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LEGAL MOVEMENTS IN INTELLECTUAL PROPERTY: TRIPS, UNILATERAL ACTION, BILATERAL AGREEMENTS, AND HIV/AIDS

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INTRODUCTION

Part of the impetus for the NEXUS Symposium was the perceived opening, as a result of the 2001 World Trade Organization (WTO) Ministerial Declaration (the "Doha Declaration"),[1] of a "window of opportunity" for initiating a development agenda to curb the global HIV/AIDS crisis.[2] The flexibilities provided in the Doha Declaration are steps in the right direction in the access to essential medicines campaign. However, this Article looks beyond the Doha Declaration to other patent and trade issues that, while tangential, may also significantly impact access to essential medicines. This Article begins with an overview of the relationship between the Agreement on Trade-Related Aspects of Intellectual Property Rights (the "TRIPS Agreement")[3] and the HIV/AIDS pandemic which created the need for the Doha Declaration. It then discusses two

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[1] *Ministerial Declaration*, Nov. 14, 2001, 4th Session, Doha Ministerial Conference, WT/MIN(01)/DEC/2, *available at* http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_e.pdf (last visited July 31, 2003) [hereinafter *Doha Declaration*].

[2] Emory International Law Review, *The NEXUS Symposium: An Interdisciplinary Forum on the Impact of International Patent & Trade Agreements in the Global Fight Against HIV & AIDS*, *at* http://www.law.emory.edu/students/eilr/symposium/links.htm (last visited Aug. 28, 2003) [hereinafter *NEXUS Symposium*].

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

trade-related movements, unilateral action and TRIPS-plus bilateral agreements, that call into question the long-term effectiveness of the multilateral the TRIPS Agreement process, generally, and the benefits of the Doha Declaration, in particular, in addressing multiple facets of the access to essential medicines problem. This Article concludes that a consideration of these issues should be included in the development of any further TRIPS-related solutions to the HIV/AIDS pandemic.

I. THE TRIPS AGREEMENT AND HIV/AIDS

Timing is everything. The Human Immunodeficiency Virus (HIV) which causes Acquired Immune Deficiency Syndrome (AIDS) was first isolated in 1983.[4] One year later, in 1984, negotiations began on the Uruguay Round of the General Agreement on Tariffs and Trade (GATT).[5] When those negotiations concluded in 1994, a new organization, the WTO, had been formed, and a new semi-global intellectual property regime had been created via the TRIPS Agreement.[6] The TRIPS Agreement was the first significant multilateral agreement requiring member countries to provide certain minimum levels of protection to owners of intellectual property.[7] It succeeded where prior intellectual property agreements failed by tying requirements for substantive protection with trade.[8] This important connection means that a member state's failure

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[4] World Health Organization, *About HIV/AIDS*, *at* http://www.who.int/hiv/abouthiv/en (last visited Aug. 2, 2003).

[5] World Trade Organization, *The WTO in Brief: Part 1*, *at* http://www.wto.org/english/thewto_e/whatis_e/inbrief_e/inbr01_e.htm (last visited Aug. 2, 2003).

[6] *Id.*

[7] However, some older regional agreements did have substantive requirements. *See, e.g.*, *European Communities: Convention on Jurisdiction and Enforcement of Judgments in Civil and Commercial Matters*, 29 I.L.M. 1413, 1417 (1990).

[8] *See, e.g.*, Rochelle C. Dreyfuss & Andreas F. Lowenfeld, *Two Achievements of the Uruguay Round: Putting TRIPS and Dispute Settlement Together*, 37 VA. J. INT'L L. 275, 277 (1997).

to comply with the requirements of the TRIPS Agreement can result in trade sanctions by other members following a binding dispute resolution proceeding.[9]

In the patent area, these minimum substantive patent requirements included protection for inventions in all areas of technology, a minimum patent term of twenty years from the patent application filing date, and the imposition of civil penalties for infringing the patent right.[10] These requirements apply to all WTO members and appear facially neutral. Yet at least one provision, which requires protection for inventions in all areas of technology, arguably has a disparate impact on developing countries that previously had not provided protection for pharmaceuticals in order to provide access to low cost generic drugs to their citizens. To call the impact of the coincidental convergence of these two events, the TRIPS Agreement and the HIV/AIDS pandemic, on the developing world "unfortunate" would be an understatement. More than seventy-five percent of the 146 WTO member countries are developing or least developed countries.[11] Ninety-five percent of all HIV infections occur in developing countries.[12] While there are numerous factors that have contributed, and continue to contribute, to the ever increasing numbers of HIV infections and AIDS deaths,[13] there is no question that the

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[9] *See* World Trade Organization, *Understanding on Rules and Procedures Governing the Settlement of Disputes*, *at* http://www.wto.org/english/doc_e/legal_e/ursum_2.htm (last visited Aug. 27, 2003) [hereinafter WTO, *Dispute Settlement*].

[10] TRIPS Agreement arts. 27.1, 28, 33, 41-46.

[11] World Trade Organization, *The WTO in Brief: Part 4*, *at* http://www.wto.org/english/thewto_e/whatis_e/inbrief_e/inbr04_e.htm (last visited May 28, 2003).

[12] *See NEXUS Symposium*, *supra* note 2.

[13] It is estimated that there are over forty million people infected with HIV/AIDS worldwide, with over 15,000 new infections each day. *See id.* *See also* Ellen 't Hoen, *Public Health and International Law: TRIPS, Pharmaceutical Patents, and Access to Essential Medicines: A Long Way from Seattle to Doha*, 3 CHI. J. INT'L L. 27, 28 (2002) (noting that "[u]navailability [of essential medicines] can be caused by logistical supply and storage problems, substandard drug quality, inappropriate selection of drugs, wasteful prescription and inappropriate use, inadequate

provisions of the TRIPS Agreement have played a role in this catastrophe.[14]

Although the TRIPS Agreement contained provisions allowing countries to override patent rights in some situations, to allow compulsory licensing of patents, and to adopt necessary measures to protect public health, the provisions were ambiguous and countries were hesitant to employ them for fear of trade reprisals.[15] For example, when the South African government tried to implement a law that allowed for compulsory licensing of AIDS drugs, it was sued by forty-two pharmaceutical companies for, among other things, violation of Article 27 of the TRIPS

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production, and prohibitive prices"); Amir Attaran, *The Doha Declaration on the TRIPS Agreement and Public Health, Access to Pharmaceuticals, and Options Under WTO Law*, 12 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 859, 861-62 (2002) (citing "an absence of international aid finance, weak political will, and poor medical infrastructure" as important factors impacting access to essential medicines in developing countries).

[14] Fear of trade sanctions for violation of the TRIPS Agreement's vague compulsory licensing provisions has hindered production and distribution of generic HIV/AIDS drugs to those in need. For example, in early 2001, the United States brought a WTO action against Brazil alleging that patent working requirements in Brazilian law discriminated against U.S. owners of Brazilian patents in violation of Articles 27.1 and 28.1 of the TRIPS Agreement. The law has been critical to Brazil's success in reducing AIDS-related mortality rates because generic anti-retroviral (ARV) drugs can be produced locally, competitively, at a fraction of the cost of branded drugs. Brazil also offered to provide technology transfer for producing generic ARV drugs to developing countries but some developing countries have been slow to accept Brazil's offer, for fear of similar trade reprisals. The United States ultimately dropped its WTO action against Brazil, under severe criticism from a variety of quarters. *See, e.g.*, Hoen, *supra* note 13, at 32-33; Nermien Al-Ali, *The Egyptian Pharmaceutical Industry After TRIPS—A Practitioner's View*, 26 FORDHAM INT'L L.J. 274, 280 (2003) (positing that "the practice of the developed countries, particularly the United States, intimidated many developing countries a few years after TRIPS came into effect. These countries feared using Articles 30 and 31 and thereby adversely affecting their trade positions."); Asia Russell, *AIDS Activists Demand an End to Escalating US Pressure against Dominican Republic as Local Generic AIDS Drug Production Begins* (Aug. 8, 2001), (discussing the U.S.Trade Representative's actions and threats against the Dominican Republic for its use of compulsory licensing to produce HIV/AIDS drugs) *at* http://www.cptech.org/ip/health/c/dr/ healthgap08092001.html (last visited July 31, 2003). *See also* discussion of South African compulsory licensing disput in above text.

[15] *See* TRIPS Agreement art. 8, 30-31.

Agreement.[16] South Africa also lost its "most favored nation" status with the United States and received significant pressure from the U.S. Trade Representative (USTR) to keep it from moving forward under the law.[17] The pharmaceutical companies ultimately dropped the lawsuit and the USTR backed down in the face of strong criticism from humanitarian organizations. However, the resulting damage caused by the lawsuit helped create the impetus for the WTO Ministerial Conference to clarify the scope of the "flexibilities" in the TRIPS Agreement.[18]

The Doha Declaration, adopted at Doha, Qatar in November of 2001, explicitly addressed some of the most problematic TRIPS provisions from the standpoint of access to essential medicines, and returned a significant measure of freedom to member countries to provide such access to their citizens within the framework of the existing the TRIPS Agreement language.[19] Specifically, it emphasized that the TRIPS Agreement does not, and should not, prevent sovereign governments from acting to protect

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[16] *See, e.g.*, Ravi Nessman, *Drug Companies Sue South Africa Over Patent Law*, C-HEALTH, Mar. 5, 2001 (noting that the law had been challenged before it was even put into effect by the government), *at* http://www.canoe.ca/Health0103/05_aids-ap.html (last visited July 31, 2003); *Pharm. Mfrs. Ass'n v. President of the Republic of S. Afr.*, No. 4183/98, para. 2.4 (Transvaal Provincial Div., filed Feb. 18, 1998), http://www.cptech.org/ip/health/sa/pharmasuit.html (last visited July 31, 2003) [hereinafter South Africa's Complaint]. Although the TRIPS Agreement was explicitly mentioned in the complaint, the Agreement itself does not provide a private right of action; disputes regarding its provisions must be brought by WTO member states to the Dispute Settlement Body to be adjudicated. *See* WTO, *Dispute Settlement*, *supra* note 9.

[17] *See, e.g.*, Shubha Ghosh, *Pills, Patents, and Power: State Creation of Gray Markets as a Limit on Patent Rights*, 14 FLA. J. INT'L L. 217, 244 (2002); Robert Block, *Big Drug Firms Defend Right to Patents on AIDS Drugs in South African Court*, WALL ST. J., Mar. 6, 2001, at A3; *South Africa's Complaint*, *supra* note 16. The United States also suspended preferential tariff treatment for several South African items. *See* U.S. Department of State Report, *U.S. Government Efforts to Negotiate the Repeal, Termination or Withdrawal of Article 15C of the South African Medicines and Related Substances Act of 1965* (Feb. 5, 1999), *at* http://www.cptech.org/ip/health/sa/stdept-feb51999.html (last visited Aug. 2, 2003).

[18] *See* Al-Ali, *supra* note 14, at 288.

[19] Doha Declaration paras. 4 - 5.

public health, and affirmed their right to use the flexibilities inherent in the TRIPS Agreement, for example, to override a patent through compulsory licensing, to that end.[20]

Unfortunately, at Doha, WTO members were unable to reach agreement on an issue critical to the access to essential medicines effort. While the Doha Declaration affirmed the right of member countries to use compulsory licensing to obtain low-cost pharmaceutical products in a member-defined national emergency, the declaration did not address the TRIPS Agreement requirement that such drugs be produced "predominately for the supply of the domestic market."[21] Thus, if members export drugs produced under compulsory license to countries that lack the manufacturing capability to produce essential medicines themselves (known as "parallel importation"), the exporting countries could still be subject to trade sanctions for violating the TRIPS Agreement.

What happened next reveals one of the TRIPS Agreement's key flaws (or virtues, depending on one's perspective) that has the potential to limit the effectiveness of TRIPS-based solutions to the access to essential medicines dilemma.

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[20] *Id.* at paras. 4, 5(c). The Doha Declaration also affirms that each Member "has the right to determine what constitutes a national emergency or other circumstance of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria, and other epidemics, can represent a national emergency or other circumstance of extreme urgency." *Id.* at para. 5(c). *See also* World Trade Organization, *The Doha Declaration Explained, at* http://www.wto.org/english/tratop_e/dda_e/dohaexplained_e.htm (last visited July 31, 2003); Hoen, *supra* note 13, at 32-33. In addition, the Doha Declaration further extended the time for least developed countries to provide protection for pharmaceutical patents from 2006 until 2016. Doha Declaration para. 7. Developing countries continue to have until January 1, 2005 to provide such protection, as long as they provide interim protective measures for pharmaceuticals. *See* TRIPS Agreement art. 70.

[21] TRIPS Agreement art. 31(f).

II. UNILATERAL ACTION

While it is true that WTO members were unable to reach agreement on the contours of a parallel importation[22] exception to the TRIPS Agreement for essential medicines, in fact, agreement was thwarted predominantly by the efforts of one country, the United States, which refused to sign on to the proposed plan. Concerned by the scope of diseases that would potentially be covered by the exception, U.S. negotiators rejected the proposal and no agreement was reached by the stated December 31, 2002 deadline.[23]

Then, in a rather surprising turn of events, the USTR announced an interim plan, intended to help poor countries fight HIV/AIDS in the absence of WTO consensus.[24] Under the plan, the United States pledged to implement the substance of the Doha Declaration by "permit[ting] . . . countries to override patents on drugs produced outside their countries in order to fight HIV/AIDS, malaria, tuberculosis, and other types of infectious epidemics, including those that may arise in the future."[25] To accomplish this, the United States pledged "not to challenge any WTO [m]ember that breaks WTO rules to export drugs produced under compulsory license to a country in need"

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[22] In the pharmaceutical context, parallel importation occurs "when a drug sold by a patent holder in one country is exported by a buyer to another country where the patent holder's price for the drug is higher. . . . [T]he effect of parallel importation is to undercut the ability of the patent holder to engage in price discrimination across national markets." Alan O. Sykes, *Public Health and International Law: TRIPS, Pharmaceuticals, Developing Countries, and the Doha "Solution,"* 3 CHI. J. INT'L L. 47, 63 (2002).

[23] According to the USTR, the proposal would have allowed wealthy countries to disregard patents for non-essential drugs as well as essential medicines, a result "that could seriously undermine the WTO rules on patents that provide incentives for development of new pharmaceutical products." U.S. Department of State, *U.S. Announces Interim HIV/AIDS Plan to Help Poor Countries*, Dec. 20, 2002, *at* http://usinfo.state.gov/topical/econ/wto/02122002.htm (last visited July 31, 2002).

[24] *Id.*

[25] *Id.*

and called on other WTO members to join it in this dispute settlement moratorium.[26]

The voluntary moratorium is wonderful in that it creates, in the near term, greater access to HIV/AIDS medications and other essential medicines and thus should save or extend lives. Certainly, it was preferable for the United States to initiate such an "immediate practical solution" as opposed to simply continuing to prevent an agreement among WTO members from being reached.[27] Moreover, U.S. concerns regarding the scope of the proposed exceptions to TRIPS were not without basis; the potential for abuse of the spirit of the Doha Declaration in the crafting of the importation exception was certainly present.[28]

But which would have been better: for the United States to agree to a proposal within the structure of the Doha negotiations (and within the designated time frame), or to take this unilateral action? Arguably the former, for at least three reasons. First, the moratorium is unstructured, vague, and time-indeterminate, and leaves member countries dependent upon the continued goodwill of the United States on this issue. It thus resembles the voluntary HIV/AIDS drug price reductions used by pharmaceutical companies to stave off compulsory licensing by developing country governments which could have provided generic competition and even lower drug prices in those countries.[29]

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[26] *Id.*

[27] *Id.*

[28] For a detailed discussion of proposals and their attendant issues, see Attaran, *supra* note 13, at 868-71 (noting that some non-government organizations' proposals would not explicitly limit an exception to developing countries with pharmaceutical access needs).

[29] *See, e.g.*, *Offers of Price Reductions for HIV/AIDS Drugs*, http://www.cptech.org/ip/health/pcuts.html (last visited Aug. 2, 2003); Letter from Robert Weissman, Co-Director of Essential Action (on behalf of HealthGAP Coalition), to Charles A. Heimbold, Jr., CEO, Bristol-Myers Squibb (Mar. 16, 2001) (requesting that Bristol-Myers Squibb turn "informal and imprecise" statements suggesting it would not enforce patent for Zerit in sub-Saharan Africa into

Second, the moratorium lessened the impetus for WTO members to reach a formal agreement, with clear safe harbors and timelines, on the drug importation issue.[30] The announcement of the moratorium was issued on December 20, 2002, the same day the Director-General of the WTO expressed his disappointment over the failure of WTO members to reach agreement, and eleven days before the actual Doha Declaration deadline for agreement of December 31, 2002.[31] By initiating the moratorium and limiting it to importation of drugs for infectious epidemics produced under compulsory license, the United States has achieved even more than it would have through a negotiated WTO agreement, since the moratorium does not cover any non-essential medicines, or include other

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"formal, . . . royalty-free, non-exclusive licenses" since manufacturers might be reluctant or unable to effectively provide the drug based on the statements alone), http://www.cptech.org/ip/health/firm/BMS/healthGAPBMS.html (last visited Aug. 2, 2003); John S. James, *Merck, Bristol-Myers Squibb Announce Major Price Reductions for Poorest Countries: Major Access Progress But Questions Remain*, THE BODY, Feb. 28, 2001 (noting that ten months after major AIDS drugs price reductions were announced by five large companies, only three countries had made it through the complex negotiations and only about 2,500 people were being served), *at* http://www.thebody.com/atn/361/price.html (last visited July 31, 2001). Based on data compiled by the Campaign for Access to Essential Medicines, generic competition, which compulsory licensing makes possible, provides the most effective means of lowering drug prices. CAMPAIGN FOR ACCESS TO ESSENTIAL MEDICINES, UNTANGLING THE WEB OF PRICE REDUCTIONS: A PRICING GUIDE FOR THE PURCHASE OF ARVS FOR DEVELOPING COUNTRIES 7 (4th ed. 2003), *at* http://www.accessmed-msf.org/documents/untangling4thapril2003.pdf (last visited July 31, 2003). *See also* World Health Organization, *Financing Mechanisms*, http://www.who.int/medicines/strategy/access/stacfin.shtml (last modified May 15, 2002) ("The average price of generic drugs can fall by as much as 30% of the innovator drug price when the number of generic versions of the drug on the market increases.").

[30] According to one news report, no progress on an agreement has been made because "Washington's fears about weakening drug patents are holding up an agreement." Naomi Koppel, *Low Cost Drugs for Poor Countries Urged*, ASSOCIATED PRESS, May 22, 2003, *available at* http://wtop.com/index.php?nid=106&sid=78282 (last visited July 31, 2002). As stated by EU Trade Commissioner Pascal Lamy, "We are working to get the American position to budge." *Id.*

[31] *See* Doha Declaration para. 6.

provisions that could have been allowed in the Ministerial meeting proposal.[32]

Third, because of the power asymmetries mentioned elsewhere by Professor Susan Sell,[33] the United States and, for example, the European Union, can call on other countries to voluntarily refrain from initiating a dispute on this issue (and other issues). However, the ability of developing countries to manipulate the dispute settlement provisions of the TRIPS Agreement in this way is doubtful. For example, if the proposal for a dispute settlement moratorium had come from the government of Uganda, how would it have been greeted? The binding dispute settlement process, which makes the TRIPS Agreement such a formidable agreement, can only be activated by the filing of a dispute by a WTO member.[34] While no agreement and a voluntary moratorium are far preferable to no agreement and no moratorium, the fact that the TRIPS Agreement can be manipulated in this way is certainly a weakness when viewed against the larger access to essential medicines dilemma and the goals to be achieved though multilateral negotiation versus unilateral action.[35]

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[32] U.S. Department of State, International Information Programs, *U.S. Announces Interim HIV/AIDS Plan for Poor Countries,* (Dec. 20, 2002) (citing USTR view that some WTO members sought to expand the focus of Doha "to allow wealthier countries to override patents on a range of unintended drugs—Viagra, for example"), *at* http://usinfo.state.gov/topical/econ/wto/02122002.htm (last visited Aug. 2, 2003).

[33] *See* Susan Sell, *Trade Issues and HIV/AIDS*, 17 EMORY INT'L LAW REV. 933 (2003).

[34] TRIPS Agreement arts. 63, 64.

[35] Another significant area of unilateral trade-related action by the United States involves Section 301 actions. Under Section 301 of the Trade Act of 1974, the USTR is required to identify foreign countries that deny what the United States perceives as adequate and effective intellectual property protection and equitable market access to U.S. intellectual property owners. *See* U.S. TRADE REPRESENTATIVE, 2000 SPECIAL 301 REPORT 1-2 (2000), *available at* http://www.ustr.gov/pdf/special.pdf (last visited July, 31, 2003). Countries failing to meet U.S. standards are placed on "watch lists" and failure to make significant progress on stopping piracy and enforcing intellectual property laws can result in trade sanctions by the United States. *See id.* (reporting detailed examination of the

III. BILATERAL AGREEMENTS

The Doha Declaration's broad flexibility mandate gives the impression of a "kinder, gentler" TRIPS Agreement and trade environment for developing countries. But appearances can be deceiving. At the same time developed countries like the United States and member-states of the European Union were agreeing to relaxed compulsory licensing provisions and extended transition periods, they were independently engaging in negotiations to bind several developing countries to even higher levels of protection of intellectual property rights (IPRs) via bilateral agreements.[36]

The U.S. Congress recently passed the Bipartisan Trade Promotion Authority Act of 2002 ("the Act") which makes it easier for bilateral agreements to be concluded.[37] The law provides the Executive branch with "fast track" authority to conclude agreements with trading partners.[38] Under the fast track system, when a proposed treaty is presented to Congress, it will, within a limited period of time, vote on the results of trade negotiations and proposed implementing legislation as a whole and will not add amendments to it.[39]

The introduction to the Act explicitly outlines TRIPS-plus bilateral agreement objectives in the intellectual property

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adequacy and effectiveness of intellectual property protection in seventy countries, identifying fifty-nine trading partners for various levels of watch list status, and noting that "while progress also has been made on improving enforcement in many countries, the unacceptably high rates of piracy and counterfeiting of U.S. intellectual property around the world require on-going vigilance"). Although the TRIPS Agreement mandates substantive protections, an amendment to the U.S. TRIPS implementing legislation allows the USTR to pursue action against a country under Section 301 even if the country is in compliance with its TRIPS obligations. *See id.* at 6.

[36] *See* Sacha Wunsch-Vincent, *The Digital Trade Agenda of the U.S.: Parallel Tracks of Bilateral, Regional and Multilateral Liberalization*, 58 AUSSENWIRTSCHAFT 7, 9 (Mar. 2003).

[37] Bipartisan Trade Promotion Authority Act, Pub. L. No. 107-210 (2002).

[38] *See* Wunsch-Vincent, *supra* note 36, at 9.

[39] *See id.*

arena, stating as a negotiating objective, "ensuring that the provisions of any multilateral or bilateral trade agreement governing intellectual property rights that is entered into by the United States reflect a standard of protection similar to that found in U.S. law."[40]

Such agreements are relevant to the present inquiry because the HIV/AIDS pandemic is an agglomeration of extremely complex problems that require a multifaceted solution. In the international patent and trade agreement arena the focus has been on a narrow (albeit very important) aspect of the TRIPS Agreement; physical access to patented essential medicines. Such a focus is understandable but incomplete since the patent provisions of the TRIPS Agreement cover more than patents on essential medicines. Collateral patent issues also have the potential to impact the HIV/AIDS pandemic and thus require attention, especially in light of TRIPS-plus provisions in various bilateral agreements between developed and developing countries.

The TRIPS Agreement specifies minimum levels of protection members must afford to IPRs, but explicitly allows members to implement "more extensive protection" as long as it does not contravene the Agreement.[41] There are currently at least twenty-three recently negotiated bilateral or regional treaties between developed and developing countries that require protection of IPRs greater than the minimums mandated by the TRIPS Agreement.[42]

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[40] Bipartisan Trade Promotion Authority Act § 2102(b)(4)(A)(i)(II). Also included as an objective is "to respect the Declaration of the TRIPS Agreement and Public Health adopted . . . at . . . Doha, Qatar." *Id.* at § 2102(b)(4)(C). However, as the Doha Declaration does not address collateral issues associated with access to essential medicines, this objective would not necessarily conflict with the pursuit of TRIPS-plus protections.

[41] TRIPS Agreement art. 1.

[42] *See* GENETIC RESOURCES ACTION INTERNATIONAL (GRAIN), "TRIPS-PLUS" THROUGH THE BACK DOOR 4 (2001), *available at* http://www.grain.org/docs/trips-plus-en.pdf (last visited July 31, 2003). TRIPS-plus provisions relate to life forms, copyright, and digital media protections. Among other things, this Article focuses on

Such agreements are thus referred to as being "TRIPS-plus." According to one report, these agreements already affect more than 150 developing countries.[43]

Several TRIPS-plus requirements in these agreements (alone or in combination) have been highlighted by some non-governmental organizations as particularly concerning. They include: (1) references to the International Union for the Protection of New Varieties of Plants Convention (UPOV) for the protection of plant varieties; (2) references to the Budapest Treaty for the deposit of biological samples; and (3) the lack of exclusions on life forms.[44] References to UPOV are considered TRIPS-plus because UPOV, a system for protecting plant breeder's rights in new and distinctive plant varieties, is not mentioned in TRIPS. Rather, TRIPS allows members to develop *sui generis* protection systems for plants which could be less restrictive than UPOV.[45] References to the Budapest Treaty are considered TRIPS-plus because the TRIPS Agreement does not mention the Budapest Treaty, and the Treaty makes it easier for a party to obtain a patent on a life form by requiring members to recognize a biological sample deposited in an international depository as a sufficient disclosure for an invention.[46] Similarly, while the TRIPS Agreement explicitly allows members to exclude plants and animals from patent protection, many of the negotiated bilateral agreements do not contain such exclusions and require patents on biological inventions.[47]

Why should the inclusion of TRIPS-plus requirements in bilateral agreements with developing countries be of

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provisions relating to life forms because those are especially likely to be troubling for agriculturally-based developing countries.

[43] *Id.*

[44] *Id.* at 3. Other troubling TRIPS-plus provisions require implementation of highest international standards, and protection of foreign "investments" that may include biotechnology. *Id.*

[45] *Id.*

[46] *Id.*

[47] *Id.*

concern after the Doha Declaration? Because drug cost is not the only factor impacting access to essential medicines. According to the World Health Organization (WHO), obtaining access to essential medicines requires three different types of access: therapeutic access (the creation of drugs and treatment), supply access, and financial access.[48] The cost of patented drugs is significantly affected by lack of competition; thus, the availability of compulsory licensing and parallel importation is crucial to creating financial access. But with HIV/AIDS, financial access is also greatly impacted by other issues.

To be able to pay even greatly reduced drug prices, governments must have sufficient sources of revenue and citizens must have sufficient funds to cover basic needs and more. If required to choose between feeding hungry children and purchasing medication, most people likely would choose to feed their children. HIV/AIDS has created millions of orphans[49] without parents to educate or feed them, and is in the process of decimating the numbers of farmers and skilled workers in many developing countries, impacting government revenue, food production and distribution, and family income.[50]

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[48] Presentation, World Health Organization, Challenges to Securing Access to Essential Drugs (Oct. 1998), *available at* www.who.int/medicines/library/pptpres/access/securingaccess.ppt (last visited Aug. 2, 2003). *See also* Judy Rein, *International Governance Through Trade Agreements: Patent Protection for Essential Medicines*, 21 NW. J. INT'L L. & BUS. 379, 381 (2001).

[49] There are more than eleven million orphans in sub-Saharan Africa alone. *See* UNAIDS, FACT SHEET 2002: SUB-SAHARAN AFRICA 1 (2002), *available at* http://www.unaids.org/barcelona/presskit/factsheets/FSssafrica_en.pdf (last visited July 31, 2003).

[50] For example, in Zimbabwe, a household with an AIDS death experienced, on average, crop reductions of 61% for maize, 47% for cotton, 49% for vegetables, 37% for groundnuts, and 29% for cattle owned. Presentation, UNAIDS (Apr. 2003) (on file with author). Moreover, findings from a report on the impact of HIV/AIDS on development in sub-Saharan Africa concluded:

> The epidemic is eroding the capacity for development through its effects on labour supplies, saving rates, national security and social cohesion. . . . Health care and education will be affected directly by the same problems of replacing lost labour and skills that afflict other sectors. In addition, the

Inadequate access to food can cause people to engage in more risky types of behavior that can increase the spread of disease. Thus, to the extent developing country citizens and their governments lack the economic means to provide for their basic needs, due in part to the implementation of TRIPS-plus protections for items such as seeds and plants, such bilateral agreements will impact access to essential medicines. The Doha Declaration does not address these types of issues, yet monopoly IPRs on seeds and plants likely will increase the cost of food, the cost of seed to farmers, and the cost of other essential items over the prices that could be available with market competition in the same way that patents on pharmaceuticals impact drug costs.[51]

Strong protection of IPRs provides important incentives for the research and development of products, such as life-saving drugs, that improve quality of life and living standards.[52] It is understandable that developed countries

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education and training systems are failing to make provisions to replace the current and likely loss of skills in the workforce. . . . AIDS is preventing both men and women from providing their full contribution to development, maintaining the structure of families and to sustaining productive capacity over the longer term. . . . The epidemic is also eroding the savings capacity of households, formal and informal enterprises and governments through its direct effects on flows of income and levels of expenditure. Over time this will lead to falling demand, reduced investment and output and declining per capita income. Governments are failing to amend or adapt their five-year development plans to take account of the loss of skills and labour.

Press Release, International Labour Organization, ILO says HIV/AIDS Impact on African Development "Underestimated," Says Major Policy Shift Needed Now (July 11, 2002), *available at* http://www.ilo.org/public/english/bureau/inf/pr/2002/35.htm (last visited July 31, 2003).

[51] *See, e.g.*, Rama Lakshmi, *India Harvests First Biotech Cotton*, GUARDIAN UNLIMITED, May 8, 2003 (citing farmer's complaint that genetically modified cotton seed cost four times as much as regular seed yet might not bring as high a market price), *available at* http://education.guardian.co.uk/businessofresearch/story/0,9860,951145,00.html (last visited July 31, 2003).

[52] *See* Sykes, *supra* note 22, at 49 (lamenting that "just as the obligations of developing nations under TRIPS are beginning to take hold, the Doha Declaration casts great doubt on the future credibility of patent rights for pharmaceuticals in developing nations. The result may be quite unfortunate for research incentives, especially those relating to particular diseases.").

would want developing countries to provide protection for what is becoming an increasingly important export: technology in its various forms. However, HIV/AIDS is devastating many developing countries on a scale unseen in recent history. As described by one commentator:

> The epidemic affects social and economic life in ways we have never seen before . . . . The main socio-economic impact of HIV/AIDS is its decimation of the labour force and the level and allocation of savings and investment. This portends a huge humanitarian disaster with dire economic and social consequences. . . . Decades of gains in development, training, skills and education are being lost forever. The belief that these losses can be replenished from a vast pool of unemployed or underemployed labour is a fallacy.[53]

With a long-term crisis of this magnitude, it is not surprising that it would be difficult for developed countries to know how best to structure trade agreements with developing countries. But negotiating as if the HIV/AIDS problem is limited to supply access to drugs may just increase the human cost of the pandemic. Instead of requiring TRIPS-plus provisions such as accession to UPOV, for example, developed countries should allow developing countries to develop truly *sui generis* plant protection systems, on transitional timing, that would be fully consistent with the TRIPS Agreement but would,

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[53] International Labour Organization, *supra* note 46 (comments of Mr. Franklyn Lisk, Director, ILO Global Programme on HIV/AIDS); *but see* OFFICE OF THE U.S. TRADE REPRESENTATIVE, 2003 COMPREHENSIVE REPORT ON U.S. TRADE AND INVESTMENT POLICY TOWARD SUB-SAHARAN AFRICA AND IMPLEMENTATION OF THE AFRICAN GROWTH AND OPPORTUNITY ACT 20 (2003) (stating that "[m]any sub-Saharan African economies are making impressive economic gains after decades of sluggish performance. The region's performance continues to improve, despite conflicts in some areas, poor governance in a few countries, adverse movements of commodity prices, and the ravages of the HIV/AIDS pandemic." Unfortunately, the worst economic and development related impacts of the epidemic are still to come.), *available at* http://www.ustr.gov/reports/2003agoa.pdf (last visited July 31, 2003).

among other things, allow farmers to save seed for replanting, with or without the breeder's permission.[54] Such a compromise, while not fully satisfying to either side, is an approach worth exploring. Until developed and developing countries recognize the differing dimensions of the access issue and the collateral problems HIV/AIDS creates, we will continue to see the negotiation of bilateral agreements with TRIPS-plus provisions that impact financial access to physically available medicines in developing countries. The ramifications of requiring developed nation-level protection of IPRs by undeveloped countries where they come at too great a cost to their citizens are too important to be ignored.[55]

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[54] Under the 1991 UPOV Act, a farmer's right to save purchased seed was eliminated. Thus, farmer's can only save protected seed with the breeder's authorization. *See generally* GRAEME B. DINWOODIE ET AL., INTERNATIONAL AND COMPARATIVE PATENT LAW 415 (2002).

[55] Many developing countries are ill-equipped to even provide patent rights yet because they lack the organizational infrastructure and technological expertise to adequately evaluate patent subject matter. As a consequence, some countries may be granting more patents than necessary. *See* Koppel, *supra* note 30 (stating that "poor nations simply grant patents without carrying out investigations. Many West African countries granted patent protection to GlaxoSmithKline's AIDS treatment Combivir within a couple of years of its 1997 filing, while the European Union is still studying the application."). As a further example of the disparity between developing countries that are being required to provide developed country-level intellectual property protections and actual developed countries, the World Health Organization recently announced a plan to fortify staple foods in certain developing with essential vitamins and minerals like Vitamin A, folic acid, iron and iodine to reduce and prevent childhood blindness, mental retardation, fetal death, and common infections prevalent in many developing countries. *See* Press Release, World Health Organization, New Global Alliance Brings Food Fortification to World's Poor (June 12, 2003) (noting that "[i]n the United States and other industrialized countries, people don't even think about the fact that our staple foods are fortified with essential vitamins and minerals.... We benefit from such programs with every slice of bread we eat and with every shake of salt. This is not so in nearly all of the poorer countries."), *available at* http://www.who.int/mediacentre/releases/2003/ prgain/en/ (last visited July 31, 2003).

CONCLUSION

The TRIPS Agreement requirements for WTO members to provide patent protection for pharmaceuticals, and its limits on compulsory licensing have played, and continue to play, a role in the lack of access to HIV/AIDS treatments in poor countries. Developing countries, in the untenable position of facing sanctions for violating the TRIPS Agreement on the one hand, and facing the deaths of millions of citizens on the other, were able to mobilize and obtain the Doha Declaration and its provisions for easing the TRIPS Agreement requirements in relation to essential medicines. But the positive flexibilities and transparency of the TRIPS Agreement are in danger of being muted, and in some cases eliminated, by TRIPS-plus provisions in bilateral agreements and the fact that the TRIPS Agreement requirements can be negated by voluntary, unilateral action by powerful developed sovereigns such as the United States or the European Union. Any TRIPS-based solution to the HIV/AIDS crisis will be incomplete if it does not address developing country obligations under TRIPS-plus bilateral agreements and the impact of such agreements on more tangential aspects of the access to essential medicines dilemma.