program.[185] The overall objective of the program is to increase access to HIV/AIDS prevention, care, and treatment programs.[186] This program represents a positive response on behalf of the governments of African nations and international organizations.

In addition, the U.N. recognized that public health is closely linked to human rights in the *Universal Declaration of Human Rights*.[187] Article 25(1) of the *Declaration* states: "Everyone has a right to a standard of living adequate for the health and well-being of himself and his family, including . . . medical care and necessary social services, and the right to security in the event of . . . sickness, disability . . . or other lack of livelihood in circumstances beyond his control."[188] Moreover, UNAIDS has noted that the link between public health and human rights is essential not only to ensure that those with AIDS are cared for, but also that people's vulnerability to infection is decreased.[189] Thus, the protection of human rights is not adequate without both ensuring the health of individuals and populations and directly addressing the AIDS plague.[190]

Extending the relation of public health to human rights strengthens the argument of the U.N. Declaration. Most societies include as fundamental human rights the rights to privacy,

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183. *See* discussion *supra* Part II.A.1 (arguing that Executive Order No. 13,155 should allow sub-Saharan countries to reproduce certain drugs without repercussions from the United States).

184. *See* discussion *supra* Part I.B and accompanying text (identifying the primary organizations involved in battling the international HIV/AIDS crisis).

185. *See* World Bank, *supra* note 42.

186. *See id.*

187. *See Universal Declaration of Human Rights*, G.A. Res. 217A (III), U.N. GAOR, 3d Sess., Supp. No. 16, at 5, U.N. Doc. A/811 (1948); *see also Intellectual Property*, *supra* note 70.

188. *See Universal Declaration of Human Rights*, *supra* note 187.

189. *See Health: Activists to Push for Human Rights of HIV/AIDS Patients*, INT'L PRESS SERV., July 9, 2000, 2000 WL 4091946.

190. *See* Lawrence O. Gostin & Zita Lazzrini, *Human Rights and Public Health in the AIDS Pandemic*, 13 ISSUES L. & MED. 358, 358 (1997).

equality, dignity, and security of persons.[191] In a country where so many citizens are suffering from this debilitating illness that ultimately results in death, these secured rights have little practical reality. In other words, AIDS and the lack of treatment infringe upon protected human rights by depriving individuals of health and life to enjoy these fundamental rights.[192]

Because the TRIPS Agreement focuses primarily on economic interests, it has been criticized for failing to give adequate weight to human rights by making prices of HIV/AIDS drugs unaffordable.[193] Thus, the Agreement as currently interpreted trammels on a basic human right to public health. The United States can play a substantial role in promoting public health by allowing the practices discussed above and not sanctioning countries for possible violations of the TRIPS Agreement.[194]

III. Conclusion

Intellectual property rights and patent protection are necessary to the success and innovation of the multi-national pharmaceutical industry.[195] The expense of such patents to the developing world, however, must also be taken into account. Currently, people in sub-Saharan Africa suffering from the HIV/AIDS pandemic do not have access to essential medicines. It is a very complex problem and cannot be attributed to any one factor. However, relaxing the protection of intellectual property clearly will lower the prices of pharmaceuticals and promote access.[196] Methods to help lower prices include compulsory licensing, voluntary licensing, parallel importing, and generic manufacturing.[197] Both the pharmaceutical industry and the U.S. government can promote access to these methods while still adequately protecting intellectual property rights.

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191. *See Health: Activists to Push for Human Rights of HIV/AIDS Patients*, *supra* note 189 (noting that drawing the parallel between human rights and public health requires using rights that are already enshrined in the law).

192. *See Intellectual Property*, *supra* note 70; *see also* International Covenant on Economic, Social and Cultural Rights, Dec. 16, 1966, 993 U.N.T.S. 3.

193. *See Intellectual Property*, *supra* note 70.

194. *See* discussion *supra* Parts II.A.2-5 (describing the methods to lower prices of drugs and arguing that the methods may fall within the TRIPS Agreement).

195. *See supra* note 92 and accompanying text (stating that drug companies claim to spend around $500 million for the development of a new drug).

196. *See* discussion *supra* Part II.A.1 (discussing the relaxing of intellectual property laws by the United States in Executive Order 13,155).

197. *See* discussion *supra* Parts II.A.2-5 (describing the methods to lower prices of drugs and arguing that the methods may fall within the TRIPS Agreement).

Of the possible mechanisms, compulsory licensing is the method most likely to promote effective changes. Because compulsory licensing is specifically addressed in the text of the TRIPS Agreement and is permitted in Executive Order 13,155, sub-Saharan African countries would face less opposition if they implemented compulsory licensing plans.[198] The lesser likelihood of legal and political repercussions is important because it allows governments of sub-Saharan African countries to use compulsory licensing to promote access to pharmaceuticals without interfering with their ability to trade with developed countries in areas unrelated to pharmaceuticals – trade that is essential to their survival. Furthermore, pharmaceutical companies do not have a legal argument to stop compulsory licensing if it is done within the framework of the TRIPS Agreement.

The pharmaceutical industry must also be cognizant of the very real possibility that if the HIV/AIDS crisis continues to grow and the situation becomes more and more desperate, the governments of these sub-Saharan African countries may decide to offer less protection to intellectual property rights and patents.[199] The TRIPS Agreement was entered into mainly for the benefit of developed nations.[200] The developing world has made efforts to comply with the Agreement in order to avoid sanctions in unrelated areas of trade.[201] Eventually, this trade-off may become

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198. *See* discussion *supra* Part II.A.2 (discussing the advantages of using compulsory licenses to reduce the cost of necessary drugs).

199. *See* Yusuf, *supra* note 47, at 4 (explaining that the disparity in industrialization between nations has historically resulted in differences in scope of protection of intellectual property); *see also* Rowe, *supra* note 41, at 109 ("The varied economic and social backgrounds of participating nations, coupled with the vast amounts of money at stake in international treaty making, cause problems when nations attempt to draft uniform intellectual property treaties."). A developing country's unwillingness to enforce patent protection is explained by the following:

> [A]t a stage when the technological capacity of a particular country is weak, and its enterprises are not able to take significant advantage of its incentive provided by intellectual property protection, the benefits gained from such protection (including the incremental contribution to technological progress world-wide) may be outweighed by the disadvantage of not being able to acquire and adapt foreign technology without reference to its creator, or to import new products and processes from alternative or cheaper sources.

Yusuf, *supra* note 47, at 4.

200. *See supra* notes 65-66 and accompanying text. The value of a patent system to the developing world remains controversial. *See supra* notes 73-76 and accompanying text.

201. *See supra* notes 47-50 and accompanying text (discussing how the strict enforcement of the TRIPS Agreement would greatly harm the economies of the

too great and the region will be forced to take any measures necessary to curb the spread of the HIV virus, including not honoring pharmaceutical patents and intellectual property rights.

The HIV/AIDS crisis has spread to catastrophic levels already. Something must be done immediately to alleviate the suffering and deaths of millions. The urgency of the situation is apparent. If the compassion for millions of people dying without access to treatment is not enough motivation, the developed world must realize that the resultant instability of the African continent caused by the health crisis will affect the entire world, not just the sub-Saharan region.[202] The solutions noted above offer adequate protection of intellectual property rights, yet promote access to essential medicines.

countries in the developing world).

202. *See supra* notes 5-10 and accompanying text.