The Battle over Life-Saving Pharmaceuticals: Are Developing Countries Being TRIPped by Developed Countries

Michelle M. Nerozzi
Notes

THE BATTLE OVER LIFE-SAVING PHARMACEUTICALS:
ARE DEVELOPING COUNTRIES BEING "TRIPped"
BY DEVELOPED COUNTRIES?

I. INTRODUCTION

The issues of cost and access to HIV/AIDS drugs are of great importance to developing countries, as over eighty-nine percent of people currently living with HIV/AIDS reside in countries ranked in the lowest ten percent in terms of Gross National Product. In South Africa, HIV is spreading faster than anywhere else in the world, with statistics showing that the workforce is likely to be twenty percent HIV-positive by next year and life expectancy will be reduced to thirty-eight by the year 2010. Even the U.S. Surgeon General commented on the AIDS epidemic, comparing it "to the plague that decimated the population of Europe in the Fourteenth century." Advances in medical research have yielded significant

1. See Marcus Mabry, No Money, No Meds, NEWSWEEK, July 12, 1999, at 32 (illustrating AIDS crisis in South Africa by pointing out that doctors fail to inform patients of treatments that could prolong life because patients do not make enough money each week to afford such treatments); Margaret Duckett, Compulsory Licensing and Parallel Importing: What Do They Mean? Will They Improve Access to Essential Drugs for People Living with HIV/AIDS?, at http://www.icaso.org/docs/compulsory-english.htm (July 1999) (discussing HIV/AIDS crisis and ways to lessen gap in access between developed and developing countries); see also Pharmaceutical Research and Manufacturers of America (PhRMA), Annual Report 2001-2002: New Medicines New Hope: Industry Serves Through Innovation, at http://www.phrma.org/publications/publications/annual2001/innovation.phtml (last visited Sept. 28, 2001) (discussing problem of AIDS in Africa). "More than 30 million people around the world are infected by AIDS—and 75 percent of them are in sub-Saharan Africa." Id.

2. See Peter Hawthorne, A Blighted Generation; Southern Africa Has Been Most Severely Hit by AIDS, Leaving Children Orphaned and the Workforce Depleted, TIME (Africa), July 26, 1999, at 57 (commenting that HIV virus in South Africa "isn’t an epidemic, it’s a disaster"). For a compelling account of the medical crises of Africa, see Karl Vick, African AIDS Victims Losers of a Drug War; U.S. Policy Keeps Prices Prohibitive, WASH. POST, Dec. 4, 1999, at A01 ("[S]wimming in [Josaphat] Nyakundi’s spinal fluid—infam ing the lining of his brain, keeping him braced in his Nairobi hospital bed against the flashing pain that comes with the slightest movement—are rampaging cells of cryptococcal meningitis, an opportunistic infection that means he has AIDS.").

improvements in treating diseases, specifically HIV/AIDS, that were only recently incurable. Nonetheless, these high priced drug cocktails are unavailable to those living with HIV/AIDS in developing countries.4

The unavailability of essential pharmaceuticals has led to recent controversy over the issue of compulsory licensing, specifically surrounding a dispute between South Africa and the United States regarding South Africa's Medicines and Related Substances Control Amendment Act of 1997 (Medicines Act).5 The controversy centers around interpreting the Agreement between Wyeth, Bristol-Myers Squibb and Pfizer—made respectively, $4.43 billion, $3.64 billion and $3.35 billion.

4. See Judy Rein, International Governance Through Trade Agreements: Patent Protection for Essential Medicines, 21 J. Int'l L. Bus. 379, 379 (2001) (discussing internationalization of infectious disease, increased globalization of economic transactions and technological innovation regarding pharmaceutical regulation). Hopefully, greater access to these essential medicines will emerge without broad sacrifice of patent protection. See id. at 380-81 (noting that there must be balancing of interests between access to essential medicines and protection of intellectual property rights); Mary T. Griffin, AIDS Drugs and the Pharmaceutical Industry: A Need for Reform, 17 Am. J.L. & Med. 363, 404 (1991) (referring to benefit of compulsory licensing of pharmaceuticals—i.e., providing access to needed anti-retroviral drugs, only form of therapy available to HIV/AIDS patients); see also Vick, supra note 2, at A01 (highlighting fact that "[m]edical advances that stalled AIDS epidemic in the West are not reaching Africa largely because these countries and their citizens face a stark choice: buy drugs at their market price, far beyond the means of all but few Africans, or risk trade sanctions by the United States for buying or developing generic drugs at lower prices.").

5. See Sara M. Ford, Note & Comments, Compulsory Licensing Provisions Under the TRIPs Agreement: Balancing Pills and Patents, 15 Am. U. Int'l L. Rev. 941, 942 (2000) (noting that recent dispute involves South African Parliament and United States Trade Representative (USTR) and centers around differing views of developed and developing countries on issue of international patent protection); see also Duane Nash, South Africa's Medicines and Related Substances Control Amendment Act of 1997, 15 Berkeley Tech. L.J. 485, 491-93 (2000) (providing that Medicines and Related Substances Control Amendment Act, specifically section 10, authorizes Minister of Health to permit compulsory licensing of pharmaceuticals as means of offering cheaper AIDS drugs to poor patients); see also Bond, supra note 3, at http://www.aidc.org.za/archives/pbond_pharmaceuticalpricing.html (describing post-apartheid South African health policy under Medicines Act). "Rebuttals by . . . PhRMA typically—e.g. according to spokesperson Tom Bombelles—accuse South Africa of theft: 'There are ways to make drugs available to the poor in a country like South Africa. We need to look for economic answers to economic questions . . . and not say the answer to this economic question is we'll just steal (patents).'" Id. The only limit on authorization is that the product must have been initially marketed by the owner or with the owner's consent. See id. Specifically, section 10 of the Act provides the following clauses be inserted into South Africa's Act 101 of 1965:

The Minister may prescribe conditions for the supply of more affordable medicines in certain circumstances so as to protect the health of the public, and in particular may (a) determine that the rights with regard to any medicine under a patent granted in the Republic shall not extend to acts in respect of such medicine which has been put onto the market by the owner of the medicine, or with his or her consent. The Minister may . . . (b) prescribe the conditions on which any medicine which is identical in composition, meets the same quality standard and is intended to have the same proprietary name as that of another medicine already registered in

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ment on Trade-Related Aspects of Intellectual Property Rights (TRIPs) and achieving the proper balance between strengthening protection of intellectual property rights worldwide and supplying developing countries with the pharmaceuticals they desperately need.6

The developed country pharmaceutical industry has not only lobbied in support of U.S. action, including the Special 301 initiative that removed South Africa from the most favored member trade status, but has also begun to pursue litigation against the South African government claiming violations of the TRIPs Agreement.7 While there are no court decisions regarding TRIPs interpretation and compulsory licensing, heated debate between developed and developing countries over the proper interpr-
tion of Article 31 of TRIPs, allowing compulsory licensing, has come to the forefront in a lawsuit initiated by thirty-nine American pharmaceutical companies against the South African Ministry. While this lawsuit, which would have been the first test of the TRIPs Agreement, settled before reaching an international court, its ramifications will be lasting.

8. See Frederick M. Abbott, Discontinuities in the Intellectual Property Regime: The TRIPS-Legality of Measures Taken to Address Public Health Crises: A Synopsis, 7 Widener L. Symp. J. 71, 71-72 (2001) (discussing industrialized country pharmaceutical industries’ pursuance of litigation against South African government to stop it from authorizing parallel importation, based on claims that government is violating TRIPs); Ravi Nessman, South Africa Now Takes Spotlight in AIDS Fight, Hous. Chron., Apr. 21, 2001, at A28 (discussing court battle between South Africa and Western pharmaceutical companies; see also Oxfam, Policy Paper: Oxfam Update on South African Court Case: South Africa vs. the Drug Giants, at http://www.oxfam.org.uk/policy/papers/safrica/safrica3.htm (Apr. 1, 2001) (highlighting background of litigation and noting that on March 5, 2001, thirty-nine of world’s largest pharmaceutical companies instituted lawsuit against South Africa, challenging validity of 1997 Medicines Act). U.S. actions, specifically the Special 301 initiative, threaten to undermine the WTO because the WTO TRIPs Agreement permits governments to authorize parallel importation and grant compulsory licenses in order to regulate public health. See Abbot, supra at 72 (noting that U.S. unilateral actions lead people to believe that WTO is hostile to developing countries’ health crises). Abbott then points out the rationale for U.S. policy against compulsory licensing in foreign countries as the legal fiction of the “slippery slope”—that is, if South Africa grants compulsory licenses to address its current health crisis, then there will be no end to the granting of compulsory licenses. See id. (questioning “slippery slope” arguments in light of current HIV/AIDS crisis); see also TRIPs, supra note 6, at 593-94, 601, 602 (authorizing, through ambiguous language, parallel importation and grants of compulsory licenses). This slippery slope argument derives from the language of TRIPs. See id. (stating language of TRIPs). Article 8, for example, provides: “members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.” Id. at 594; see also Griffin, supra note 4, at 403-05 (reviewing U.S. policy on compulsory licensing). But see Ford, supra note 5, at 943 (stating that “[w]hile disputes between the governments of developed nations holding critical patents and governments with most of the pharmaceutical needs are not new, the issue of compulsory licensing remains an unresolved matter”).

9. See Ravi Nessman, Drug Firms Drop Lawsuit in South Africa; AIDS Activists Hail Move, Hous. Chron., Apr. 20, 2001, at A1 (discussing pharmaceutical industry decision to drop lawsuit against South African government and possible ramifications of litigation). Mark Heywood of the Treatment Action Campaign stated that “there is no doubt that [major pharmaceutical companies] have received a black eye. And I think it will embolden people in developing countries around the world to stand up for medicines that are affordable.” Id. One ramification of the lawsuit hinted at by Heywood is the negative public opinion of the pharmaceutical companies. See id. (offering criticisms of Western pharmaceutical companies handling of AIDS crisis). In fact, the companies came under intense pressure to back down and watched their reputations battered as they were criticized for putting profits above human health. See id. (offering criticisms of Western pharmaceutical companies regarding AIDS crisis). In response to negative public opinion and in an effort to save face, the companies that make AIDS medication now offer them to developing countries at or below cost. See id. (providing that GlaxoSmithKline offers antiretroviral Combivir to AIDS patients at only four dollars per day); see also Nessman, supra note 8, at A28 (noting that court battle with drug companies...
This Note discusses the current tension between developed and developing countries relating to TRIPs and compulsory licensing, and access to expensive life-sustaining pharmaceuticals. Part II summarizes the TRIPs Agreement of the World Trade Organization (WTO), focusing on compelled South African government into new alliance with AIDS groups and humanitarian organizations; Vick, supra note 2, at A01 (recognizing that humanitarian organizations, such as Doctors Without Borders and World Bank, have attacked U.S. policy and lawsuit). But see Drug Induced Dilemma, ECONOMIST, Apr. 21, 2001, at Business (discussing public debate over how to get medicines to developing countries and fact that drug companies backed down from lawsuit). One commentator suggests that the public should not hastily condemn the companies because the lack of access to expensive medicines in developing countries is not only due to high drug prices, but also poor-country governments failing to invest in health care and developed country donors devoting little of their overseas budgets to medical problems. See id. (explaining that besides high prices, other barriers to AIDS drug therapies exist in developing countries). Moreover, the commentator noted the price cuts and donation programs of some pharmaceutical companies including Merck and Boehringer Ingelheim. See id. (suggesting that drug companies treat drug access as public relations problem instead of good governance problem); see also Pfizer, Press Release: Pfizer to Offer Antifungal Medicine at No Charge to HIV/AIDS Patients in 50 Least Developed Countries Around the World, at http://www.pfizer.com/pfizerinc/about/press/nochargediflucan.html (June 6, 2001) (discussing Pfizer’s actions in developing donation programs following end of litigation). For example, the lawsuit was dropped on April 19, 2001, and on June 6, 2001, Pfizer announced a collaboration with the South African Ministry of Health to offer Diflucan antifungal medicine to HIV/AIDS patients to treat two opportunistic infections associated with the disease. See id. (reviewing Diflucan Partnership and noting that 185 institutions in South Africa have begun to distribute medicine through program). Furthermore, there are no dollar or time limits on this collaboration. See id. (providing that Pfizer will work until all patients have cheap and easy access to Diflucan). On June 11, 2001, Pfizer announced plans to help construct an AIDS medical training clinic in Africa in order to strengthen medical infrastructure. See Pfizer, Press Release: African and Western Alliance to Build First Large-Scale AIDS Medical Training Facility in Africa, at http://www.pfizer.com/pfizerinc/about/press/aidsfacility.html (June 11, 2001) (describing goals of clinic, including strengthening medical infrastructure, replicating program across Africa and putting more patients under antiretroviral treatment).


The publicity surrounding the court case intensified the price war on anti-retroviral drugs both between the pharmaceutical giants, and between them and the generic drug companies. Large companies such as Merck cut drug prices as they sought to recoup some public support, to blunt the offers from generic-drug companies, and to stave off growing public disquiet about patents on medicines.

Oxfam, supra note 8, at http://www.oxfam.org.uk/policy/papers/safrica/sfrica2.htm. While these programs are beneficial to developing countries, one must question the motives behind them and whether they will last after pharmaceutical companies regain public confidence. See id. (hinting that motive behind donation is to regain public approval).
pulsory licensing and dispute settlement. Specifically, compulsory licensing is defined and discussed as it applies under Article 31 of TRIPs. Dispute settlement is discussed in light of the unique aspect of the WTO, the Dispute Settlement Body (DSB), which was created to resolve issues arising under TRIPs. Nevertheless, nations in dispute have thus far failed to involve the DSB in problem resolution, and have instead opted to reach agreements on their own terms. Part III discusses the oppositional stances of developed and developing countries on interpretation of TRIPs. Part IV outlines already proposed solutions for interpreting the TRIPs Agreement and proposals for resolving the tensions between developed and developing countries. Finally, Part V offers solutions to the problem of access to essential AIDS drugs including modifying TRIPs to allow compulsory licensing, developing an inquiry into what constitutes a

10. For an overview of TRIPs, see infra notes 17-25 and accompanying text.
11. For an overview of compulsory licensing, see infra notes 26-30 and accompanying text.
12. See Ford, supra note 5, at 943-44 n.8 (explaining Dispute Settlement Body (DSB) that exists under WTO). The DSB was established through the Understanding on Dispute Settlement (DSU) to resolve issues arising under TRIPs. See id. (discussing DSB).
13. See id. at 944, 967-74 (referring to failure of disputing countries to involve DSB in conflict resolution and suggesting that this is because countries do not want to damage relations with important trading nations). Ford notes that developing countries would have incentive to bring disputes to the DSB. See id. at 969 (stating that “developing nations present the best chance for challenging those unilateral measures”). Ford states that:

By bringing a compulsory licensing dispute before the DSB, they stand to gain legitimacy in their compulsory licensing schemes and international recognition for paving the road for other developing nations and potential trading partners to create similar mechanisms. The only potential harm in bringing the matter before the DSB is the potential risk of damaging their relationships with important trading nations.

14. For a further discussion of developed and developing countries’ views on the issue of compulsory licensing, see infra notes 42-54 and accompanying text.
15. For a further discussion of already proposed solutions to pharmaceutical access, see infra notes 55-122 and accompanying text.
“national emergency” and proposing a test program that combines a number of already suggested solutions.16

II. BACKGROUND

A. Overview of TRIPs Agreement

The TRIPs Agreement was adopted as part of the Uruguay Round in Marrakesh and signed on April 15, 1994.17 TRIPs is part of the WTO and establishes minimum international standards regarding intellectual property rights, but requires individual member countries to enact laws enforcing those rights.18 Nonetheless, problems have arisen in countries that, before TRIPs, did not require protection of pharmaceuticals.19

TRIPs was enacted because of efforts by developed countries, specifically the United States, for strict protection of intellectual property rights in a globalizing world in which markets in developed countries are beginning to rely heavily on technology.20 The agreement incorporates provisions of the Paris Convention, Berne Convention and Washington Treaty, which are major treaties adopted by the U.S. and other countries in favor of intellectual property protection.21 Additionally, TRIPs addresses the shortcomings of these treaties.22 For example, two criticized weaknesses

16. For a better solution to pharmaceutical access in developing countries, see infra notes 123-80 and accompanying text.
17. See Ford, supra note 5, at 948 (noting development of TRIPs).
18. See TRIPs, supra note 6, at 601-03 (outlining member’s responsibilities regarding international patents, but also containing Article 31 exception for countries to violate TRIPs). For example, Article 28 addresses the rights conferred to a patent holder:

1. A patent shall confer on its owner the following exclusive rights: (a) where the subject matter of a patent is a product, to prevent third parties not having the owner’s consent from the acts of: making, using, offering for sale, selling, or importing for these purposes that product; (b) where the subject matter of a patent is a process, to prevent third parties not having the owner’s consent from the act of using the process, and from the acts of: using, offering for sale, selling, or importing for these purposes at least the product obtained directly by that process. 2. Patent owners shall also have the right to assign, or transfer by succession, the patent and to conclude licensing contracts.

Id.
19. See Pechman, supra note 7, at 182 (suggesting need for adoption of stronger intellectual property rights than provided by past treaties). Pechman notes that an inherent problem of the Paris Convention was that, although it provided for reciprocity of patent rights, there were no standards of protection and member countries were only required to afford as much patent protection to other members as they afforded to those seeking domestic patents. See id. (offering Brazil and India as examples of reciprocity problem with Paris Convention).
20. For a further discussion on globalizing economies, see infra notes 48, 49 and 59 and accompanying text.
21. For a discussion of the shortcomings of the Paris Convention, which applies to patent protection, see infra notes 23-24 and accompanying text.
22. See TRIPs, supra note 6, at 592 (requiring all members to adhere to patent protection conferred in Paris Convention). Article 9 of TRIPs incorporates provi-
of the Paris Convention were that it did not harmonize patent laws among countries and it did not offer enforcement provisions, but acted merely as “guiding principles that member countries may or may not adopt.” TRIPs was created to alleviate these weaknesses and regulate the degree of intellectual property protection to which all members must apply. In recognition of problems faced by developing member States, TRIPs allows certain concessions including: extended transition periods for implementation of TRIPs provisions, exclusion of certain items from patentability, compulsory licensing under certain conditions, parallel importation and technical and financial cooperation in favor of developing and least-developed member states.

B. Overview of Compulsory Licensing

A compulsory license is a judicial or governmental annulment of patent rights, depriving a patentee of a monopoly or “an involuntary contract between a willing buyer and an unwilling seller imposed and enforced by the state.” In other words, an inventor is issued a patent, conferring exclusive rights to make, use and sell an original subject matter for a temporary period. A compulsory license takes away the patentees exclusions of the Berne Convention. See id. at 594 (relating to copyright protection). Article 35 of TRIPs incorporates provisions of the Washington Treaty. See id. at 604 (relating to integrated circuit protection); see also George K. Foster, Comment, 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. & FOREIGN AFF. 283, 285-87 (1998) (explaining meanings of Paris Convention, core principles of national treatment and priority); John E. Giust, Noncompliance with TRIPs by Developed and Developing Countries: Is TRIPs Working?, 8 IND. INT’L & COMP. L. Rev. 69, 72 (1997) (noting that TRIPs adopted Articles 1 through 12 and 19 of Paris Convention establishing right of priority and national treatment of patent protection).

23. Robert J. Gutowski, Comment, The Marriage of Intellectual Property and International Trade in the TRIPs Agreement: Strange Bedfellows or a Match Made in Heaven?, 47 BUFF. L. Rev. 713, 737 (1999); see Foster, supra note 22, at 287-88 (noting no remedies for violations of Paris Convention requirements and lack of degree of protection members must afford patent rights).

24. See Giust, supra note 22, at 71 (emphasizing that TRIPs, unlike Paris Convention, directly regulates degree of intellectual property protection which applies to all members).

25. See TRIPs, supra note 6, at 601-02, 615-16 (addressing concessions allowed by TRIPs in light of developing countries implementation difficulties). The provisions on parallel importation (Article 6) and technical cooperation (Article 67) are outside the main scope of this Note and therefore are only briefly mentioned.


27. See INTERNATIONAL INTELLECTUAL PROPERTY LAW 3 (Anthony D’Amato & Doris Estelle Long eds., 1997) (supplying definition of patent and rights conferred); Rein, supra note 4, at 380-81 (discussing patent scheme as part of global trade regime); Weissman, supra note 7, at 1071 (identifying logic underlying crea-
Article 31 of TRIPs appears to allow countries to grant compulsory licenses in limited circumstances. This provision, however, contains ambiguous language that developed and developing countries read differently. As one commentator notes, "without terming it such, TRIPs allows for compulsory licensing amidst several provisions in Article 31."30

C. Overview of the Dispute Settlement Process

In 1994, members of the General Agreement on Tariffs and Trade (GATT), dissatisfied with its informally structured organization, created the WTO, a formal international organization, to administer its procedures.31 Arguably, the most important feature resulting from the WTO was its official dispute settlement procedure, set out in an agreement called the Understanding on Rules and Procedures Governing the Settlement of Disputes (DSU), establishing the Dispute Settlement Body (DSB); the DSB was an attempt by the WTO to "clean up" the ambiguity of GATT's old dispute settlement process.32 This creation coincided with the adoption of TRIPS and, as a result, TRIPS agreement standards are sup-

28. See Ford, supra note 5, at 945 (describing compulsory licensing as applied to international intellectual property rights); Griffin, supra note 4, at 403-04 (explaining compulsory licensing and scheme suggested by members of Congress for allowing compulsory licensing of pharmaceuticals in United States). The scheme suggested was entitled the Public Health Price Protection Act of 1972 and would have required patent holders to license drugs to generic manufacturers on a royalty basis, to be determined by the FTC; however, this legislation never became law. See id. (discussing scheme).

29. See TRIPS, supra note 6, at 602 (providing ambiguities as to legality of compulsory licensing under Article 31); see also Abbott, supra note 8, at 73-77 (discussing legality of compulsory licensing under TRIPs).

30. Ford, supra note 5, at 949; see Weissman, supra note 7, at 1113-15 (suggesting that Article 31 authorizes countries to use compulsory licensing, but also noting that provisions 31(f) and 31(h) may create obstacles to compulsory licensing program).

31. See Hudec, supra note 13, at 4 (discussing history of GATT dispute procedures). "[D]uring the first thirty years of GATT history . . . [i]ts operating procedures were quite ill-defined, its legal rulings were written in vague language that suggested more than it said, and both its procedures and its rulings left plenty of room for negotiation." Id.; see also Pechman, supra note 7, at 187-88 (noting that DSU improved old system by guaranteeing right to panel, adopting panel report in absence of consensus to reject, establishing appellate review and placing time limits on compliance).

32. See Hudec, supra note 13, at 3-15 (describing development of DSU from GATT).
posed to be enforced through the DSU. Thus, it is important to understand how the dispute process is used.

The dispute settlement process under the WTO occurs in twelve stages, beginning with consultation among disputing countries and culminating in rulings made by a panel, which are subsequently adopted, rejected or appealed by the WTO members. It must be stressed, however, that priority is to settle disputes through consultation. If consultation fails, then the DSU prefers that members resort to the DSB instead of taking unilateral action against a non-complying country. The premise of the DSU is the same as earlier GATT procedures, but it expands settlement powers in four ways: (1) it confers the right to bring complaints before a dispute settlement board; (2) it makes board rulings binding on all parties; (3) it introduces appellate review; and (4) it confers the right to automatic trade sanctions when the losing party fails to comply with a legal ruling.

This process is important to member countries of TRIPs because, while a council for TRIPs will monitor agreements between countries, the DSU provisions of GATT apply to consultation and dispute settlement under TRIPs. These aspects of dispute settlement under TRIPs are hel
ful in that their goal is to settle conflicts through negotiation.\textsuperscript{40} Thus, dispute settlement under TRIPs is important in dealing with the tensions between developed and developing countries over interpretation of TRIPs, specifically any litigation arising out of those tensions.\textsuperscript{41}

III. TENSIONS BETWEEN DEVELOPED AND DEVELOPING COUNTRIES WITH RESPECT TO INTERPRETING TRIPs

The ambiguous language in TRIPs articles led to a rise in tension between developed and developing countries over proper interpretation.\textsuperscript{42} Developed countries tend to view TRIPs narrowly, while developing countries view it broadly.\textsuperscript{43} These differing views resulted in developed country pharmaceutical companies bringing suit against the South African government based on South Africa's interpretation of TRIPs to include compulsory licensing under its Medicines Act.\textsuperscript{44}

A. View of Developed Countries

Developed countries, specifically the United States, interpret the TRIPs Agreement narrowly, proposing to give more control to the patent holder.\textsuperscript{45} The view advanced by the Pharmaceutical Research and Manu-

\textsuperscript{40}. See World Trade Organization, supra note 35, at http://www.wto.org/english/thewto_e/whatis_e/tif_e/displ_e.htm (providing that main goal in dispute settlement process is negotiation).

\textsuperscript{41}. For a further discussion of tensions between developed and developing countries over interpretation of TRIPs, see infra notes 42-54 and accompanying text.

\textsuperscript{42}. For a further discussion of developed countries' narrow interpretation of TRIPs, see infra notes 45-50 and accompanying text. For a further discussion of developing countries' broad interpretation of TRIPs, see infra notes 51-54 and accompanying text.

\textsuperscript{43}. For a discussion of the divergent views of developing and developed countries, see infra notes 45-54 and accompanying text.

\textsuperscript{44}. For a brief discussion of the litigation against South Africa, see supra notes 5-9 and accompanying text.

\textsuperscript{45}. See Weissman, supra note 7, at 1075 (noting pharmaceutical industry's attempt, before signing of TRIPs, to persuade developing countries to adopt strict regulation of patents). Pharmaceutical companies exerted heavy pressure on U.S. policy makers to coerce developing countries into adopting U.S.-style patent laws. See id. (discussing tactics of pharmaceutical companies, including acquisition of seats on government advisory boards). Examples of this include "officials from the PMA, Pfizer and Immunon Technologies join[ing] a technical advisory committee to the USTR on intellectual property rights. Officials from DuPont, Monsanto and Proctor & Gamble . . . [also] serv[ing] on the same committee." Id. at 1076; see also Foster, supra note 22, at 298 (describing pharmaceutical industry campaign to make protection of intellectual property rights priority of U.S. trade policy). Pharmaceutical companies began making campaign donations including more than $8.5 million to House and Senate candidates and $1.7 million to the 1992 presi-
facturers of America (PhRMA), of which most large U.S. pharmaceutical companies are members, states: “In an environment of strong protection for patent rights, TRIPs provides limited exceptions where, in cases of extreme urgency, compulsory licensing may complement generally high levels of protection. Unfortunately, at this time, these conditions do not prevail in countries where compulsory licensing is practiced.”

In fact, the United States has threatened to curtail economic aid programs and to impose trade sanctions on the governments of South Africa and Thailand, among others, for adopting or preparing to adopt measures to allow them to address their health care crises, including broadly interpreting TRIPs to allow compulsory licensing and other forms of loose patent protection.

The United States takes this position because its economy is increasingly
dential election. See id. (describing pharmaceutical industry campaign to make protection of intellectual property rights priority of U.S. trade policy); see also Abbott, supra note 8, at 72 (stating that “U.S. government and the pharmaceutical industry are invoking the TRIPs Agreement to impede governments [of developing countries] from taking actions that are urgently needed to save lives”). Abbott then outlines the rationale behind those opposed to a reading of the TRIPs Agreement to permit compulsory licensing. See id. (labeling pharmaceutical industry’s rationale as legal fiction of “slippery slope”). Nevertheless, Abbott notes that although pharmaceutical countries intensely lobbied, they lost the battle “to prevent the TRIPs Agreement from incorporating permissive rules on parallel trade and compulsory licensing.” Id.; see also John A. Harrelson, Note, TRIPS, Pharmaceutical Patents, and the HIV/AIDS Crisis: Finding the Proper Balance Between Intellectual Property Rights and Compassion, 7 Widener L. Symp. J. 175, 188-92 (2001) (offering analysis of U.S. position against compulsory licensing). Members abiding by TRIPs, although not required, have the option of negotiating stricter intellectual property rights. See id. (discussing USTR policy of threatening loss of U.S. trade unless developing country does not use compulsory licensing and outlining reasons behind the policy, including lack of innovation leading to production of lower quality drugs). Harrelson argues that the United States contradicts itself because several U.S. statutes call for compulsory licensing, particularly to the military. See id. at 191 (“[T]he United States government can issue a compulsory license for air pollution control patents, for nuclear power patents, for public health related patents, and for items needed for governmental use.”).


47. See Abbott, supra note 8, at 72 (noting that developing countries may have won legal battle regarding compulsory licensing, but it hurt them economically and politically). Abbott eludes to the fact that developing countries may decide to disregard TRIPs. See id. (“The decision by the United States government to use its economic power as a weapon against developing countries fighting a battle against a deadly plague would plausibly lead developing country government officials and common citizens to question the economic, social and political foundations of the TRIPs Agreement.”). The United States also opposes reading TRIPs to allow parallel importing, another method used by developing countries to provide cheap access to pharmaceuticals. See Duckett, supra note 1, at http://www.icaso.org/docs/compulsoryenglish.htm (“[I]mporting consists of purchasing proprietary drugs from a third party in another country, rather than directly from the manufacturer, and taking advantage of the fact that pharmaceutical companies sometimes charge significantly lower prices in one country than another.”). Parallel importing is outside the scope of this Note.
moving away from basic manufacturing and toward high-technology industries, including biotechnology and pharmaceuticals.\(^{48}\) Thus, the importance of intellectual property is a key concern.\(^{49}\) The United States also believes that compulsory licensing is not the solution because it has negative outcomes, including decreased access to medicines in developing countries.\(^{50}\)

**B. View of Developing Countries**

Developing countries, including South Africa, India and Thailand, interpret TRIPs broadly, proposing less control to the patent holder because these countries traditionally did not offer strong (or any) protection to intellectual property in the pharmaceutical area.\(^{51}\) For example, before

\(^{48}\) See Michael L. Doane, *TRIPs and International Intellectual Property Protection in an Age of Advancing Technology*, 9 Am. U. Int'L L. \\& Pol'y 465, 465 (1994) (noting growth and development of international market over last twenty-five years, specifically in technology-based industries, including pharmaceuticals). A result of this growth is that these products have become a vital part of the U.S. economy, with international trade of these products accounting for five percent of the United States Gross National Product. See *id.* (noting that American innovators suffer from inadequate protection of intellectual property rights in foreign countries). “It is estimated that worldwide losses to U.S. industries from piracy and other forms of intellectual property right infringement exceed $60 billion annually.” *Id.* at 466.

\(^{49}\) See Foster, *supra* note 22, at 297-98 (discussing dependence of U.S. economy upon innovators in pharmaceutical industry to narrow trade deficit since shift to high-technology manufacturing, and emphasizing innovators’ dependency on strong patent protection to recoup R&D costs; thus, allowing more pharmaceuticals to reach market); Laurinda L. Hicks \\& James R. Holbein, *Convergence of National Intellectual Property Norms in International Trading Agreements*, 12 Am. U. Int'L L. \\& Pol'y 769, 770-71 (1997) (describing ways in which national intellectual property norms can be fused into globalizing international trade markets and noting that intellectual property rights are global commodities).

\(^{50}\) See PhRMA, *supra* note 46, at 103 (illustrating drawbacks of compulsory licensing). Canada, for example, implemented legislation in the 1970s that permitted compulsory licensing. See *id.* As a result, research and development decreased rapidly and did not increase until Canada made its compulsory licensing provisions TRIPs compliant. See *id.* at 104 (“Subsequent to the strengthening of the patent system, R&D expenditures increased by over 700 percent during 1987-98, and the ratio of R&D spending to sales doubled during the same period.”).

\(^{51}\) See TRIPs, *supra* note 6, at 594, 601-02 (offering exceptions to imposing TRIPs minimum standard intellectual property rights). Article 8, section 1 states that “[m]embers may adopt measures necessary to protect public health and nutrition . . . provided that such measures are consistent with the provisions of this agreement.” *Id.* at 594 (emphasis added). Article 27 offers a public health exception to patentability: “Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health . . . provided such exclusion is not made merely because exploitation is prohibited by their law.” *Id.* at 601. Article 31, entitled Other Use Without Authorization of the Right Holder, states:

Where the law of a member allows for other use of the subject matter of a patent without the authorization of the right holder, including use by the government, the following provisions shall be respected: . . . (b) such use
adopting TRIPs, developing member States, such as India, deliberately removed the pharmaceutical industry from the patent system, choosing instead to protect the industry by imposing tariffs on bulk drugs. 

Developing countries additionally argue that they do not have the capacity or resources to currently maintain high-technology industries and that their citizens cannot afford expensive medications. Thus, these nations, may be only permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms. . . . This requirement may be waived by a member in the case of a national emergency or other circumstances of extreme urgency.

Id. at 602 (emphasis added). Developing countries use Articles 27 and 31 as the crux of their argument for allowing loose protection to pharmaceutical patent holders in light of the HIV/AIDS crisis. See Weissman, supra note 7, at 1099-1116 (using public health provision of Article 27 to conclude that countries can deny patents on drugs as long as reasons are legitimate and applying Article 31 to support compulsory licenses that meet criteria); see also Harrelson, supra note 45, at 190-92 (noting that compulsory licensing can decrease cost of pharmaceuticals in developing countries by over seventy-five percent with no significant loss in profits). Harrelson gives an example in India, where “one can obtain a two dollar generic form of Pfizer’s patented fluconazole, an AIDS related meningitis drug, that originally cost seventeen dollars.” Id. at 190-91.

52. See Giust, supra note 22, at 95-96 (explaining India’s past treatment of pharmaceutical patenting as example of why high levels of intellectual property protection may not be in best interests of developing countries, but also noting that TRIPs requires developed members to cooperate, both financially and technically, with needs of least developed countries). In India, before the signing of TRIPs, pharmaceuticals were not offered patent protection, and “the result [was] that Indian manufacturers of bulk drugs and formulations not only dominate[d] the Indian market, but [were] among the most competitive in the world, especially with regard to production of generic drugs.” Id. at 95. Giust notes that some scholars believe TRIPs will cause India to invest more in R&D to develop a more competitive drug sector. See id. (citing Martin J. Adelman & Sonia Balda, Prospects and Limits of the Patent Provision in the TRIPs Agreement: The Case of India, 29 VAND. J. TRANSNAT’L L. 507, 530 (1996)). Nonetheless, Giust cites the pharmaceutical industry in Italy as an example of TRIPs hurting developing countries. See id. at 96 (noting Italy’s industry was thriving before TRIPs and now is fairing poorly); see also Harrelson, supra note 45, at 176 (explaining that intellectual property protection is not culturally accepted by many developing countries, particularly based on their sense of community). The cultural aspects of intellectual property rights are outside the scope of this Note, but for an elegant discussion on the developing countries’ cultural arguments against strict protection of intellectual property rights, see Gutowski, supra note 23, at 744-52 (supplying fears of developing countries of Western economic and moral imperialism). Gutowski notes one critic’s explanation of the inconsistency of Western individualism and developing countries ideals of community:

Most Third World societies are organized around a social unit, which extends certainly beyond the individual and, in most cases, beyond the nuclear family. The forms and very definition of ownership are thus crafted in a way opposite to property conceptions of western legal and economic structures central to the development of private and public law.


53. See Kevin W. McCabe, The January 1999 Review of Article 27 of the TRIPs Agreement: Diverging Views of Developed and Developing Countries Toward the Patentability
in light of the AIDS crisis, must use compulsory licensing as a way to offer cheaper medications.  

IV. ANALYSIS OF SOLUTIONS PROPOSED BY OTHERS

Many scholars have proposed solutions to undercut tensions created by ambiguities in TRIPs. These solutions include: allowing a narrow interpretation of TRIPS; allowing a broad interpretation of TRIPS; leaving interpretation matters to the DSB; implementing direct price control; using a pooled procurement scheme; and utilizing planned donation programs. Some of these proposals are more viable and accepted than others. None of the proposals, however, offer a country such as South Africa a long-term solution to the AIDS crisis.

54. See Robert Weissman, AIDS and Developing Countries: Democratizing Access to Essential Medicines, at http://www.foreignpolicy-infocus.org/briefs/vol4/v4n23aids_body.html (August 1999) (describing lack of medical infrastructure in African countries); see also Claire Bisseker, SA in Race to Develop an Affordable Vaccine AIDS Research, Fin. Mail (South Africa), Feb. 5, 1999, at 38 (discussing South African AIDS Vaccine Initiative, which will rely on funding from government, business and international donor community to promote better medical infrastructure and allow patients to receive affordable AIDS medications). But see Harrelson, supra note 45, at 177 (reviewing compulsory licensing and suggesting that compulsory licensing is not solution to high pharmaceutical costs in some developing countries because of lack of sufficient manufacturing resources). See generally Hawthorne, supra note 2 (describing lack of medical infrastructure in African countries, where some patients have to supply their own drugs, bedding and nurses and noting that governments do not have money, facilities or manpower to cope with AIDS). Countries with an adequate infrastructure and technology will benefit from compulsory licensing, but in less developed countries, such as sub-Saharan Africa, compulsory licensing will not make drugs more affordable. See Harrelson, supra note 45, at 192 (noting that least developed countries do not have sophistication or money to manufacture and distribute HIV drugs, even with use of compulsory licensing).

55. For a discussion of proposed solutions intended to remedy the current tensions between developed and developing countries, see infra notes 56-122 and accompanying text.

56. For a discussion of proposed solutions for interpreting TRIPs and allowing better access to essential AIDS pharmaceuticals, see infra notes 57-122 and accompanying text.

57. For a discussion of the viability of proposed solutions, see infra notes 74-75, 82-86, 90-93, 98-104, 111-14, 119-22 and accompanying text.

58. For a discussion of long-term solutions, see infra notes 123-80 and accompanying text.
A. Allowing a Narrow Interpretation of TRIPs

Some commentators have proposed to allow the narrow interpretation of TRIPs held by the developed countries, thereby giving more control to patent holders in a globalizing international economy. The main reason advanced is that inadequate patent protection will impede research and development in the pharmaceutical industry. "The U.S. Government estimated in 1990 that it cost an average of $359 million and took ten to twelve years to bring just one new pharmaceutical compound to the market." Shannon S.S. Herzteld, Senior Vice President of International

59. For a discussion of the view of developed countries, see supra notes 45-50 and accompanying text.

60. See Foster, supra note 22, at 297-98 (noting dependence of pharmaceutical companies on strong intellectual property rights to recoup R&D costs). The United States is comfortable in protection of intellectual property rights at home, with its main concern stemming from incidences of piracy by foreign countries. See id. (discussing adverse effects on pharmaceutical sales and R&D efforts caused by foreign pirates). "United States pharmaceutical innovators generally have more than 40% of their sales in foreign markets, but government agencies have estimated that innovators lose . . . $5 billion annually in revenue from sales lost to foreign copiers." Id.; see also Griffin, supra note 4, at 368 (observing market of pharmaceutical industry and noting that Pharmaceutical Manufacturers Association has over one hundred member firms, which devoted over sixteen percent of their sales, or $7.3 billion, to R&D in 1989); McCabe, supra note 53, at 47-50 (explaining special characteristics of biotechnology industry and noting that only one in five thousand prospective drugs is good enough to reach market and those that do are highly susceptible to piracy, which results in cheap and simple replication, causing pharmaceutical industry to suffer massive economic losses). McCabe states that:

The biotechnology industry, as all industries, is regulated by two fundamental economic theories. First, as rational actors, biotechnology companies will seek to maximize their investment return. Second, because investors are risk averse, they would be less willing to invest in biotechnology if they are not guaranteed adequate patent protection. Although the aim of the biotechnology industry is to alleviate the world’s health problems, “[w]e need to remember that health care, at least in the United States, is part of our society’s free-market economic system,” and therefore it is motivated by profit.

Id. at 48-49. But see Griffin, supra note 4, at 392-97 (questioning R&D and cost of drugs, particularly AZT costs of $8,000-$10,000 per patient). The cost would not seem so substantial, considering the estimation of $231 million supposedly spent on R&D, but the government conducted pre-clinical and clinical trials and continues to support research on the drug, leading one to wonder why the price is so high if the government is sponsoring the R&D. See id. at 393 (noting discrepancies between where companies get money for R&D and how much they charge patients for drugs in order to “recoup their R&D costs”); Duckett, supra note 1, at http://www.icaso.org/docs/compulsoryenglish.htm (suggesting that patients in poor countries should not pay for R&D costs because they are only small portion of global pharmaceutical market). Duckett advances the same argument as Griffin in questioning whether drug prices are related to replacement of R&D costs, focusing on Pentamidine, whose cost increased by five hundred percent once it was discovered that it could treat AIDS-related diseases. See id. (discussing original use of Pentamidine as cheap treatment for sleeping sickness).

61. Foster, supra note 22, at 297. But see Bond, supra note 3, at http://www.aids.org.za/archives/pbond_pharmaceutical_pricing.html (citing studies that
Affairs at PhRMA stated that, "for every 15,000 compounds that you look at, three become medicines. Of those three, one makes a profit. . . ."62 Furthermore, a 1994 World Bank study determined that eighty-six to one hundred percent of developed country pharmaceutical companies reported that their decision whether to invest or not invest in a country depends significantly on the amount of patent protection afforded by that country.63

Developed countries raise three other secondary issues arising out of allowing broad interpretation of TRIPS: (1) the concessions already granted to developing countries in the TRIPs Agreement; (2) the misuse and abuse of drugs in developing countries; and (3) the fear that peoples of developing nations will sell the cheaper pharmaceuticals on the black market back to developed countries at cheaper prices.64 The concessions argument advanced by the United States is that TRIPs already gives developing countries too much leeway for becoming TRIPs compliant.65 First, illustrate large share of R&D covered by U.S. government). Scientists from the National Institute of Health (NIH) stated on the development of AZT:

The Sept. 16 letter from T.E. Haigler Jr., president of the Burroughs Wellcome Company, was astonishing in both substance and tone. Mr. Haigler asserts that azidothymidine, or AZT, was essentially discovered and developed entirely by Burroughs Wellcome with no substantive role from Government scientists and Government-supported research . . . . Indeed, one of the key obstacles to the development of AZT was that Burroughs Wellcome did not work with live AIDS virus nor wish to receive samples from AIDS patients. In a number of specific ways, Government scientists made it possible to take a drug in the public domain with no medical use and make it a practical reality as a new therapy for AIDS. It is unlikely that any drug company could have found a better partner than the Government in developing a new product.

Id.

62. Harrelson, supra note 45, at 190.

63. See PhRMA, supra note 46, at 105 ("[T]he strength or weakness of a country's system of intellectual property protection seems to have a substantial effect, particularly in high-technology industries, on the kinds of technology transferred by many U.S. firms to that country.").

64. See David P. Fidler, Perspectives on Globalization from Developing States: Neither Science Nor Shamans: Globalization of Markets and Health in the Developing World, 7 IND. J. GLOBAL LEGAL STUD. 191, 209-12 (1999) (explaining downside to compulsory licensing through problems of developing countries abusing antimicrobial HIV/AIDS drugs because of weak public health infrastructure, but attributing weak infrastructure to impacts of globalization); see also International Intellectual Property Institution (IIPI), HIV/AIDS Pilot Project: To Deliver Patented Therapies & Other Treatments to Patients in Developing Countries, at http://www.iipi.org/eng/projects/aids.asp (last visited Aug. 31, 2001) (discussing various drawbacks of allowing compulsory licensing, including undermining innovation, not addressing affordability of drugs and causing formation of gray or black markets). Today, absence of patent protection is not providing inexpensive or effective access to patients who need them because the sophistication of manufacture and distribution of AIDS drugs is beyond both the financial and infrastructural means of developing countries. See id. (commenting on need for balancing innovation and investment with patient costs).

65. See Pechman, supra note 7, at 190-93 (setting forth concerns of United States regarding concessions granted under TRIPs to developing countries).
TRIPs' Articles 65 and 66 allow developing countries extended transition periods for compliance. Second, commentators argue that public policy exceptions to compliance conferred by Article 27 are broad escape clauses that a country can invoke without meeting specific standards. Developed countries feel they should not have to concede anything else under TRIPs.

The misuse and abuse argument centers on the poor medical infrastructure of developing countries and their lack of control over prescription and distribution of drugs, thereby leading to the development of resistant strains of HIV. The lack of poor medical infrastructure is illustrated not only by the deteriorating health care systems, but also by the lack of HIV/AIDS awareness and prevention programs. Even with easy and cheap access to antiretroviral drugs, who is to say that the people in...
developing countries will actually purchase and use them, especially when other situations, such as poverty, impose larger, more immediate concerns to the people of developing countries.\textsuperscript{70}

The "gray market" argument is based on two different markets emerging for pharmaceuticals, one in developed countries for selling patented drugs at higher monopolistic prices, and one in developing countries for selling the same drugs at extremely low prices.\textsuperscript{71} One commentator argues that this two-market system will lead to re-export markets where people will buy pharmaceuticals at discounted prices in developing countries and then re-export them to developed countries for a profit.\textsuperscript{72} As noted by the International Intellectual Property Institution (IIPI), "[w]here pharmaceutical companies to establish significantly lower prices for developing country markets, they would risk having products sold in those markets re-imported into their profit-generating home markets—creating a 'gray market' for their own products."\textsuperscript{73} These arguments all have valid concerns. Nonetheless, allowing too narrow of an interpretation is not the best solution because it does nothing to relieve the tension between developing and developed countries and is too one-sided.\textsuperscript{74} Consequently, de-

\textsuperscript{70} See Nash, supra note 5, at 498-99 (emphasizing Medicines Act and generic substitution provisions allowing access to adequate AIDS therapy are not full solution to South Africa's AIDS crisis). Nash further states: [G]iven South Africa's poor living conditions and poorly educated population, a supply of antiretrovirals cannot be expected to address HIV infection on its own. For example, South Africa is currently experiencing 1600 new cases a day of an almost entirely preventable infection. How compliant this population will be in following a rigid and often complex antiretroviral drug regimen is, at this point, only speculative.


\textsuperscript{72} See id. (noting drawback of compulsory licensing and generic substitution under Medicines Act, causing pharmaceutical companies to assess patent protection position of each country in which they wish to invest). Australia and the European Union are examples: Australia uses border patrols to prevent cross-border trade and parallel importations, while the European Union, by purpose of its goal of free movement of goods across member borders, may not be able to prevent development of gray markets. See id. (highlighting concern of developed countries over substantially discounted prices in developing countries).

\textsuperscript{73} IIPI, supra note 64, at http://www.iipi.org/eng/projects/aids.asp. The IIPI suggests that consumer groups in the United States favor the "gray market" because they will be able to take advantage of the lower prices. See id. (discussing side effect of price differentials between developed country and developing country markets).

\textsuperscript{74} See Abbot, supra note 8, at 72 (opining that United States use of unilateral economic sanctions may lead developing countries to question fundamentals of TRIPs). "Would any developing country government deliberately negotiate away its discretion to take measures to redress a health crisis of the most severe magnitude? Indeed, would any government or any group of citizens deliberately enter into a legal agreement condemning itself to early death?" Id.
developing countries may ignore the narrow interpretation just as they have ignored past attempts at regulation of intellectual property rights. 75

B. Allowing a Broad Interpretation of TRIPs

Developing countries acknowledge that effective patent protection is a prerequisite for an innovative pharmaceutical industry; however, they also believe in balancing all interests to provide protection against abuse by the patent holder. 76 The benefits of limiting the patent right will accrue to pharmaceutical consumers and Third World generic manufacturers, with consumers paying lower prices. 77 Proponents of limiting patent rights and allowing compulsory licenses do not believe that research and development (R&D) will be discouraged because those costs are recovered from sales in industrialized countries, where most of the patients have health insurance. 78

Developing countries also argue for allowing compulsory licensing under TRIPs in light of the historical practice of Western pharmaceutical companies exploiting therapeutic remedies developed and applied by

75. See Ford, supra note 5, at 970 (suggesting that interpreting TRIPs too narrowly may lead to its denunciation by developing countries); Harrelson, supra note 45, at 201 (eluding to fact that pharmaceutical companies and United States may seem uncompassionate to society if measures are not taken to address HIV/AIDS crisis in developing countries); Weissman, supra note 7, at 1070 (suggesting that pharmaceutical industry knows of alternatives to its restrictive reading of TRIPs and is trying to suppress them); PhRMA, supra note 46, at 100 (describing ineffective enforcement of intellectual property protection under TRIPs by various countries including India, Argentina and Egypt). "The Government of India is aware of its WTO TRIPs obligations, but has failed to meet them. Thus, India remains the single worst WTO scofflaw." Id. PhRMA also notes that both Argentina and Egypt violate their TRIPs obligations and that a number of other countries, including Canada, do not provide the TRIPs twenty-year exclusivity term. See id. (addressing inefficiency of intellectual property protection in many countries, even some developed countries).

76. See Duckett, supra note 1, at http://www.icaso.org/docs/compulsoryenglish.htm (offering example of Indian drug industry whose companies are given authority to produce drugs for local market without paying high licensing fees, leading to lower cost to consumers and high return to Indian pharmaceutical company).

77. See Weissman, supra note 7, at 1116 (advancing benefits of allowing broad interpretation of compulsory licensing by limiting patent right).

78. See Duckett, supra note 1, at http://www.icaso.org/docs/compulsoryenglish.htm (advancing argument that Africa accounts for just over one percent of global pharmaceutical market and thus is not threat to R&D funding). Professor Richard Laing, of Boston University's School of Public Health, has argued: "The global pharmaceutical market is so large (over $400 billion per year) and the proportional contribution of Africa, Southeast Asia, and the Commonwealth of Independent States to both turnover and profit so small, that these markets could be completely isolated from the global total and pharmaceutical manufacturers would not be affected in any measurable way."

Id. For a comparison of who bears the cost of pharmaceutical R&D, pharmaceutical companies or the government, see supra note 60 and accompanying text.
traditional healers in developing countries. Commentators refer to this practice as biopiracy. They contend that allowing too much protection under TRIPs will shift control of traditional practices away from local communities and to large, foreign corporations.

While these arguments present valid concerns for developing countries, simply allowing a broad interpretation of TRIPs is as futile as allowing a narrow one. Industrialized countries should not alone bear the recovery of pharmaceutical development costs for the simple reason that

79. See Fidler, supra note 64, at 212-13 (noting that traditional medicine is viewed by Western pharmaceutical companies as commodity whereby Western companies take traditional cures, develop them and export them back into developing country at high cost). Fidler further states:

Typically, a Western pharmaceutical company finds a compound of therapeutic value in traditional medical practices, takes the compound back to its headquarters, refinesthe chemistry, and patents the research and development, giving it the opportunity to reap monopoly profits without returning anything to the society from which the knowledge originally came.

80. See The Right to Good Ideas: Patents and the Poor, ECONOMIST, June 23, 2001, at Special (stating that developing countries apply different meaning to word "piracy" than developed countries and suggesting moral objection of developing countries to exclusive exploitation of living things). Developing countries would like to see an end to "biopiracy," which demonstrates that poor countries are not opposed to a proper patent regime; they just want one that fits their needs. See id. (discussing Costa Rican laws exempting genes from patent and Brazil's desire for TRIPs to include "biopiracy" provisions). Some countries "are introducing laws that would require all those applying for intellectual-property rights over, say, a plant variety, to declare where they got it and to prove that they not only have the consent of its native users, but have arranged to share the eventual rewards of commercialisation." Id.

81. See Gutowski, supra note 23, at 748 (explaining differences in ownership standards of developing and developed countries). Gutowski explains that natives of developing countries believe natural resources are gifts from gods, with properties self-evident to all; thus, no one is the owner or inventor of processes utilizing natural resources. See id. (noting native concept of ownership). Developed countries, on the other hand, believe in free reign over natural resources, which Gutowski illustrates in his example of the neem tree in India. See id. (describing that W.R. Grace, U.S. pharmaceutical company, patented process for extracting chemicals from neem tree traditionally used by indigenous peoples for making medicines, insecticides, contraceptives and soap); see also The Right to Good Ideas: Patents and the Poor, supra note 80, at Special (advancing that developing countries contain many natural resources, which could lead to new drugs and crops to benefit poor but few of these people can afford $20,000 cost of obtaining patent or $1.5 million cost to challenge one). "Money is little object, however, to many western entrepreneurs who venture to far-flung parts, bring home such riches [and natural resources] and then proceed to patent them." Id.

82. See Ford, supra note 5, at 971 (suggesting that allowing overly broad interpretation of compulsory licensing will cause developed countries to pursue options outside TRIPs dispute settlement procedure to enforce their patent rights in developing countries); see also Pechman, supra note 7, at 199 (noting that current concessions given by TRIPs to developing nations already provoke United States to rely on unilateral actions outside scope of TRIPs such as Special 301).
developing countries are poor. 83 Sympathy for developing countries can only go so far. 84 Allowing too broad of an interpretation will heighten tensions, possibly widening the gap between developed and developing countries. 85 Also, at least one commentator eludes to the possibility that compulsory licensing is probably not the most feasible solution for developing countries because they lack proper infrastructure. 86

C. Leaving Interpretation of TRIPs to the DSB

Commentators suggest that disputing parties should utilize WTO’s DSB instead of continuing to rely on diplomatic measures to resolve their disputes. 87 While developed countries may have nothing to gain, developing countries could secure legitimacy in compulsory licensing schemes by bringing a dispute to the DSB. 88 A practical method for the WTO to resolve the uncertainty surrounding compulsory licensing’s applicability would be to use the DSB to clarify the language of these provisions in Article 31 of TRIPs. 89

83. See PhRMA, supra note 46, at 103 (noting that TRIPs limits exceptions for compulsory licensing to cases of extreme urgency and that those conditions do not prevail in any countries practicing compulsory licensing).

84. See id. (discussing TRIPs exceptions for compulsory licensing).

85. See Fidler, supra note 64, at 191 (claiming that globalization of markets, laws and culture, including international regime of protecting patents, are increasing gap between developed and developing countries).

86. See Harrelson, supra note 45, at 192 (opining that compulsory licensing will lessen AIDS problem in countries with infrastructure and technology to manufacture HIV drugs but will not solve problem of affordability in least developed countries—e.g., countries in sub-Saharan Africa that lack proper infrastructure and technology). For arguments of developed countries on allowing a narrow reading of TRIPs concerning compulsory licensing, see supra notes 59-75 and accompanying text.

87. See Ford, supra note 5, at 968-70 (emphasizing need for disputing parties to utilize DSB and its underlying goals of negotiation); Rein, supra note 4, at 396-98 (relaying example cases of pharmaceutical patent protection brought under WTO dispute settlement procedures). In May 1999, the United States simultaneously requested consultations with Argentina and Canada alleging violations of TRIPs. See id. at 397 (noting U.S. allegations that Argentina failed to implement exclusive marketing provisions and Canada’s grandfather provision violated twenty year exclusivity period under TRIPs). In February 1999, the DSB established a panel to review Canada’s pharmaceutical patent system at the request of the European Union. See id. (describing Canada’s pharmaceutical patent laws). The European Union alleged that Canada’s patent legislation, allowing for stockpiling of generic pharmaceuticals six months before patent expiration, violated the exclusive rights provision of TRIPs (Article 28.1) and the panel agreed with the European Union. See id. at 397-98 (noting panel decision that stockpiling of generic pharmaceuticals is not limited exception defined by Article 30 of TRIPs and violates Agreement).

88. See Ford, supra note 5, at 968-69 (advancing that developed countries are more likely to use unilateral sanctions to avoid binding negative decisions by DSB, but developing countries bringing and winning disputes on compulsory licensing might pave way for other developing countries to enact similar legislation).

89. See id. at 970 (explaining that DSB either needs to clearly define language of Article 31 or base its interpretation of compulsory licensing provision on DSB
This appears to be a viable approach. Nevertheless, the power of developed countries has already been demonstrated and exerted against developing countries. Because developed countries have nothing to gain by bringing a dispute in front of the DSB, mandating they do so most likely will meet strong opposition and the use of unilateral action against the TRIPs-violating developing country. Developing countries would then be forced to accept the terms set forth by the powerful developed countries or risk harm to their relationship in the international trade market.

D. Direct Price Control

Some scholars suggest that developing countries should employ direct price control systems, like those used in Europe, which could result in cheaper drug prices. These systems vary in structure, but most entail negotiations between manufacturers and governmental agencies to determine a proper price. The negotiating parties consider both the consumers’ ability to pay and the manufacturers’ expected profits. Some definition of “inadequate usage” concept from Paris Convention adopted by TRIPs).

90. See id. at 972 (opining that to balance interests of developed and developing countries, “the WTO should permit compulsory licenses for cases of ‘inadequate usage’ of all pharmaceutical patents for drugs used to treat life-threatening diseases, which affect a significant portion of a nation’s citizens and are not available to those affected through the current market practices.”). But see id. (noting that questions will arise as to meaning of life-threatening disease, with burden on developing country to prove that goal of its licensing scheme is to alleviate life-threatening disease).

91. See Pechman, supra note 7, at 197-98 (describing U.S. Special 301 action against Brazil in response to pharmaceutical industry complaints that Brazil encouraged piracy). Pechman notes that the United States retaliated by imposing 100% tariffs on Brazilian exports, including items having no relation to pharmaceuticals such as paper products and electronics. See id. at 198, 204 (emphasizing that Special 301 allowed United States to retaliate in sectors not under dispute while, if brought before DSB, the United States would only be allowed same sector pharmaceutical retaliation).

92. See Ford supra note 5, at 968-69 (discussing how developed countries have greater incentive to rely on unilateral action). For a further discussion of the U.S. argument that TRIPs already concedes too much to developing countries, see supra notes 65-67 and accompanying text.

93. For a further discussion of U.S. bullying tactics, see supra note 7 and accompanying text.

94. See Griffin, supra note 4, at 405-10 (providing Australia, New Zealand, Japan and most European countries as examples where direct price controls are employed and offering proposal for direct price control system in United States to alleviate expense of AIDS drugs).

95. See id. at 406 (noting that prices in controlled markets generally decreased relative to consumer price index in 1980s).

96. See id. at 406-07 (relaying study in Europe which surveyed drug prices and concluded that prices for selected products in United States were eighty-six percent more than those in countries with strict price control systems in place).
commentators believe that direct price controls could force the drug industry to streamline R&D.97

Direct price controls might work in European countries, which already have sophisticated pharmaceutical infrastructure and national health care systems.98 In developing countries, however, direct price controls might not work because of the lack of adequate infrastructure and health care programs.99 Lack of money to construct a better medical infrastructure will require wealthy countries to implement international subsidization in order to provide necessary funds.100 Another criticism of direct price control is that it leads to a lack of innovation and lower quality drugs.101 Developing countries employing a direct price control system also might appear unfavorable to Western pharmaceutical companies because direct price control is not based on a free-market system.102 Still, there is the noteworthy example of India, a less developed country whose pharmaceutical market is flourishing under the direct control system.103 India, however, did not become a member of the WTO until recently and might have to change its laws to comply with TRIPs.104

97. See id. at 406 (arguing that direct price controls might allow focus to shift to "truly innovative products rather than 'me-too' products currently flooding the market."). But see id. (noting opposition of pharmaceutical companies to direct price control on grounds that it would impede innovation).

98. See id. at 407 (offering that national health care systems employed by European countries result in lower out-of-pocket drug costs, but in countries that do not use national health care systems, including United States, prescription drugs may be one of consumers' highest out-of-pocket expenses).

99. See id. (listing only developed countries in examples of direct price control systems that work). For a discussion on the lack of adequate infrastructure in developing countries, see supra notes 68-70, 86 and accompanying text.

100. See IIPI, supra note 64, at http://www.iipi.org/eng/projects/aids.asp (proposing policy to resolve AIDS crisis utilizing national exhaustion principles coupled with price controls and international subsidization of pharmaceutical purchases).

101. See Griffin, supra note 4, at 407 (advancing that industry can draw conclusion, although speculative, that price controls are reason for decreased innovation in Europe and duplicative innovation in Japan).

102. See McCabe, supra note 53, at 60 (stating that restrictive price controls—i.e., not allowing adequate return on investment—will restrain importation of patented pharmaceuticals into developing countries).

103. See Matthew Kramer, Comment, The Bolar Amendment Abroad: Preserving the Integrity of American Patents Overseas After the South African Medicines Act, 18 DICK. J. INT'L L. 553, 569 (2000) (describing Indian model under Drug Price Control Order that placed price controls on drugs and production). "By the mid-1990s, the Indian pharmaceutical industry had become a net exporter of drugs, focusing on lower margin markets such as the former Soviet states, developing nations and South Africa." Id. But see Martin J. Adelman & Sonia Baldia, Prospects and Limits of the Patent Provision in the TRIPS Agreement: The Case of India, 29 VAND. J. TRANSNAT'L L. 507, 527 (1996) (noting that Indian drug companies have grown and become competitive, but have failed to innovate due to lack of pharmaceutical patent protection).

104. See Kramer, supra note 103, at 569 (suggesting that Indian pharmaceutical industry flourished only because it did not have to comply with international patent protection agreements); PhRMA, supra note 46, at 99-100 (noting that In-
E. Pooled Procurement

Under a pooled procurement scheme, countries with small national populations join together to purchase drugs and sell them on a common market, which ultimately leads to cheaper prices. The combined operation allows the countries involved to develop a single multi-country unit, thereby leading to better drug evaluation. The scheme is also utilized by large organizations. Doctors Without Borders, a non-governmental organization (NGO), has noted that global procurement guarantees high demand, reliable payment and straightforward negotiation of lower prices. Under this type of system, which relies on bulk purchasing, there is a fear of lower quality drugs, but commentators agree that the United Nations (UN) can pre-qualify producers participating in the system to ensure drug quality. Pooled procurement has worked for small countries, such as those in the Caribbean. The main crisis however, is occurring in Africa, which is a considerable portion of the world’s population and where procurement might not be feasible. Another drawback of the procurement system, as noted above, is the tendency for drugs purchased by bulk to be lower in quality. Pooled procurement also tends to discourage local production and manufacturing, which might have neg-
ative impacts on a country's economy. Finally, pooled procurement fails to overcome the patent barrier to use and transport.

F. Planned Donations

The World Health Organization (WHO) is now encouraging planned donation programs for drugs, whereby developed nations donate stocks of drugs currently in use for treatment of an array of diseases. Many U.S. pharmaceutical companies implemented donation programs after dropping their lawsuit against South Africa, including Merck, GlaxoSmithKline (GSK), Pfizer and Bristol-Myers Squibb. For example, Bristol-Myers Squibb recently announced a program to fight HIV/AIDS in Africa, selling antiretroviral drugs at over ninety-percent below cost. Similarly, in August, Merck announced its collaboration with the government of Botswana, whereby Merck would give free antiretroviral drugs to Botswana for five years and one hundred million dollars for training, education and condoms.

113. See id. (encouraging development of local generic production as part of pooled procurement strategy).

114. See id. ("For example, the lowest priced antiretroviral drugs are currently produced generically in India, but today they cannot be used in countries where these products are under patent.").

115. See Duckett, supra note 1, at http://www.icaso.org/docs/compulsoryenglish.htm (encouraging donations of drugs still in use and not just about-to-expire stocks of drugs).

116. See GlaxoSmithKline Reaffirms Commitment to Fight Diseases of the Developing World, at http://corp.gsk.com/press_archive/press_0612001.htm (June 11, 2001) (emphasizing that "GSK [GlaxoSmithKline] is the only company currently involved in research and development for both prevention and treatment of all three top priority diseases of the World Health Organization: malaria, tuberculosis and HIV/AIDS"). GSK also emphasizes its commitments to expand the number of countries and consumer groups eligible for preferential pricing, and to offer its antiretroviral AIDS cocktail at a ninety percent discount from the world average price and offer new antiretrovirals at preferential prices to developing countries. See id. (noting GSK's commitment to fighting diseases of developing countries).


118. See A New Approach, ECONOMIST, Aug. 11, 2001, at International (outlining proposed program for free antiretroviral drugs by Merck and medical foundation started by Bill Gates). But see id. (discussing how Botswana is "rich" when compared to other African countries). Botswana is ideal for the program because it has a small population and growing economy, and even without the donation, the dollar a day it currently costs each Botswana AIDS patient for triple therapy drugs is manageable. See id. ("Most of sub-Saharan Africa lacks Botswana's wealth, health system, foreign assistance and political leadership. . . . South Africa next door has at least . . . [four million infected] . . . The cost and logistics of handing out pills there are daunting.").
Planned drug donations are helpful and seem to be a viable solution at first glance. What pharmaceutical press releases are not reporting, however, is that many of these donations come with imposed conditions or other strings. Recently, Doctors Without Borders and other NGOs have criticized planned donation programs for attaching conditions, limiting the scope of donations and taking too much time to implement donation programs. Most NGOs now believe that donations may be helpful but are only a short-term unsustainable solution.

119. For a discussion of various donation programs instituted by pharmaceutical companies to give poor people in developing countries greater access to essential AIDS medicines, see supra notes 116-18 and accompanying text. For an outline of Pfizer’s donation programs, see supra note 9. But see Doctors Without Borders, Pfizer Limits Scope of Donation of HIV Drug in South Africa. MSF Reiterates Demand That Pfizer Unconditionally Reduce Price or Issue Voluntary License for Fluconazole, at http://www.accessmed-msf.org/prod/publications.asp?scntid=2282001256162&content type& (June 20, 2000) (noting that Pfizer has not fulfilled promise to provide Fluconazole (Diflucan) for free to people with HIV/AIDS in South Africa and that Pfizer has imposed conditions on donation).

120. See id. ("Most outrageous is Pfizer’s attempt to structure this donation like a clinical trial, adding onerous reporting and training requirements. South African physicians are experienced professionals and it is patronizing to require special training for routine treatments."). Another condition imposed by Pfizer is placing a time limit on the offer. See id. (discussing disappointment of NGOs with Pfizer’s donation program and strings attached). The time limit on the offer directly contradicts Pfizer’s press release concerning the Diflucan Partnership, which states, “Pfizer’s support has no dollar or time limits.” Pfizer, Pfizer to Offer Diflucan Antifungal Medicine At No Charge to HIV/AIDS Patients in 50 Least Developed Countries Around the World, at http://www.pfizer.com/pfizerinc/about/press/nochargediflucan.html (June 6, 2001).

121. See Doctors Without Borders, World AIDS Day Teleconference Transcript November 28, 2000, at http://www.doctorswithoutborders.org/news/wad2000_transcript.htm (last visited Oct. 15, 2001) (discussing current drug donation programs). Mark Heywood, a representative of the Treatment Action Campaign, a NGO that serves as a grassroots AIDS activist organization in South Africa, stated: We are prepared to welcome this offer, this donation, but what we regret is that it has taken nine months for this donation to become any kind of reality. . . . It is not going to be immediately available to people who suffer from [opportunistic infections related to AIDS]. The second thing is that Pfizer is still limiting the offer to the public health sector. And yet in South Africa many poor people with HIV and AIDS use the private health sector. . . . We therefore are critical of the offer and do not accept it in the terms with which it is being made available.

Id. Again, these conditions seem in direct conflict with Pfizer’s press release concerning the Diflucan donation program. See Pfizer, supra note 120, at http://www.pfizer.com/pfizerinc/about/press/nochargediflucan.html ("The company will work closely with governments, non-governmental organizations, the UN and the WHO to ensure Diflucan reaches all eligible patients who cannot afford treatment.") (emphasis added).


[Doctors Without Borders] does not believe that drug donations are a long-term solution to the access crisis. . . . Drug donation programs can also have other drawbacks, including: donations usually do not cover global need and are limited in time and place; they often come with bur-
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In light of the current AIDS crisis faced by many developing countries, programs should be implemented that will lead to long-term solutions to the problem of essential pharmaceutical access, rather than short-term gratification.123 This Note proposes reforming TRIPs to conform to the realities of the twenty-first century.124 The suggested reforms include: (1) modifying TRIPs to exclude patentability of AIDS drugs under Article 27 or (2) developing a standard inquiry to determine what constitutes a “national emergency” or “life-threatening” disease.125 In addition, this Note offers a test program to be implemented in one developing country that would concentrate money and manpower on HIV/AIDS education and prevention programs, as well as access to essential pharmaceuticals.126 The goal of the program would be to establish a long-term feasible solution to AIDS and other national crises that may arise in the future.127

A. Modifying TRIPs to Address the Present Situation

When TRIPs was created as a product of the Uruguay Round in 1994, the global atmosphere was not the same as it is today.128 Developed countries pushing for patent protection were most concerned with protecting

dense restrictions on recipient health ministries; they often require extra administrative work, diverting scarce resources from health systems; they can distort rational drug use; tax deductions given for donations may cost donor countries more than other options. Considering the weaknesses, donations should neither be relied-upon, portrayed, nor promoted as the best way to improve access to medicines.

Id.

123. See Alain Guilloux & Suerie Moon, Hidden Price Tags: Disease-Specific Drug Donations: Costs and Alternatives, at http://www.accessmed-msf.org/prod/publications.asp?scntid=492001217158&contenttype& (Oct. 1, 2000) (“National Governments, NGOs and intergovernmental organizations including WHO, the World Bank, UNICEF and [United Nations Program on HIV/AIDS], should promote solutions that are more sustainable . . . for the access crisis, such as encouraging generic production and negotiating dramatically-reduced differential pricing for branded products.”).

124. For a discussion of the current HIV/AIDS crisis occurring in developing countries, specifically South Africa, see supra notes 1-4 and accompanying text.

125. For a discussion of proposed modifications to Article 27 and advancing the need to develop a standard inquiry as to what constitutes “national emergency” in terms of Article 31, see infra notes 128-51 and accompanying text.

126. For a discussion of the need for a long-term solution to national crises and setting forth a test program to develop a permanent solution to the current AIDS crisis in developing countries, see infra notes 152-80 and accompanying text.

127. For a discussion of long-term goals of the test program, see infra notes 152-76 and accompanying text.

128. For a discussion on the current AIDS crisis in developing countries, see supra notes 1-4 and accompanying text.
In contrast, developing countries today have the pressing issues of poverty, inadequate infrastructure and medical crises, including AIDS. As a result, TRIPs does not adequately address the current AIDS pandemic faced by developing countries. For example, the U.S. Census Bureau recently compiled data gathered on HIV seroprevalence for pregnant women in South Africa from 1991 to 1999 to map the epidemic state. The data illustrate an increase in HIV infection from about seven percent in 1994 to twenty-two percent in 1999. In light of this current situation faced by developing countries TRIPS should be modified, or at least reviewed carefully, at the next meeting of the WTO to better explain remedial measures for health crises.

The modifications should leave in place standard protection of intellectual property rights, but should also clearly address when exceptions, such as compulsory licenses, can and must be used to alleviate hardships faced by developing countries. As one commentator noted, “It is easy to understand why developed countries would advocate an international intellectual property system. It is less clear why developing countries finally agreed to the TRIPs Agreement. Conventional wisdom is that such nations joined TRIPs in exchange for other trading advantages from developed countries . . . .” Thus, if developing countries gave up certain rights of pharmaceutical exploitation in the process, developed coun-

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129. For a discussion of developed countries' view of intellectual property in light of globalization and growth in technology-based markets, see supra notes 48-50 and accompanying text.

130. For a discussion offering a view on developing countries concerning interpretation of TRIPs in light of the AIDS crisis, see supra notes 51-54 and accompanying text.

131. See International Programs Center, Population Division, United States Census Bureau, HIV/AIDS Profile: South Africa: HIV/AIDS Surveillance Data Base, at http://www.census.gov/ipc/hiv/safrica.pdf (June 2000) (offering demographic indicators for AIDS profile of South Africa). The estimated percentage of adults living with HIV/AIDS at the end of 1999 was 19.9%, with a 15-year difference in life expectancy between those with AIDS and those without AIDS, and the cumulative AIDS rate as of 1996 was 0.30 per thousand. See id. (noting that life expectancy of those without AIDS is sixty-six years, while it is only fifty-one years for those with AIDS).

132. See id. (presenting epidemiological data on AIDS crisis in South Africa).

133. See id. (noting that AIDS epidemic began later in South Africa than in other African countries). “By the mid 1990's, infection rates among pregnant women were increasing tremendously. South Africa is now facing one of the most serious HIV epidemics in the world.” Id.

134. See Ford, supra note 5, at 969-70 (recommending that most practical method WTO could implement to resolve dispute over compulsory licensing is to review and clarify language in Article 31 of TRIPs).

135. See Marschall, supra note 39, at 1188-89 (arguing that compulsory licensing should be used only when appropriate and current TRIPs Agreement does not clearly identify scope of exceptions under Articles 8, 30 and 31, which could all justify compulsory licensing).

136. Id. at 1187.
tries should recognize this and give them some leeway in determining the proper use of provisions such as compulsory licensing.\textsuperscript{137}

This is not the first time amendment or modification of TRIPs has been suggested.\textsuperscript{138} The solution suggested here, however, is to modify Article 27, concerning patentable subject matter and the possibility of compulsory licensing.\textsuperscript{139} According to one commentator, "Article 71 of the TRIPS Agreement authorizes the TRIPS Council, established in Article 68, to undertake reviews in the light of any relevant new developments which might warrant modifications or amendment of this [TRIPS] Agreement."\textsuperscript{140} The TRIPS Council can utilize this power to modify TRIPs to conform to the AIDS crisis in developing countries.\textsuperscript{141} For example, Article 27(3) (a) provides that "members may also exclude from patentability: (a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals[.]."\textsuperscript{142} Developing countries could make the argument to the TRIPS Council that essential AIDS drugs constitute a therapeutic method for the treatment of humans and should be excluded from patentability.\textsuperscript{143} Developing countries and NGOs would then unite and lobby the TRIPS Council for the modification.\textsuperscript{144} Developing countries have a good chance for success and acceptance of their interpretation, given the international public opinion regarding developed country pharmaceutical

\textsuperscript{137.} See id. at 1189 (noting that provisions of TRIPs justifying compulsory licenses may be reason why developing countries signed on to TRIPs). Nevertheless, some commentators feel that TRIPs conceded too much to developing countries. For a further discussion offering the developed countries' argument as to why TRIPs should be interpreted narrowly to make it more difficult for developing countries to issue compulsory licenses, see supra notes 65-67 and accompanying text. The concessions argument touches on sovereignty, which is outside the scope of this Note.

\textsuperscript{138.} See McCabe, supra note 53, at 63 (explaining that it appears TRIPs may be modified without consent of Full Ministerial Conference of WTO, while amendment must be reviewed by Ministerial Conference); Marschall, supra note 39, at 1190 ("This Note proposes an amendment to the TRIPS agreement that would curtail the use of the broadly worded escape clause currently available to developing nations.").

\textsuperscript{139.} See TRIPs, supra note 6, at 601 (setting forth patentable subject matter under TRIPs).

\textsuperscript{140.} McCabe, supra note 53, at 63; see TRIPs, supra note 6, at 618 (referring to review and amendment of TRIPs by Council for TRIPs).

\textsuperscript{141.} Cf. McCabe, supra note 53, at 63-64 (advancing modification of TRIPs Article 27(3) based on provision excluding plants and animals from patentability).

\textsuperscript{142.} See TRIPs, supra note 6, at 601 (discussing patentable subject matter).

\textsuperscript{143.} Cf. McCabe, supra note 53, at 64 (noting that United States should lobby for TRIPs modification of Article 27(3)).

\textsuperscript{144.} See Guilloux & Moon, supra note 123, at http://www.accessmed-msf.org/prod/publications.asp?scntid=492001217138&contenttype=PARA& (recommending unity of national governments, NGOs and intergovernmental organizations in promoting sustainable solutions for access to essential AIDS medicines).
companies and the realization by organizations, including the WHO, that something must be done to remedy the AIDS crisis.145

B. Developing Standard Inquiry Under TRIPs As to What Constitutes a National Emergency

In the instance that developing countries fail to persuade the TRIPs Council to accept their interpretation of Article 27, developing countries can lobby for clarification as to what constitutes a “national emergency” under Article 31 of TRIPs.146 This Note does not suggest that developing countries ask for a bright line rule or definition of “national emergency.”147 Instead, a better option would be to develop a standard inquiry under which a panel, including DSB representatives, developing country representatives and developed country representatives, would decide if the crisis was extreme enough to be considered a “national emergency” and outweighed developed country interests in patent protection.148 Factors to be considered in determining a “national emergency” should include:

1. the nature of the disease: for example does it kill or just maim;
2. if the disease results in death, are there significant differences in morbidity rate in lower socioeconomic groups as compared to upper socioeconomic groups;
3. the expected decimation in total population attributable to the disease;
4. the estimated drop in life expectancy due to the disease;
5. the amount of people in the country affected by the disease, both directly and indirectly;
6. the impact of the disease on the country's economy;
7. the number of people who can currently afford treatment;
8. the estimated number of people who will receive treatment if the exception is allowed; and
9. the adequacy of treatment facilities or, in other words, the feasibility of compulsory licensing given the infrastructure of the country.149 This inquiry would be a start, with other necessary factors added over time.

145. See Toby Kasper, South Africa's Victory for the Developing World, at http://www.accessmed-msf.org/prod/publications.asp?scntid=3182001040389&contenttype& (July 1, 2001) (explaining special session of Council for TRIPs, wherein developing countries mandated TRIPs be interpreted to allow developing countries to place health protection above patent protection). For a discussion of planned donation programs encouraged by the WHO to alleviate medical crises in developing countries, see supra notes 115-18 and accompanying text.

146. See Ford, supra note 5, at 969-70 (recommendating that DSB should clarify language of TRIPs by basing interpretation of Article 31 on strong definition of “inadequate usage” language of Paris Convention).

147. But see id. at 972 (offering definition of “inadequate usage” and opining that offered definition would in turn define concept of “national emergency” and place burden on license-seeking nation to prove existence of life-threatening disease).

148. Cf. Griffin, supra note 4, at 408-10 (providing proposal for direct price control of AIDS drugs in United States, utilizing AIDS control board to determine price of drug based on fifteen different factors).

149. Cf. id. at 409 (listing fifteen different factors for determining price of drug under direct price control system).
Utilizing this inquiry, the panel would decide if the crisis in the developing country would warrant the term "national emergency," allowing the country to undercut patent protection rules to alleviate the medical crisis. Under this inquiry, the current AIDS pandemic clearly outweighs developed country interests in patent protection.\textsuperscript{150} Thus, AIDS constitutes a "national emergency" under Article 31 of TRIPs, qualifying essential AIDS pharmaceuticals for compulsory licensing or "other use . . . without the authorization of the right holder."\textsuperscript{151}

C. Test Program Proposal

In addition to modification and clarification of TRIPs, a test program should be implemented to develop long-term economical practices and solutions to national emergencies that may arise in both developed and developing countries.\textsuperscript{152} This program would be implemented in one developing country and test a combination of proposed solutions to determine the best solution to combat AIDS and eventually other national crises.\textsuperscript{153} Cooperation of governments, international financial institutions (for example, the World Bank), non-governmental organizations (such as

\textsuperscript{150}. See Doctors Without Borders, World AIDS Day 2000 Fact Sheet, at http://www.doctorswithoutborders.org/news/wad2000.htm (last visited Oct. 15, 2001) (listing facts about AIDS). The facts listed include: HIV-positive people are fired from their jobs, AIDS can cripple economic development of many countries by striking people in their most productive years (twenty to forty year olds), AIDS has orphaned thirteen million children, "high numbers of AIDS patients strain already overburdened health care systems" and AIDS can be treated with antiretroviral drugs but ninety-five percent of those infected cannot afford them. See id. (describing impact of AIDS on many developing countries); see also A New Approach, supra note 118, at International (discussing AIDS crisis in Botswana).

\textsuperscript{151}. See TRIPs, supra note 6, at 602.

\textsuperscript{152}. See Doctors Without Borders, supra note 122, at http://www.accessmed-msf.org/campaign/faq.shtml (last visited Oct. 15, 2001) (noting that campaign has been working internationally to find long-term solution to lack of pharmaceutical access).

\textsuperscript{153}. See Hoen 't & Moon, supra note 108, at http://www.accessmed-msf.org/prod/publications.asp?scntid=318200146197&contenttype=PARA& (setting forth that there will be no single measure to achieve access; only mix of "mutually supportive strategies" will have impact).
ACT UP) and test country citizens would be essential in order to supply the proper funds, manpower and materials to the program.154

As part of the program, pharmaceutical companies in developed countries would donate a certain stock of essential drugs to the test country or agree to sell them at a lower price in exchange for a small royalty payment.155 This plan would utilize the DSB and TRIPs Council, as the agreements should be drafted and policed by these bodies.156 The DSB and TRIPs Council would decide, under the standards and agreed-to exceptions of TRIPs, the proper terms and scope of these agreements, the means of implementation, the proper royalty payments and the expiration period.157

The agreements also would include projects for building an adequate medical infrastructure and educating the people of the country.158 The education programs need to reach the rural masses and should be taught by Africans, as the masses may be more apt to listen to them than foreigners given the history of imperialism.159 The communal and sharing culture of South Africa, which would lead many citizens to favor generic substitution over patent protection, may be an obstacle to success.160 Nevertheless, under the test program, a more traditional African approach, including community involvement, should be favored, as Western-style approaches to Africa’s problems have failed miserably in the past.161 The developed countries of the West will play a larger role in the drug donation, monetary investment and medical training of Africans, with South

154. For further discussion of cooperative efforts, see supra note 144 and accompanying text.

155. For a discussion of current donation programs, see supra notes 115-18 and accompanying text.

156. See World Trade Organization, supra note 35, at http://www.wto.org/english/thewto_e/whatis_e/tif_e/displ_e.htm (noting that WTO’s “most individual contribution” is providing means of settling disputes to make trading system more secure and predictable). The DSB and TRIPs Council are the proper bodies to implement this program because they were developed specifically to handle disputes arising under TRIPs and to review TRIPs. See id. (discussing contribution of dispute settlement procedures). For a further discussion of the formation of the DSB and TRIPs Council, see supra notes 31-32, 140 and accompanying text.

157. For a further discussion of the DSB and TRIPs Council, see supra note 156 and accompanying text.


159. See generally Gutowski, supra note 23, at 744-45 (discussing developing country fears of Western economic and moral imperialism).

160. For a discussion of the African cultural sense of community, see supra note 52 and accompanying text.

161. See Fidler, supra note 64, at 205-06 (explaining that Western neo-liberal structural adjustment programs implemented in late 1980s undercut public health and health care systems in developing countries).
African communities taking the forefront in distribution and education once the proper medical infrastructure is in place.162

The proposed plan would create a balance between developing countries and developed countries, as the developed nations would receive a royalty payment, which they could utilize in R&D.163 In exchange for the royalty, developing countries would receive a one-time donation of drugs, accompanied by larger quantities of drugs sold at lower prices.164 The incentives would be high for both developed and developing countries, as economic development would follow the increased investments in adequate infrastructure.165 Thus, the South African economy would grow and intellectual property rights would receive proper protection, resulting in South Africa becoming more attractive to international investors.166 As a result of economic growth, South Africans would have more money to purchase pharmaceuticals and prices could then be raised, generating more money for pharmaceutical companies.167

The temptation to sell the drugs on the "gray market" could be advanced as a possible drawback to this proposal.168 Nevertheless, the DSB would serve as the policing agent and have the power to implement harsh penalties toward the test country if the stocks of drugs reached the "gray market."169 For example, as a sanction for disobedience, the DSB could end the program and enforce strict compliance with TRIPs, thereby banning the use of exceptions.170 By applying harsh sanctions for non-compliance, the government then would be required to offer adequate policing mechanisms of its own to ensure that the stock of drugs is in the

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162. Cf. IIPI, supra note 64, at http://www.iipi.org/eng/projects/aids.asp (stating that, "any comprehensive effort to supply state-of-the-art pharmaceuticals to these [developing] countries will require a significant international subsidization by wealthy states and manufacturers"). "The World Bank has a history of organizing such programs . . . [and] could put together a coordinated plan, involving international aid programs from developed countries and private sector humanitarian organizations, to supply the necessary funding." Id.

163. For a discussion on royalty payments, see supra note 155 and accompanying text.

164. For a discussion of already existing drug donation programs, see generally supra notes 115-18 and accompanying text.

165. For a discussion on inadequate infrastructure in developing countries, see supra notes 68-70 and accompanying text.

166. See PrRMA, supra note 46, at 105 ("Progress in intellectual property protection has occurred because countries all over the world have recognized that such protection encourages investment, innovation, and economic growth.").

167. See id. (noting that stronger intellectual property rights help developing countries by "improving the conditions for investment, encouraging the development of local industry, and enabling more goods to be produced").

168. For a discussion on the "gray market," see supra notes 71-73 and accompanying text.

169. For a further discussion on the functions of the DSB, see supra note 156 and accompanying text.

proper hands. This policing approach would negate the gray marketing of drugs. The DSB would also monitor the progress of the test country and compile data on program performance. If the test program shows promise, other countries could begin to institute the same type of program.

This solution seems viable as it would allow developing countries to alleviate part of their AIDS crises, would give developed countries incentive to research and develop new drugs to aid in international health crises and would create a favorable trading atmosphere. Thus, the test proposal would negate the tension that currently exists between developed and developing countries. The program would require large amounts of time, money and manpower investment but, if proven successful, would offer a permanent solution filling part of the economic and health gap between developed and developing countries in a world where globalization is the norm. The time and manpower required would only be a temporary burden on developed countries because citizens of the test country will be used to implement the program. Time and manpower from the United States, for example, would be minimal and used for training African citizens in proper distribution, prevention and education practices. The trained Africans can in turn train and inform other African citizens, resulting in a domino effect. On the other hand, monetary effort would come mainly from international financial institutions and developing countries.

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173. See generally id. (discussing power of DSB panel decisions).

174. For further discussion of solutions for developing countries, see supra notes 123-73 and accompanying text, and infra notes 175-80 and accompanying text.

175. For further discussion of how this proposal would negate tensions between developed and developing countries, with respect to TRIPs, see supra notes 152-74 and accompanying text, and infra notes 176-80 and accompanying text.

176. See Fidler, supra note 64, at 191 (discussing belief of many critics that current globalization processes are increasing health and economic gaps between developed and developing countries).

177. For discussion of long-term solutions, see supra notes 152-76 and accompanying text, and infra notes 178-80 and accompanying text.

178. For discussion of long-term solutions, see supra notes 152-76 and accompanying text, and infra notes 178-80 and accompanying text.

179. Cf. Pfizer, supra note 9, at http://www.pfizer.com/pfizerinc/about/press/aidsfacility.html (discussing establishment of AIDS clinic in Uganda). [T]he [AIDS] clinic [in Uganda] "will have an influence far beyond the doctors trained in it and the patients whom it treats. It is a reverse pyramid: each doctor can train dozens of other doctors, and each doctor can treat 200-300 AIDS patients at any one time. And other clinics, using the center's guidelines, can be established across Africa.

Id.
VI. Conclusion

Living in the twenty-first century, we have at our fingertips technology that was only dreamed of not long ago. In the biotechnological field, Western pharmaceutical companies have made significant advances. These advances created the powerful AIDS cocktail, which has reduced AIDS-related mortality by seventy-five percent in the United States. These statistics show that AIDS is no longer considered an epidemic by the Western world. How is it then, with all of these advances, that AIDS is a threat to the very existence of whole countries in the developing world? No one argues against protecting technology and intellectual property to encourage investment and innovation. Nevertheless, protection must yield when part of the world is faced with an epidemic likened to the European plague. The TRIPs Agreement was created not only to allow protection of intellectual property rights, but also to allow developing countries flexibility in implementing those rights, especially in times of national emergency. While the framers of TRIPs may have believed it was a well-defined agreement, providing clear requirements and exceptions, the current tensions between developed and developing countries indicate that the framers were incorrect.
The time has come for the TRIPs Council and DSB to review TRIPs and either modify it to fit the current AIDS pandemic or develop an inquiry to determine when a country can declare a national emergency, thereby invoking TRIPs exceptions such as compulsory licensing. In addition to clarifying TRIPs, both the developed and developing world should come together and negotiate a long-term solution to the problem of access to essential medicines in developing countries.

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189. For a discussion on modifying TRIPs and establishing an inquiry as to what constitutes a national emergency, see supra notes 128-51 and accompanying text.

190. See Nessman, supra note 9, at A1 (noting that South African government cannot afford widespread program to provide AIDS medication to 4.7 million infected with HIV). For a discussion on developing a test program to create a long-term solution, see supra notes 123-80 and accompanying text.