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Resolving the Public Health Crisis in the Developing World: Problems and Barriers of Access to Essential Medicines

Bryan Mercurio*

I. INTRODUCTION

¶1 Over the last decade, public health and development issues have become topics of great international concern. Public health in many parts of the world has reached crisis level: Over 14 million people are killed by infectious diseases each year (90% of which are in the developing world); over 40 million people globally are infected with HIV/AIDS (90% of which are in the developing world) and the disease kills over three million people annually; over 500 million people are infected with malaria each year and the disease kills upwards of two million people annually; over eight million people develop active tuberculosis (TB) each year and the disease kills over two million people annually (95% of those afflicted and 99% of deaths resulting from TB are found in the developing world).[1] Hundreds of thousands more people die each year from other, lesser known, diseases which predominantly affect developing countries.[2]

¶2 Perhaps even more alarming is the fact that while most illnesses – especially infectious diseases – are preventable or treatable with existing medicines, the World Health Organization (WHO) estimates that over 1.7 billion people – nearly one-third of the world's population – have inadequate or no access to these essential medicines.[3]

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[1] *See* MÉDECINS SANS FRONTIÈRES [Doctors without Borders] (MSF), MILLIONS HAVE A DRUG PROBLEM: THEY CAN'T GET ANY 6-7 (2004), *available at* http://www.accessmed-msf.org/documents/campaignbrochure2004.pdf [hereinafter MSF 2004]; UN MILLENNIUM PROJECT, PRESCRIPTION FOR HEALTHY DEVELOPMENT: INCREASING ACCESS TO MEDICINES, REPORT OF THE TASK FORCE ON HIV/AIDS, MALARIA, TB, AND ACCESS TO ESSENTIAL MEDICINES, PRESCRIPTIONS FOR HEALTHY DEVELOPMENT: INCREASING ACCESS TO ESSENTIAL MEDICINES 26 (Beryl Leach et al. eds., 2005), *available at* http://www.unmillenniumproject.org/documents/TF5-medicines-Complete.pdf [hereinafter UN MILLENNIUM PROJECT 2005].

[2] For instance, lesser known diseases such as the African trypanosomiasis, Chagas, leishmaniasis, and dengue fever also kill thousands of people each year. *See* MSF 2004, *supra* note 1, at 7. *See generally* PHILIP STEVENS, DISEASES OF POVERTY AND THE 10/90 GAP (2004).

[3] WORLD HEALTH ORGANIZATION (WHO), THE WORLD MEDICINES SITUATION 61 (2004), *available at* http://www.searo.who.int/LinkFiles/Reports_World_Medicines_Situation.pdf [hereinafter WHO 2004]. A WHO study conducted in 1999 reveals that low-income countries make up approximately 80% of those persons without sufficient access to essential medicines. *Id.* The problem is most severe in India and Africa, which make up 53% of those individuals without sufficient access to essential medicines. *Id*. It must be noted that in percentage terms, the situation has improved over the last thirty years (in 1975, less than 50%

Moreover, another study recently found that 10 million children a year die from preventable diseases and conditions, with almost all these deaths occurring in poor nations.[4] Another study found that prompt diagnosis and treatment of health problems in Africa and Southeast Asia alone could save approximately 4 million lives each year.[5] In addition, resistance to existing treatments due to improper use or over-exposure plays a significant role in increasing the severity of the public health crises in many nations.[6] Other studies link health with the economic prosperity of nations and persuasively demonstrate the dramatic role the HIV/AIDS epidemic has played in the declining economic growth in sub-Saharan Africa.[7] The consequences of the vicious cycle between poverty and illness are clear[8] and the situation will become even more untenable unless the world comes together to resolve the public health crisis engulfing much of the developing world.

¶3 Fortunately, and in large part due to the tireless efforts of several well-funded non-governmental organisations (NGOs),[9] health-related issues of developing countries, and

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of people had regular access to essential medicines). However, due to population growth, the actual number of persons without access to essential medicines has remained at approximately 1.7 billion. *See id*. at 61-63.

[4] Robert E. Black et al., *Where and Why are 10 Million Children Dying Every Year?*, 361 The Lancet 2226 (2003). For similar statistics, see U.K. Dept. for Int'l Dev. (DFID), Increasing Access to Essential Medicines in the Developing World: United Kingdom Government Policy and Plans 7 (2004), *available at* www.dfid.gov.uk/Pubs/files/accessmedicines.pdf [hereinafter DFID 2004].

[5] DFID 2004, *supra* note 4, at 8.

[6] UN MILLENNIUM PROJECT 2005, *supra* note 1, at 26. It is clear that inappropriate use of medicines leads to resistance. In fact, one study found that in Tanzania, 75% of health workers were dispensing inappropriate doses of malaria regiments to stretch inadequate supplies. Reducing the required dosage of malaria treatment induces resistance and is a major cause of the malaria crisis engulfing part of the developing world. *See id*. at 88. *See also* Melinda Pavin et al., *Prescribing Practices of Rural Primary Health Care Physicians in Uzbekistan*, 8(2) TROP. MED. INT'L HEALTH 182, 182–90 (2003). For approaches resolving this issue, including acquiring more qualified health workers and dealing with illiterate users see R.O. Laing et al., *Ten Recommendations to Improve Use of Medicines in Developing Countries*, 16(1) HEALTH POLICY PLAN. 13, 13-20 (2001).

[7] *See generally* WHO, WORLD HEALTH REPORT 2002: REDUCING RISKS, PROMOTING HEALTHY LIFE (2002), *available at* http://www.who.int/whr/2002/en/whr02_en.pdf; *see also* Brazil Ministry of Health, *National AIDS Drug Policy 2001*, *available at* http://www.aids.gov.br/final/biblioteca/drug/drug2.htm (last visited Jan. 1, 2007) (linking improved health and prolonged life expectancy to increased productivity, improved use of resources and lower medical costs). Moreover, life expectancy in Africa increased by nine years between 1960 and 1990, while life expectancy in high-income countries increased by six years. The impact of these gains added between 1.7% and 2.7% per annum to the growth rate of per capita GDP. Recently, however, HIV/AIDS induced a decline in economic welfare approximated at 1.7% per annum, leading to an overall growth rate of –2.6%. In addition, economic welfare in countries heavily impacted by AIDS, such as Botswana, decreased by over 8% per annum for the past decade. Dean T. Jamison et al., *The Effect of the AIDS Epidemic on Economic Welfare in Sub-Saharan Africa* (Comm'n on Macroeconomics and Health Working Paper Series, Paper No. WG1: 13, 2001). For more on the linkage between health and economic prosperity, see, for example WORLD BANK, WORLD DEVELOPMENT REPORT 1993--INVESTING IN HEALTH (1993); David E. Bloom & Ajay S. Mahal, *Does the AIDS Epidemic Threaten Economic Growth?*, 77 J. ECONOMETRICS 105 (1997); William D. Nordhaus, *The Health of Nations: The Contribution of Improved Health to Living Standards* (Nat'l. Bureau of Econ. Res., Working Paper No. W8818, 2002); John Luke Gallup & Jeffrey D. Sachs, *The Economic Burden of Malaria* (Ctr. for Int'l Dev. at Harvard, Working Paper No. 52, 2000), *available at* http://www2.cid.harvard.edu/cidwp/052.pdf; WHO, WORLD HEALTH REPORT 2000, HEALTH SYSTEMS: IMPROVING PERFORMANCE (2000); HEALTH AND ECONOMIC GROWTH: FINDINGS AND POLICY IMPLICATIONS (Guillem López-Casasnovas et al. eds., 2005).

[8] K. Balasubramaniam, *Access to Medicines and Public Policy Safeguards under TRIPS*, *in* TRADING IN KNOWLEDGE: DEVELOPMENT PERSPECTIVES ON TRIPS, TRADE AND SUSTAINABILITY 135-42 (Christophe Bellmann et al. eds., 2003).

[9] For more information on the work of one such NGO on the issue, see Ruth Mayne, *The Global Campaign on Patents and Access to Medicines: An Oxfam Perspective*, *in* GLOBAL INTELLECTUAL

more particularly the issue of accessibility to essential medicines, have garnered much worldwide attention in recent years.[10] Unfortunately, public debate on the issue is most often limited to blaming the pharmaceutical industry and patent regulations under the World Trade Organization (WTO) and its Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)[11] for the lack of accessibility and affordability of much needed drugs in developing countries. While it may be 'in vogue' to attack the pharmaceutical industry, TRIPS and the WTO more generally,[12] such attacks are usually simplistic, myopic and apart from adding little substance to the debate, they divert precious time and resources away from efforts that really count toward alleviating the suffering caused by the devastating health crisis. In reality, the impact of patents on public health is moot for many in the developing countries where inadequate healthcare and health infrastructure poses a much more immediate and significant problem. Put simply, patents do not even come into consideration if one cannot get a diagnosis by virtue of the fact that they do not have access to a doctor, or more accurately, a properly trained and equipped doctor.

¶4 This article examines the many factors that have created and continue to perpetuate the ongoing health crisis in developing countries. In so doing, the article will reveal that the focus on patent regulation is largely misguided and that the targeting of pharmaceutical companies and TRIPS has lead to an unfortunate divergence from the actual critical issues that affect the delivery of much-needed care and medicines to the developing world. The article then argues that the critical issues lie not in constructing appropriate TRIPS provisions, but more so in providing financial resources to build, maintain and stabilize proper healthcare systems in those developing countries afflicted with public health crises. Just as importantly, the article also illustrates the need for developing countries to prioritize public health while at the same time minimize the effects of poor economic planning and policies as well as societal problems such as corruption and civil strife. This article does not fully absolve pharmaceutical companies from blame nor does it claim that TRIPS strikes the appropriate balance between creators

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PROPERTY RIGHTS: KNOWLEDGE, ACCESS AND DEVELOPMENT 244-58 (Peter Drahos & Ruth Mayne eds., 2002).

[10] For a definition of access to essential medicines see WHO, THE WORLD MEDICINES SITUATION 61-74 (1999). This definition was essentially incorporated into the Millennium Development Goals (MDGs): "The world's time-bound and quantified targets for addressing extreme poverty in its many dimensions-income poverty, hunger, disease, lack of adequate shelter, and exclusion-while promoting gender equality, education, and environmental sustainability. They are also basic human rights-the rights of each person on the planet to health, education, shelter, and security." UN Millennium Project website, http://www.unmillenniumproject.org/goals/index.htm (last visited Jan. 1, 2007). Goal 6 seeks to combat HIV/AIDS, Malaria and other diseases, and targets 2015 for halting and beginning to reverse the incidence and spread of these and other diseases. *Id.*

[11] *See* Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations, Apr. 15, 1994, Legal Instruments--Results of the Uruguay Round vol. 1 (1994), 33 I.L.M. 1125 (1994) [hereinafter Uruguay Round] (establishing the WTO in the last round of GATT and also creating treaties covering various trade topics); 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] (establishing a multilateral agreement creating minimum protection standards for various forms of intellectual property among Member States).

[12] *See, e.g.*, PASCALE BOULET ET AL., MSF, DRUG PATENTS UNDER THE SPOTLIGHT: SHARING PRACTICAL KNOWLEDGE ABOUT PHARMACEUTICAL PATENTS (2004), *available at* http://www.accessmed-msf.org/documents/Patent%20report%20.pdf.

and users in every situation, but much has already been written on these two issues.[13] Instead, this article focuses on and examines possible solutions or initiatives that may be adopted to alleviate the current public health problem and assesses their practicability in light of the particular situations and circumstances affecting the developing world.

¶5 Part II briefly reviews the TRIPS Agreement and analyses efforts to rebalance the Agreement in favor of developing countries in the form of the Doha Declaration on Public Health and its derivative agreements. Part III shows that, although the regime of patent protection has been blamed for creating or at least worsening the public health crises inflicting much of the developing world, the situations is far more complex and, in reality, patents and TRIPS have played a very small role in the crisis. Part IV reviews several contributing factors into the crisis and offers several suggestions which, if fully implemented, will go a long way in alleviating the public health crises and improving the lives of millions in the developing world. Part V concludes that the health crisis raging through much of the developing world can be alleviated, but only through a global commitment from the international community whereby developed countries increase the amount as well as the coordination of funding and aid activities and developing countries prioritize public health, improve infrastructure and work towards creating an environment conducive to growth and sustainability, and study and implement alternatives to current research and development schemes that provide more incentive to research certain diseases.

II. TRIPS AND THE DOHA DECLARATION ON PUBLIC HEALTH

¶6 The TRIPS Agreement is comprehensive in its coverage and includes copyright and related rights, trademarks, geographical indications, industrial designs, product and process patents, layout-designs (topographies) of integrated circuits, and protection of undisclosed information.[14] Like other covered agreements of the WTO, TRIPS is based on the most-favored-nation and national treatment principles, but unlike any of the other WTO agreements, TRIPS also establishes minimum levels of protection that each Member must provide and grant to other Members.[15] It is imperative to understand that such a regulatory, harmonized approach to this issue is unlike the approach taken in any of the other WTO Agreements.

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[13] *See, e.g.*, Peter Drahos, *Expanding Intellectual Property's Empire: the Role of FTAs*, GRAIN, Nov. 2003, http://www.grain.org/rights/tripsplus.cfm?id=28 (last visited July 16, 2006); Laurence R. Helfer, *Regime Shifting: The TRIPS Agreement and New Dynamics of International Intellectual Property Lawmaking*, 29 YALE J. INT'L L. 1 (2004); Frederick M. Abbott, *The TRIPS Agreement, Access to Medicines and the WTO Doha Ministerial Conference* (Fla. St. Univ. Coll. of Law, Pub. Law Working Paper No. 36 and QUNO Occasional Paper No. 7, 2001), *available at* http://papers.ssrn.com/sol3/papers.cfm?abstract_id=285934; Gregory Shaffer, *Recognizing Public Goods in WTO Dispute Settlement: Who Participates? Who Decides? The Case of TRIPS and Pharmaceutical Patent Protection*, 7 J. INT'L ECON. L. 459 (2004); Bradly Condon & Tapen Sinha, *Global Diseases, Global Patents and Differential Treatment in WTO Law: Criteria for Suspending Patent Obligations in Developing Countries*, 26 NW. J. INT'L L. & BUS. 1 (2005).

[14] *See* TRIPS Agreement, *supra* note 11, at Part II.

[15] *Id.; see generally* General Agreement on Tariffs and Trade, Oct. 30, 1947, 61 Stat. A-11, T.I.A.S. 1700, 55 U.N.T.S. 194; General Agreement on Tariffs and Trade 1994, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1A, 1867 U.N.T.S. 187, 33 I.L.M. 1153 (1994).

¶7 The controversial inclusion of intellectual property into the multilateral trading system has already been well-traversed in existing literature and will not be repeated here.[16] It must be noted, however, that even with the lengthy implementation periods and 'flexibilities' built into TRIPS, several WTO Members and interested observers have long recognized that TRIPS results in overall trade gains for developed nations,[17] while at the same time failing to reach an appropriate balance with respect to patent protection and access to life-saving medicines in developing and least-developed countries.[18] Unfortunately, reaching agreement on improvements to the system has proven to be a much harder proposition and in this regard, the work of several NGOs should be given due credit for their persistent efforts and pressure in forcing the issue onto the agenda and keeping it in the spotlight of multilateral discussions.[19] Those organizations were undoubtedly partially responsible for getting public health issues on the agenda at the Third Ministerial Conference held in Seattle in 1999.[20] Regrettably, the Seattle Ministerial ended without success and the resolution of several key health issues did not solidify until the Fourth Ministerial Conference, held in Doha, Qatar in 2001, launched the Doha Round of multilateral trade negotiations (Doha Round).[21]

¶8 At Doha, Members adopted a Declaration on TRIPS and Public Health (Doha Declaration or the Declaration) which restated and affirmed the right of Member States to take measures to protect public health, clarified certain textual ambiguities contained in TRIPS and attempted to provide assistance to developing countries and LDCs in resolving the public health crises that are devastating many parts of the developing world.[22] The Declaration is significant for a number of reasons. First, it "represented the first time international health and development was discussed at every level of WTO governance."[23] Second, it was "the first significant victory for developing countries in

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[16] *See, e.g.,* Bryan C. Mercurio, *TRIPs, Patents and Access to Life-Saving Drugs in the Developing World*, 8 MARQ. INTELL. PROP. L. REV. 211, 215-16 (2004); Robert Weissman, *A Long, Strange TRIPs: The Pharmaceutical Industry Drive to Harmonize Global Intellectual Property Rules, and the Remaining WTO Legal Alternatives Available to Third World Countries*, 17 U. PA. J. INT'L ECON. L. 1069, 1072-77 (1996); Ruth L. Okediji, *Back to Bilateralism? Pendulum Swings in International Intellectual Property Protection*, 1 U. OTTAWA L. & TECH. J. 125 (2003-04); Adronico O. Adede, *Origins and History of the TRIPS Negotiations, in* TRADING IN KNOWLEDGE: DEVELOPMENT PERSPECTIVES ON TRIPS, TRADE AND SUSTAINABILITY 23, 23-35 (Christophe Bellmann et al. eds., 2003).

[17] *See, e.g.*, Keith E. Maskus, *Intellectual Property Rights and Economic Development*, 32 CASE W. RES. J. OF INT'L L. 471 (2000).

[18] *See, e.g.,* UK COMMISSION ON INTELLECTUAL PROPERTY RIGHTS, REPORT OF THE COMMISSION ON INTELLECTUAL PROPERTY RIGHTS, INTEGRATING INTELLECTUAL PROPERTY RIGHTS AND DEVELOPMENT POLICY (2002), *available at* http://www.iprcommission.org/papers/pdfs/final_report/CIPRfullfinal.pdf [hereinafter UK CIPR]; TRADING IN KNOWLEDGE: DEVELOPMENT PERSPECTIVES ON TRIPS, TRADE AND SUSTAINABILITY (Christophe Bellmann et al. eds., 2003).

[19] For a listing of NGO position papers filed with the WTO before the Doha Round see WTO, Non-Governmental Organizations: Working Papers, http://www.wto.org/english/forums_e/ngo_e/posp21_e.htm (last visited Dec. 30, 2006).

[20] For a worthy discussion on the negotiating history of TRIPS and the Doha Declaration see SUSAN K. SELL, PRIVATE POWER, PUBLIC LAW, THE GLOBALIZATION OF INTELLECTUAL PROPERTY RIGHTS 121, 121-62 (2003).

[21] Elizabeth Olson, *Squabbles at the Start for World Trade Talks*, N.Y. TIMES, Jan. 29, 2002, at W1.

[22] *See* World Trade Organization (WTO), Ministerial Declaration on the TRIPS Agreement and Public Health, WT/MIN(01)/DEC/2, 41 I.L.M. 755 (2002) [hereinafter Doha Declaration]. For detailed information and analysis regarding the lead up to the Implementation Agreement see Mercurio, *supra* note 16. *See also* KATHARINA GAMHARTER, ACCESS TO AFFORDABLE MEDICINES: DEVELOPING RESPONSES UNDER THE TRIPS AGREEMENT AND EC LAW 159-246 (2004).

[23] Mercurio, *supra* note 16, at 212.

the short history of TRIPS."[24] Finally, the Declaration recognized that public health issues can take precedence over the rights of private intellectual property holders.[25] India called the Declaration "the most important single achievement of the Doha Round," while the Philippines hailed the Declaration as being "the crowning glory of the WTO's contribution to global welfare and humanitarian concerns, especially for those who were gravely afflicted by the scourge of epidemics and other public health problems."[26]

¶9 Broadly speaking, the Declaration sought to "clarify" the TRIPS Agreement while giving emphasis to the "flexibilities" already written into the agreement, including the right of Members to invoke those provisions when needed.[27] Paragraphs 1 through 5 contain the Declaration's most significant conclusions. Paragraphs 1 through 3 outline the concerns of both developing and developed countries by providing context for the issue of intellectual property protection for medicines while recognizing the need to balance private property and public welfare interests.[28] More specifically, paragraph 1 "recognizes the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics,"[29] while paragraphs 2 and 3 express the need for TRIPS to be part of the wider national and international action to address the problems and recognize that the link between intellectual property protection for the creation of new medicines as well as the concerns about the effect of intellectual property rights (IPRs) on prices.[30]

¶10 Paragraph 4 affirms the principle that protecting public health and promoting access to medicines is a valid basis for Members to enact exceptions to patent protection in their domestic legislation.[31] Specifically, paragraph 4 states that TRIPS "does not and should not prevent Members from taking measures to protect public health" and "affirms that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all."[32] Thus, paragraph 4 reinforces the plain meaning of Article 8 of the TRIPS Agreement, which permits Members to "adopt measures necessary to protect public health…"[33]

¶11 Paragraph 5 provides Members with flexibilities in implementing TRIPS and reaffirms the right of WTO Members to use the provisions in TRIPS for the purposes of Paragraph 4.[34] The paragraph sets out the "provisions," which may be used for this purpose:

> (a) In applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of

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[24] *Id*.
[25] *Id*. *See generally* Doha Declaration, *supra* note 22, at para. 4.
[26] Council for Trade-Related Aspects of Intellectual Property Rights, Minutes of Meeting held in the Centre William Rappard on Nov. 25-27, 29, and Dec. 20, 2002, IP/C/M/38 (Feb. 5, 2003) at 38, 45.
[27] *See generally* Doha Declaration, *supra* note 22.
[28] *See* Doha Declaration, *supra* note 22, at paras. 1-3.
[29] *Id.* at para. 1.
[30] *Id*. at paras. 2 and 3.
[31] *Id*. at para. 4.
[32] *Id*.
[33] *Id*.; TRIPS Agreement, *supra* note 11, at Article 8.
[34] *Id*. at para. 5.

> the object and purpose of the Agreement as expressed, in particular, in its objectives and principles.
>
> (b) Each member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted.
>
> (c) Each member has the right to determine what constitutes a national emergency or other circumstances 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 circumstances of extreme urgency.
>
> (d) The effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each member free to establish its own regime for such exhaustion without challenge, subject to the MFN and national treatment provisions of Articles 3 and 4.[35]

¶12 Paragraph 6 "recognizes that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement," but the paragraph left the issue unresolved, instead instructing the Council for TRIPS to find an "expeditious solution" to the problem and to report to the General Council before the end of 2002.[36]

¶13 The failure to resolve the availability of compulsory licensing exceptions to patent protection for countries suffering a public health crisis with insufficient or no manufacturing capabilities tempered the success of the Declaration.[37] As TRIPS Article 31(f) conditions the issuance of compulsory licenses on being "predominantly for the supply of the domestic market of the Member authorizing such use," a Member State could only override valid patent laws so long as it obtained the generic drugs from domestic producers.[38] Whether intentionally or accidentally, Article 31(f) prevents a country from benefiting from the compulsory licensing provision if it does not have sufficient manufacturing capabilities because, in practice, the provision limits the licensee's ability to export medicines to a country with public health needs, thereby preventing countries with insufficient or no manufacturing capabilities from taking advantage of the provision.[39] Additionally, as most countries needing to make use of the patent exceptions are economically troubled nations with insufficient or no manufacturing capabilities, Article 31 of TRIPS failed in its purpose of assisting those nations it was designed to benefit.[40]

¶14 After several delays and weeks of constant negotiation in the days leading to the Fifth Ministerial Conference (Cancun Ministerial), a resolution to the issue was finally reached on August 30, 2003.[41] In fact, when endless debate over technical points looked

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[35] *Id.*
[36] *Id.* at para. 6.
[37] *See generally id*.
[38] *See* TRIPS, *supra* note 11, at art. 31(f).
[39] *Id*.
[40] Mercurio, *supra* note 16, at 213.
[41] On November 25, 2002, the Chairperson of the TRIPS Council informed the Members that he was

as if it would hamper an agreement being formed, a group of African countries reminded Ministers that while potential solutions had been discussed in the interim years, the situation of medicinal access in poor countries had worsened.[42] During this time, those countries continued to lose the battle against such public health epidemics as tuberculosis, malaria, and HIV/AIDS.[43] In a joint statement, the group poignantly stated that "8,480 people had died unnecessarily in Africa from HIV/AIDS and other diseases since the talks stalled over an accompanying document to the Agreement only two days earlier [Aug. 28, 2003]."[44] The statement had the desired effect: the Ministers put their differences aside and reached agreement on a "temporary waiver" in the form of The Implementation of Paragraph 6 of the Doha Declaration on TRIPS Agreement and Public Health (Implementation Agreement) and accompanying Chairperson's Statement.[45] At the time, Canadian Ambassador Sergio Marchi commented: "[The African countries] showed that the poorest among us do make a difference in this organization... They helped the WTO find its heart and soul."[46]

¶15 The Implementation Agreement resolved the Article 31(f) situation by creating an exception to Article 31(f) of TRIPS that allows nations with insufficient or no manufacturing capabilities to override intellectual property protection and import generic copies of patented drugs to combat public health crises.[47] However, in order to be TRIPS compliant, the importing Member must abide by several procedural steps, namely that the importing Member:

> (1) must notify the TRIPS Council of the "names and expected quantities of the products needed";

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holding consultations on implementing the Paragraph 6 mandate of the Doha Declaration. On November 29, the Chairperson reported that intensive consultations had led to significant progress and that a draft legal instrument was almost finalized. The draft was tabled on December 16, but was not adopted when the U.S. would not agree to the paragraph concerning the scope of diseases covered. *See* Minutes of TRIPS Council Meeting, *supra* note 26, at 33-34; Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, Note from the Chairperson, JOB(02)/217 (2002).

[42] Naomi Koppel, *WTO Lets Poor Nations Import Cheap Drugs*, ASSOCIATED PRESS, Aug. 30, 2003, *available at* http://www.aegis.com/news/ap/2003/AP030847.html (last visited Jan. 3, 2007).

[43] *Id.*

[44] *Id.*

[45] Council for TRIPS, *Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, WT/L/540 (Aug. 30, 2003) [hereinafter *Implementation Agreement*]. The agreement was only finalized when the Members agreed to attach a statement to the text setting out the conditions under which the measure detailed in the Implementation Agreement can be used. Among other things, the Statement: (i) "recognizes that the [compulsory licensing] system ... should be used in good faith to protect public health and [not as] an instrument to pursue industrial or commercial policy objectives"; (ii) "recognizes that the purpose of the [Implementation Agreement] would be defeated if [drugs were] diverted from the [intended] markets" and calls on Members to take "all reasonable measures" to "prevent such diversion"; and (iii) reiterates the importance of Members to seek expeditious and amicable resolutions to issues arising from the Implementation Agreement. *See The General Council Chairperson's Statement*, WTO NEWS, Aug. 30, 2003, http://www.wto.org/english/news_e/news03_e/trips_stat_28aug03_e.htm [hereinafter Chairperson's Statement]. The Implementation Agreement was transformed into a permanent amendment of the TRIPS on December 6, 2005. This represented the first time a WTO Agreement had been amended.

[46] Koppel, *supra* note 42.

[47] *See Implementation Agreement*, *supra* note 45.

> (2) must confirm that it is either a LDC or "establish[] that it has insufficient or no manufacturing capacities in the pharmaceutical sector for the products in question"; and
>
> (3) confirm that, if the "product is patented in its territory, [that] it has granted or intends to grant a compulsory licence in accordance with [TRIPS] Article 31."[48]

¶16 The Implementation Agreement also outlines several procedural conditions an exporting Member must fulfill when issuing a compulsory license:

> 2. The obligations of an exporting Member under Article 31(f) of the TRIPS Agreement shall be waived with respect to the grant by it of a compulsory licence to the extent necessary for the purposes of production of a pharmaceutical product(s) and its export to an eligible importing Member(s) in accordance with the terms set out below in this paragraph:
>
> a) the eligible importing Member(s) has made a notification to the Council for TRIPS, that:
>
> (i) specifies the names and expected quantities of the product(s) needed;
>
> (ii) confirms that the eligible importing Member in question, other than a least developed country Member, has established that it has insufficient or no manufacturing capacities in the pharmaceutical sector for the product(s) in question in one of the ways set out in the Annex to this Decision; and
>
> (iii) confirms that, where a pharmaceutical product is patented in its territory, it has granted or intends to grant a compulsory licence in accordance with Article 31 of the TRIPS Agreement and the provisions of this Decision;
>
> (b) the compulsory licence issued by the exporting Member under this Decision shall contain the following conditions:
>
> (i) only the amount necessary to meet the needs of the eligible importing Member(s) may be manufactured under the licence and the entirety of this production shall be exported to the Member(s) which has notified its needs to the Council for TRIPS;
>
> (ii) products produced under the licence shall be clearly identified as being produced under the system set out in this Decision through specific labelling or marking. Suppliers should distinguish such products through

[48] *Id.* at para. 2(a).

> special packaging and/or special colouring/shaping of the products themselves, provided that such distinction is feasible and does not have a significant impact on price; and
>
> (iii) before shipment begins, the licensee shall post on a website the following information:
>
> - the quantities being supplied to each destination as referred to in indent (i) above; and
> - the distinguishing features of the product(s) referred to in indent (ii) above;
>
> (c) the exporting Member shall notify the Council for TRIPS of the grant of the licence, including the conditions attached to it. The information provided shall include the name and address of the licensee, the product(s) for which the licence has been granted, the quantity(ies) for which it has been granted, the country(ies) to which the product(s) is (are) to be supplied and the duration of the licence. The notification shall also indicate the address of the website referred to in subparagraph (b)(iii) above.[49]

¶17 While the Implementation Agreement goes some way in addressing the legal hole that existed, it is not a miracle solution and to hold it out as such would be extremely misleading.[50] To some, the Implementation Agreement fails to satisfactorily resolve several issues, including: (i) the scope of diseases and product coverage; (ii) countries that would be eligible to use the system; (iii) ensuring adequate remuneration; and (iv) safeguarding the system against diversion of drugs into other markets.[51] Health and policy advocates, meanwhile, have also criticized the Implementation Agreement, in particular the prerequisite that a drug supplied under compulsory licence must normally be clearly identifiable as a generic version.[52] These critics often argue that even though the requirement may be met through a variety of features – such as labelling, marking,

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[49] *Implementation Agreement*, *supra* note 45, at para. 2.

[50] *See* Frederick M. Abbott, *The WTO Medicines Decision: World Pharmaceutical Trade and the Protection of Public Health*, 99 AM. J. OF INT'L L. 317, 325 (2005); Jacques H. J. Bourgeois & Thaddeus J. Burns, *Implementing Paragraph 6 of the Doha Declaration on Trade and Public Health: The Waiver Solution*, 5 J. OF WORLD INTELL. PROP. 835, 838 (2002).

[51] *See generally* Mercurio, *supra* note 16.

[52] For criticism, see MSF, MSF Comments on the Draft Chairman's Statement of 21 August 2003 (Aug. 26, 2003), http://www.accessmed-msf.org/prod/publications.asp?scntid=26820031712133&contenttype=PARA& [hereinafter MSF Comments]; MSF, Neither Expeditious, Nor a Solution: The WTO August 30th Decision is Unworkable, http://www.accessmed-msf.org/prod/publications.asp?scntid=10820061618476&contenttype=PARA& (last visited Nov. 17, 2006) [hereinafter MSF, Neither Expeditious]. MSF also criticizes the requirement of prior negotiation before issuing a compulsory licence (which can be waived for a "national emergency" or for public non-commercial use), the anti-diversion measures built into the waiver, notification of intention to use the Implementation Agreement, and–somewhat bizarrely–even the requirement that the licensee must post on a website the quantities being supplied by compulsory licence and the distinguishing features of the supplied drugs. *Id.*

special packaging, or by the specific colouring of shaping of the drug – ensuring that such distinguishing characteristics are present could raise procedural and administrative costs in the export of generic versions.[53] This could possibly render the process less cost-effective and efficient than initially presumed and lengthen the time it takes to get the generic drugs to countries where they are needed.[54] Furthermore, many in the international community believe that meeting other requirements of the Implementation Agreement will also make the waiver hard to exploit.[55]

¶18 In addition, and importantly as will be discussed below, both developing and developed countries have been slow to secure the necessary domestic implementing legislation operationalizing the Implementation Agreement. For instance, countries that may wish to take advantage of the provision in the future – that is, those which could possibly have insufficient or no manufacturing capability to meet a public health need – have by and large not passed domestic legislation which would override patent laws and allow them to import necessary medicines under a compulsory licence. In addition, countries which have pharmaceutical manufacturing capabilities have been slow to pass legislation allowing their respective industry to supply nations attempting to make use of the provision with the requested drugs under compulsory licence.[56] For some time, only Canada and Norway had passed the necessary implementing legislation.[57] At the time of this writing, China, the European Communities, India, Korea, the Netherlands, and Switzerland have also enacted comprehensive legislation implementing the 30 August decision.[58] Even more worrisome is the fact that some developed nations do not appear interested in promoting and passing such legislation.[59]

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[53] *See, e.g.*, MSF Comments, *supra* note 52; MSF, Neither Expeditious, *supra* note 52 ; Cecilia Oh, *The New "Deal" On Trips and Drugs: What Does it Mean for Access to Medicines?*, *in* TWN BRIEFINGS FOR CANCUN 4, 4 (2003), *available at* http://www.twnside.org.sg/title/cancun4.doc; *contra* CARLOS CORREA, DEPARTMENT OF ESSENTIAL DRUGS AND MEDICINES POLICY, IMPLEMENTATION OF THE WTO GENERAL COUNCIL DECISION ON PARAGRAPH 6 OF THE DOHA DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH 22 (2004), www.who.int/medicines/areas/policy/WTO_DOHA_DecisionPara6final.pdf. It must also be noted that the Implementation Agreement waives the obligation for packaging, colouring or shaping when it is either not feasible or significantly impacts upon the price. *Implementation Agreement*, *supra* note 45, at para. 2(b)(ii).

[54] *See, e.g.*, Duncan Matthews, *WTO Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: A Solution to the Access to Essential Medicines Problem?*, 7 J. INT'L ECON. L. 73, 96-97 (2004).

[55] *See, e.g.*, Oh, *supra* note 53; Campaign For Access To Essential Medicines, Joint NGO Statement on TRIPS and Public Health WTO Deal on Medicines: a "Gift" Bound in Red Tape, http://www.accessmed-msf.org/prod/publications.asp?scntid=1292003916443&contenttype=PARA& (last visited Nov. 17, 2006). For a model arrangement, see Condon & Sinha, *supra* note 13.

[56] For detail on the legal and administrative burdens and obstacles to legislating, see DFID HEALTH SYSTEMS RESOURCE CENTRE, ACCESS TO MEDICINES IN UNDER-SERVED MARKETS: WHAT ARE THE IMPLICATIONS OF CHANGES IN INTELLECTUAL PROPERTY RIGHTS, TRADE AND DRUG REGISTRATION POLICY? 6 (2004), *available at* http://www.dfid.gov.uk/pubs/files/dfidsynthesispaper.pdf [hereinafter DFID].

[57] *Id.*

[58] For links to the implementing legislation and supporting documents, see Legislation to Allow for the Export of Pharmaceuticals Produced Under Compulsory License, http://www.cptech.org/ip/health/cl/cl-export-legislation.html (last visited July 16, 2006). The domestic legislation enacted in most, if not all, countries has also been criticized. *See, e.g.*, Neither Expeditious, *surpa* note 52, at 2; Matthew Rimmer, *The Jean Chretien Pledge to Africa Act: Patent Law and Humanitarian Aid*, 15(7) EXP. OPIN. THER. PATENTS 889 (2005).

[59] *See* Rimmer, *supra* note 58, at 905; *TRIPS Council Remains Divided on Public Health Amendment*, 9(36) BRIDGES WKLY. TRADE NEWS DIG. (2005), *available at* http://www.ictsd.org/weekly/05-10-

¶19 To date, there have not been any notifications to the TRIPS Council regarding the issuance of a compulsory licence. This is not surprising, as prior to 2005, developing country members such as India and Brazil could produce and supply generic versions of patented drugs without the need for the issuance of a compulsory license.[60] TRIPS, however, is playing an increasingly bigger role and becoming more important in the expansion of access to medicines and public health in the developing world following the expiration of certain transitory flexibilities and implementation periods in January 2005.[61] TRIPS now has the potential to become a barrier to access to affordable new medicines and vaccines as the rules on compulsory licensing become operational for a number of developing country Members who are now subject to totality of the TRIPS Agreement.[62] The practical result of this is that TRIPS now affects generic producers' ability to provide existing medicines for developing countries without sufficient manufacturing capabilities.[63] Thus, developed nations passing the necessary legislation operationalizing the Implementation Agreement takes on even more importance.

¶20 Perhaps more worrisome with regards to the development of essential medicines in the developing world is the addition of intellectual property provisions in bilateral and regional free trade agreements (FTAs) requiring signatories to advance protection beyond

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26/story3.htm; *see also* MSF, THE JEAN CHRÉTIEN, PLEDGE TO AFRICA ACT OR CANADA'S ATTEMPT TO PROVIDE MEDICINES FOR THE POOR (2002), *available at* http://www.msf.ca/tour2006/press/images/BRIEF_jcpa.pdf.

[60] Several countries, including India, Malaysia, Indonesia, Cameroon, Zimbabwe, Mozambique and Zambia, have all in the past issued compulsory licenses for the importation of generic drugs or authorized local production of generic drugs for patented AIDS drugs. MSF, WILL THE LIFELINE OF AFFORDABLE MEDICINES FOR POOR COUNTRIES BE CUT? CONSEQUENCES OF MEDICINES PATENTING IN INDIA (2005), http://www.msf.fr/documents/base/2005-02-01-msf.pdf [hereinafter MSF 2005].

[61] These transitional periods are of the utmost importance in terms of access to medicines in the developing world, as the delayed implementation of TRIPS allows several countries that possess the ability to cheaply produce copies of patented drugs and sell them for much lower prices than the patent holder. This practice became more difficult as of January 1, 2005, when the leading generic manufacturing nations (including India) became subject to TRIPS. As a result, compulsory licensing may be less effective in the absence of a generic industry. UK CIPR, *supra* note 18 ("[After January 1, 2005,] without special arrangements, the possibility of compulsory licensing being a vehicle for price reductions will be more limited than at present, even in the few technologically advanced developing countries. For most countries, the only feasible supplier may be the patentee (or his licensee).").

[62] Many believe the introduction of generic competition reduces the price of drugs. For instance, the price of one AIDS treatment reportedly dropped by 82% in Brazil after the government began producing generics. MSF 2004, *supra* note 1, at 2 ("The single most important factor in forcing down the prices of medicines is generic competition. The lowest price of an AIDS drug combination plummeted from more than US $10,000 per patient per year to less than US $200 between 2000 and 2004."). For a table showing the prices of drugs pre- and post- generic competition, see *id*. at 3. It has been estimated that the post-2005 cost of new drugs will rise by 200%. F.M. Scherer & Jayashree Watal, *Post-Trips Options for Access to Patented Medicines in Developing Countries* 7-8 (Comm'n on Macroeconomics and Heath, Working Paper No. WG4:1, 2001). *See also* Balasubramniam, *supra* note 8, at 137-38; DFID, *supra* note 56, 12-13; *contra*, Carol C. Adelman et al., *The Full Cost of HIV/AIDS Treatment*, HUDSON INST. 8-9 (2nd ed. 2005) (finding the majority of patented drug prices to be within the range of lower than generic/copy drug prices for both single dose and combination AIDS drugs) [hereinafter Adelman, et al., *The Full Cost of HIV/AIDS Treatment*].

[63] That being said, patents are crucial to the development of drugs: "Without patents, existing anti-AIDS drugs would not have been produced. Without patents, new and better drugs that are needed to overcome the increasing resistance of the AIDS virus would not be developed." WORLD INTELLECTUAL PROPERTY ORGANISATION, STRIKING A BALANCE: THE PATENT SYSTEM AND ACCESS TO DRUGS AND HEALTH CARE, WIPO Publication No. 491(E), *available at* http://www.wipo.int/freepublications/en/patents/491/wipo_pub_491.pdf [hereinafter WIPO No. 491(E)].

the minimum standards required by TRIPS (the so-called TRIPS-Plus provisions).[64] Not only is the addition of the so-called "TRIPS-Plus" part of a larger strategy to achieve outcomes which are not feasible multilaterally, but it is also apparent that such provisions are in response to the powerful and persistent lobbying efforts of the pharmaceutical industry.[65] These provisions have the potential to hinder access to essential medicines by limiting access to the flexibilities that currently exist in TRIPS to protect public health. Such TRIPS-consistent flexibilities that are now forming part of many FTA provisions limiting the flexibilities granted in TRIPS and potentially curtailing possible government responses to public health crises include, inter alia, restricting the conditions for the issuance of compulsory licensing, extending the period of data exclusivity and other protections, extending the patent term and 'new use' patents (so called 'evergreening'), preventing parallel importation, and linking the 'market approval' of a drug to patent status (requiring drug and health regulatory agencies to intersect with national patent offices and undertake some form of oversight duties).[66] These provisions are, however, WTO-consistent as the standards elucidated in TRIPS are simply minimum standards, and Members are allowed to grant greater protection to intellectual property rights if they so desire.[67]

¶21 Thus, despite the Doha Round's merits in bringing the issue of the international health to the fore, serious gaps must still be addressed in the regulation of intellectual property at the global level.[68] The impact of the Implementation Agreement may be debated,[69] but even if intellectual property provisions contained in TRIPS were

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[64] For more on the development of TRIPS-Plus provisions, see Bryan Mercurio, *TRIPS-Plus Provisions in RTAs: Recent Trends*, *in* REGIONAL TRADE AGREEMENTS AND THE WTO LEGAL SYSTEM (Lorand Bartels & Federico Ortino eds., 2006).

[65] *See* REPORT OF THE INDUSTRY FUNCTIONAL ADVISORY COMMITTEE ON INTELLECTUAL PROPERTY RIGHTS FOR TRADE POLICY MATTERS (IFAC-3), THE US-CENTRAL AMERICAN FREE TRADE AGREEMENT: THE INTELLECTUAL PROPERTY PROVISIONS (2004), http://www.ustr.gov/assets/Trade_Agreements/Bilateral/CAFTA/CAFTA_Reports/asset_upload_file571_5945.pdf.

[66] *See, e.g.*, Mercurio, *supra* note 64; Peter Drahos, *Expanding Intellectual Property's Empire: the Role of FTAs*, GRAIN, Nov. 2003, http://www.grain.org/rights_files/drahos-fta-2003-en.pdf.

[67] Article 4 of the TRIPS agreement states that a Member who grants "any advantage, favour, privilege or immunity" to the nationals of *any* other country (whether that country be a Member of the WTO/TRIPS or not) must accord the same treatment to the nationals of other Members of TRIPS. The clause operates in a relatively unqualified way because, unlike art. XXIV of the GATT, which may serve to exempt FTAs from the operation of MFN, TRIPS does not contain a similar provision; thus, the principle of MFN applies to FTAs. Therefore, if enough FTAs are negotiated containing TRIPS-plus provisions, these provisions will essentially become the new minimum standard from which any future WTO trade round will proceed. For a detailed analysis, see Drahos, *supra* note 66. *See also* FREDERICK ABBOTT, THE DOHA DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH AND THE CONTRADICTORY TREND IN BILATERAL AND REGIONAL TRADE AGREEMENTS (2004), http://www.quno.org/geneva/pdf/economic/Occassional/TRIPS-Public-Health-FTAs.pdf.

[68] It is important to note that the issue of TRIPS and public health is now firmly on the international agenda, with the topic regularly discussed and debated at intra- and inter-institutional meetings. For more on the importance of this development see Frederick M. Abbott, *Toward a New Era of Objective Assessment in the Field of TRIPS and Variable Geometry for the Preservation of Multilateralism* 8 J. of Int'l Econ. L. 77 (2005).

[69] For instance, on the day of the Implementation Agreement (August 30, 2003) the WTO headlined a press release "Decision Removes Final Patent Obstacle to Cheap Drug Imports," Oxfam titled their press release "Flawed WTO Drugs Deal Will do Little to Secure Future Access to Medicines in Developing Countries," and the European Federation of Pharmaceutical Industries and Association stated in their press release, "Now it is time to focus on the real access barriers." *See* Press Release, WTO, Decision Removes Final Patent Obstacle to Cheap Drug Imports (Aug. 30, 2003), *available at*

completely pro-developing country, or if the (mostly western) NGOs purporting to represent the interests of the developing world received everything that they demanded of the WTO, would the continuing health crises in the developing world be alleviated? Would the health crises even be minimized? The pharmaceutical industry and the patent provisions in TRIPS have been subjected to much criticism over the last decade and charges that they are to blame for the lack of access to medicine in developing countries are not uncommon. However, there is strong evidence which shows that patent protection of pharmaceuticals and TRIPS alone are not impeding access to essential medicines in developing countries. In fact, this article argues that IPRs have not even been a significant factor when the situation is objectively assessed and considered in its entirety.

III. CRITICAL ISSUES INVOLVED IN SOLVING THE ACCESS TO MEDICINE PROBLEM

¶22 Even under the best circumstances, merely alleviating the public health crisis in many parts of the developing world to a noticeable degree will be difficult to achieve. The situation requires international cooperation on a massive scale to not only ensure that the developing world has access to essential medicines but to also create incentives to stimulate (or directly fund) research and development into new medicines and vaccines to treat the diseases primarily affecting the developing world.

¶23 It is unfortunate that several high profile NGOs have concentrated their effort in blaming the pharmaceutical industry and the patent regime for worsening the crises.[70] While these groups have spent significant monetary resources and intellectual effort directing much of the debate over the access to essential medicines in the developing world on the issue of patent protection of pharmaceuticals to the actions of the pharmaceutical industry and the patent regime, the constant accusations and resulting publicity have not helped the situation and, to the contrary, have been highly divisive, arguably lengthening the time between the Doha Ministerial and the implementation of the Implementation Agreement and obscuring longstanding impediments to improving the lives and health of millions. In order to control the problem and even hope to alleviate suffering, all interested parties must realize that patent protection is only one of many factors that play a role in the health of the developing world and other critical factors, such as poor living conditions, the lack of medical facilities and proper

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www.wto.org/english/news_e/pres03_e/pr350_e.htm; Press Release, Oxfam, Flawed WTO Drugs Deal Will do Little to Secure Future Access to Medicines in Developing Countries (Aug. 30, 2003), *available at* www.oxfam.org/en/news/pressreleases2003/pr030830_wto_final.htm; Press Release, European Federation of Pharmaceutical Industries and Association, EFPIA Statement on Compulsory License for Export ("Paragraph 6" of the Doha Declaration on TRIPS & Public Health) (Aug. 30, 2003), *available at* www.efpia.org/3_press/20030830.htm.

[70] *See, e.g.*, MSF, Publications on Patents, http://www.accessmed-msf.org/prod/morepublications.asp?catid=1&subcatid=185&status=182 (last visited Dec. 3, 2006); MSF, WTO TRIPS Agreement, http://www.accessmed-msf.org/prod/morepublications.asp?catid=1&subcatid=185&status=182 (last visited Jan. 3, 2007); MSF, Pricing Policy, http://www.accessmed-msf.org/prod/morepublications.asp?catid=1&subcatid=187&status=182 (last visited Jan. 3, 2007); OXFAM, DARE TO LEAD: PUBLIC HEALTH AND COMPANY WEALTH (2001), http://www.oxfam.org.uk/what_we_do/issues/health/downloads/daretolead.pdf.

infrastructure, malnutrition, and the lack of means for distributing and administrating medicine, must be addressed in order to alleviate the public health crises.[71]

¶24 Somewhere in the past decade, important facts such as the appallingly low levels of medical infrastructure in developing nations, inadequate levels of foreign assistance and seeming lack of political will in some developing countries to alleviate the suffering were marginalized as the debate focused on TRIPS.[72] Thus, even though infrastructure, aid from developed countries and political will in developing countries is not even remotely adequate to ease the worsening health situation in the developing world, the international debate diverted key monetary resources, intellectual efforts and negotiating capacity on a secondary issue. One noted expert concludes: "AIDS activists have done a huge disservice to the problem of providing relief to people in the developing world by directing a disproportionate focus on the patent issue."[73]

¶25 Crises such as HIV/AIDS, tuberculosis and others gripping much of the developing world are a very real and escalating problem in many developing nations. But the fact is that if patent regulation did not exist, much of the developing world would still lack access to essential medicines. Importantly, 95% of the pharmaceutical products on the WHO Essential Drug List (such as medicines to treat AIDS, tuberculosis and malaria) are off-patent and, due to flexibilities contained in TRIPS and extended by Paragraph 7 of the Declaration and waivers granted in 2002 by the Council for TRIPS, the grace period for LDCs delaying implementation of Sections 5 (patents) and 7 (confidential information) in relation to pharmaceutical products and the marketing rights thereof have been extended until 2016; meaning LDCs do not currently have to provide patent protection for pharmaceuticals.[74]

¶26 To illustrate, as of 2003, of the fifteen antiretroviral (ARV) drugs used for treating AIDS, patent coverage is below 20%, with 172 patents out of the 759 that could theoretically apply.[75] Moreover, of the 52 African nations, only South Africa has patent

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[71] It is conceded, however, that combination/cocktail drugs have proven the most effective means of controlling AIDS and, given that the pharmaceutical companies are normally only able to combine their own drugs (although this is beginning to change as pharmaceutical companies see the benefit of forming joint ventures with rival companies), patent protection may be preventing another potential treatment from coming onto the market. Fortunately, generic Indian manufacturers who were not stifled by IPRs have mixed drugs with some success and the innovative pharmaceutical industry is showing signs of cooperation.

[72] *See, e.g.,* G.A. Res. S-26/2, U.N. Doc. A/RES/S-26/2 (June 27, 2001). For instance, it has been estimated that researching and developing a new malaria treatment requires $300-$500 million dollars more per year than it currently receives.

[73] Bruce A. Lehman, *Globalization's Impact on International Trade and Intellectual Property Law: Intellectual Property Rights as a Trade, Health and Economic Development Issue*, 17 ST. JOHN'S J. 417, 419-20 (2003).

[74] *See* Doha Declaration, *supra* note 22, at para 7; *see also* Press Release, WTO, Extension of the Transition Period under Article 66.1 of the TRIPS Agreement for Least-Developed Country Members for Certain Obligations with Respect to Pharmaceutical Product, Decision of the Council for TRIPS of 27 June 2002 (June 28, 2002), http://www.wto.org/english/news_e/pres02_e/pr301_e.htm[hereinafter WTO, Extension of Transition Period]; General Council, Least-Developed Country Members--Obligations under Article 70.9 of the TRIPS Agreement with Respect to Pharmaceutical Products, WT/L/478 (July 12, 2002). On June 27, 2002, the Council for TRIPS extended the transition period during which LDCs do not have to provide patent protection for pharmaceuticals. WTO, Extension of Transition Period. The Council also approved a waiver that exempts LDCs having to provide exclusive marketing rights for any new drugs in the period when they do not provide patent protection. *Id*.

[75] Pharmaceutical Research and Manufacturers of America (PhRMA), Health Care in the Developing World: Intellectual Property and Access to AIDS Drugs,

protection for more than half of its AIDS drugs, with 15 patents out of a possible 16. Importantly, 25% of the countries provide no patents and the rest have an average of 4 patented drugs, with no patents on more than a dozen different triple-therapy cocktails used to combat HIV/AIDS.[76] Thus, while the majority of African countries do not patent most ARV drugs used to treat AIDS and the majority of countries of sub-Saharan Africa do not have any patent protection for any of the drugs, the AIDS epidemic continues to infect and kill millions of people per year on the continent.

¶27 Interestingly, several members of the medical community also contest the view that patent protection has exacerbated the HIV/AIDS crisis or significantly impeded access to essential medicines. For instance, a widely cited study conducted in 2001 by Amir Attaran and Lee Gillespie-White and published in the *Journal of the American Medical Association* states:

> [It appears that] patents and patent law are not a major barrier to treatment access in and of themselves.[77]

¶28 Yet the developing world continues to suffer without adequate supply of the needed medicines, begging the question what are the primary causes of, or more appropriately, what are the barriers to resolving, the continuing crises and lack of access to life-saving medicines in the developing world. This article suggests that there are two main solutions for the ongoing public health crises in the developing world:

(1) access to existing medicines must increase; and
(2) incentives to promote the development of new medicines and vaccines must increase.

¶29 Part IV elaborates upon these two issues by addressing several barriers currently present and offering indicatives and suggestions in an attempt to alleviate the suffering and resolve the public health crises.

IV. POLICY BASED SOLUTIONS/INITIATIVES AND THEIR VIABILITY

¶30 The public health crisis in the developing world is a global problem and any potential solution cannot be borne by one entity. Instead, the problem requires a commitment from all members of the international community to provide funding and strategic planning to improve the currently insufficient medical infrastructure of many developing world countries. The burden cannot be placed solely on governments of developing or developed countries, on pharmaceutical companies or on international organisations, such as the WHO. Rather, those entities as well as research groups, the media and even the citizenry of developed nations all must participate as vital actors. This section examines how these entities can *all* play a pivotal role in easing the suffering

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http://world.phrma.org/ip.access.aids.drugs.html.html (last visited Jan. 2, 2007) [hereinafter PhRMA 2003].

[76] *Id*.; *see also* INTERNATIONAL INTELLECTUAL PROPERTY INSTITUTE (IIPI), PATENT PROTECTION AND ACCESS TO HIV/AIDS PHARMACEUTICALS IN SUB-SAHARAN AFRICA 52 (2000), *available at* http://www.wipo.int/about-ip/en/studies/pdf/iipi_hiv.pdf (finding the substantial majority of pharmaceuticals to combat HIV/AIDS have never been patented in most African countries).

[77] Amir Attaran & Lee Gillespie-White, *Do Patents for Antiretroviral Drugs Constrain Access to AIDS Treatment in Africa?*, 286 J. AM. MED. ASS'N 1881, 1881-92 (2001). The authors focused on capacity relating problems and concluded that "patents generally do not appear to be a substantial barrier to antiretroviral treatment access in Africa today." *Id*. at 1891.

in the developing world. At the outset, it must be noted that as situations differ for every region and for every disease it is not possible to design one encompassing solution to the problem. Therefore, the following merely offers general indicatives and suggestions which should be further studied and employed as the situation dictates.

A. Global commitment from developed countries

¶31 The suffering in the developing world will not be alleviated without a global commitment to finance health improvements. As developing countries historically do not have the necessary resources and/or will to finance such an initiative, advanced industrialized countries must take on more responsibility and lead the way in funding the restructuring of the current inadequate medical infrastructure that exists in so many developing countries. One funding initiative governments could take is to raise general revenues through the wide range of available tax instruments or shift financing from other domestic areas to fund this global initiative.[78] Practically speaking, however, neither option is particularly appealing as governments are hesitant to raise taxes or shift funds from certain domestic areas to any international effort due to potential opposition by their citizens or embarrassment by opposing political parties.

¶32 In this regard, the media and international organisations – such as the WHO – may be able to play a significant role in raising awareness of the extent to which widespread epidemics ravage much of the developing world. Unfortunately, for many in the developed world, epidemics such as malaria and tuberculosis seem so far removed from their highly industrialized societies, where such diseases do not exist or are controlled to acceptable levels, that often the awareness generated does not arouse sufficient empathy to the cause. This apathy, and corresponding shortage of international funding, is a major contributing factor to the ongoing public health crises in the developing world. This fact led Attaran and Gillespie-White to conclude that "the extreme dearth of international aid finance, rather than patents, is most to blame for the lack of antiretroviral treatment in Africa."[79]

¶33 On the other hand, there is clear evidence that both governments and citizens of the industrialized world can be generously responsive to public health crises. For instance, one need only look back at the international response to the 2004 Boxing Day Tsunami disaster, where worldwide broadcasting of the sudden devastation resulted in billions of dollars of aid donations within a matter of weeks to fund the provision of necessary medicines, food, clean water and other relief efforts.[80] The large-scale international outpouring of aid was no doubt largely a result of people visualising the suffering of

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[78] For instance, the often posed, so-called Tobin Tax (a tax on cross border currency trades across borders) could be implemented nationally by industrialized countries (but enforced multi-nationally) to raise an estimated $100-$300 billion per year. However, in addition to a lack of support within the citizenry of most nations, leading developed countries also oppose the Tobin Tax as it would reduce the currency exchange market, the consequences of which are unknown.

[79] Attaran & Gillespie-White, *supra* note 77, at 1891.

[80] See, for example, the responses of the British Red Cross, Boxing Day Tsunami, 2004: Background Information, http://www.redcross.org.uk/standard.asp?id=46361 (last visited Jan. 2, 2007), USAID, USAID Rebuilds Lives After the Tsunami, http://www.usaid.gov/locations/asia_near_east/tsunami/ (last visited Jan. 2, 2007), Asia Relief, Indonesia Floods, http://asiarelief.win.aplus.net/ (last visited Jan. 2, 2007) and MSF/DWB, MSF Operations & Financial Overview: One Year After The Indian Ocean Tsunami Disaster, http://www.doctorswithoutborders-usa.org/news/sasia_tsunami/index.cfm (last visited Jan. 2, 2007).

millions of displaced people and the death of hundreds of thousands of people in the days following the disaster.[81] Perhaps if there was extensive coverage of public health issues in the media informing of the urgency to control widespread epidemics such as HIV/AIDS and malaria, a similar outpouring of aid relief may be possible. At the very least, the campaign may lead to a positive and willing response by citizens of developed countries to support government actions to raise taxes or redistribute domestic funding for this international initiative.[82]

¶34 Developed countries do currently contribute to the fight against diseases in a number of ways, including partially financing medical programmes such as the Global Fund to fight AIDS, Tuberculosis and Malaria[83] While such initiatives are certainly a step in the right direction, developed countries have been criticized for their lack of commitment to the effort.[84] In this regard, not only must the international community commit to increased financing and aid efforts, but perhaps more importantly, it needs to actually execute and fulfill its existing aid promises and commitments. Increased levels of properly targeted, long-term aid would go a long way towards alleviating the public health crises while at the same time assisting countries in working to end economic dependency.[85] In fact, the situation would improve if countries merely fulfill their commitment to providing an amount equal to 0.7% of gross national income (GNI) on official development assistance (ODA).[86] Increased aid, however, will not materialize without effective monitoring coupled with the minimisation of waste and a reduction in corruption; in other words, the international community will only increase their financial obligations and commitment to the developing world when they are confident the aid will be effective.[87]

¶35 Closely tied to the above is the fact that a lack of coordination of international aid currently impedes the efficient and effective use of aid.[88] The need for large-scale, long

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[81] See sources cited *supra* note 80 for facts, figures and stories of the disaster and relief efforts.

[82] It has been suggested that economic prosperity or recession may play a part in countries increasing aid–or meeting their targets–to the developing need world. In this regard, a well-functioning global economy can be viewed as a precondition to increased aid. *See* UN MILLENNIUM PROJECT 2005, *supra* note 1, at 94.

[83] The Global Fund is a partnership between governments, civil society, the private sector and affected communities created to support international health financing. The Global Fund has, to date, committed $4.9 billion in 131 countries to support aggressive interventions against all three. For more information, see The Global Fund, http://www.theglobalfund.org/en (last visited Jan. 2, 2007).

[84] *See, e.g.*, Frederick M. Abbott, *Commentary: The International Intellectual Property Order Enters the 21st Century*, 29 VANDERBILT J. TRANSN'L L. 471 (1996).

[85] *See generally* UN MILLENNIUM PROJECT 2005, *supra* note 1, and specifically the recommendations on pages 147-49.

[86] This now widely cited figure was first pledged in a 1970 General Assembly Resolution and has been affirmed many times, including at the International Conference on Financing for Development in Monterrey, Mexico at paragraph 42 and at the World Summit on Sustainable Development in Johannesburg at page 52. In 2004, the total ODA to developing countries increased 4.6% from the previous year to $78.6 billion, a figure which represents only 0.25% of Development Assistance Committee (DAC) members' combined GNI. *See* Organisation for Economic Co-operation and Development, Official Development Assistance increases further--but 2006 Targets Still a Challenge, http://www.oecd.org/document/3/0,2340,en_2649_201185_34700611_1_1_1_1,00.html (last visited Jan. 2, 2007).

[87] UN MILLENNIUM PROJECT 2005, *supra* note 1, at 104.

[88] A number of efforts also discount the need for effective community inclusion, participation and empowerment in any international efforts. *See, e.g., id.* at 101. However, a WHO study found that the more successful aid efforts involve the local community and most also respond to an area of need, on the request

term assistance and aid is well known and understood, but the present system of distributing aid and assistance is disparate, wasteful and lacking transparency.[89] The current system sees groups and organisations competing with each other and duplicating technical, research and on the ground efforts.[90] In short, useful information and analysis is not well known or published and experiences within organisations, nations or regions are not transferred to others. Not only does this damage and marginalize aid efforts, but it also makes it hard to get adequate levels of assistance and even maintain sufficient quality of drugs.[91] A properly administered system which increases coordination and transparency of activities would improve the situation by combining resources and efforts to maximize efficiency and targeted assistance. While financing is certainly imperative to controlling the pubic health crisis in the developing world, it is not the only global initiative in which nations must engage. Other positive actions that developed countries and international bodies such as the WHO and UN could take to control the crises in the developing world include negotiations and planning efforts with the heads of the affected developing nations to devise strategic plans to distribute funds efficiently and effectively in those affected countries.[92]

B. Political commitment from developing nations

¶36 The burden and responsibility for alleviating the public health crisis in the developing world should not fall solely on developed country governments. On the contrary, important to any effort is a concurrent political commitment from the governments of the developing nations in the midst of widespread epidemics to control and alleviate the problem. At present, it is clear that there is an inadequate level of national commitment of developing country governments to prioritize healthcare.[93] Like many of the other barriers listed in this section, the lack of commitment transcends

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of the beneficiary country. *See generally* WHO, GUIDELINES FOR DRUG DONATIONS (1999), http://www.drugdonations.org/eng/richtlijnen/eng_guidelinesdrugdonation.pdf.

[89] *See* ROY WIDDUS & KATHERINE WHITE, COMBATING DISEASES ASSOCIATED WITH POVERTY: FINANCING STRATEGIES FOR PRODUCT DEVELOPMENT AND THE POTENTIAL ROLE OF PUBLIC-PRIVATE PARTNERSHIPS 23 (Abr. ver. 2004), *available at* http://www.globalforumhealth.org/filesupld/ippph/CombatingDiseases.pdf; UN MILLENNIUM PROJECT 2005, *supra* note 1, at 5-6, 30, 42-45, 63.

[90] For a specific example, see Widdus & White, *supra* note 89, at 21-22.

[91] *See* UN MILLENNIUM PROJECT 2005, *supra* note 1, at 41, 100; Patrice Troullier et al., *Drug Development for Neglected Diseases: A Deficient Market and a Public Policy Failure*, 359 THE LANCET 2188 (2002); *see generally* WARREN A. KAPLAN, ET AL., THE IMPACT OF REGULATORY INTERVENTIONS ON PHARMACEUTICAL ACCESS AND QUALITY: WHAT IS THE EVIDENCE AND WHERE ARE THE GAPS IN OUR KNOWLEDGE? (2003), *available at* http://dcc2.bumc.bu.edu/richardl/RPM+_Project/Regulation&QA/Regulation-evidence-Feb2003.doc; WHO CMH, MACROECONOMICS AND HEALTH: INVESTING IN HEALTH FOR ECONOMIC DEVELOPMENT (2001), *available at* http://www.cid.harvard.edu/cidcmh/CMHReport.pdf [hereinafter WHO CMH 2001].

[92] A possible avenue for the distribution of funding could be to establish domestic manufacturers in non-producing countries to save these countries from relying on TRIPS mechanisms for imports of generic versions of drugs. However, there is evidence to suggest that this would not be a viable expenditure of funding due to the need for the drugs to meet an internationally recognized quality standard, which would make it difficult for these producers to offer competitive prices. *See* BROOK BAKER, DFID HEALTH SYS. RES. CTR., PROCESSES AND ISSUES FOR IMPROVING ACCESS TO MEDICINES: WILLINGNESS AND ABILITY TO UTILISE TRIPS FLEXIBILITIES IN NON-PRODUCING COUNTRIES (2004), *available at* http://www.iprsonline.org/resources/docs/Baker_TRIPS_Flex.pdf.

[93] *See* UN MILLENNIUM PROJECT 2005, *supra* note 1, at 29.

boundaries and depends upon a number of factors. Reasons for the lack of prioritization, however, include a lack of political will by policymakers, blatant corruption at every level of the public sector,[94] a lack of health infrastructure or even pre-conditions necessary for adequate healthcare, restrictive donor programs, large scale debt repayments, and strict conditions for loans from international financial institutions that may have the effect of further precluding basic social service needs of citizens.[95]

¶37 The lack of political will of developing countries combined with a lack of capacity to deliver proper healthcare solutions is the most prominent detriment to resolving, alleviating or even lessening the health crises.[96] At present, even when essential vaccines and medicines are heavily discounted or even donated to developing markets, the cost of transportation, storage and administration of vaccines and medicines often cost more than the drugs themselves.[97]

¶38 Evidence indicates that the majority of developing countries and LDCs lack the economic foundation to sustain a properly functioning public health climate, which includes the costs of purchasing, storing, transporting, and administering needed medicines.[98] For instance, LDCs, on average, spend approximately US$11 per capita on health[99] – as compared with $US93 for lower middle-income nations and $US1,907 for developed nations – thus, even when pharmaceutical companies donate necessary drugs

[94] In 2006, Forbes magazine named Teodoro Obiang Nguema Mbasogo, the president of troubled Equatorial Guinea, as the eighth wealthiest leader in the world with an estimated wealth of $600 million. In addition, while oil was discovered in 1995, little money has reportedly been released outside the Obiang family and the country has declined in almost all UN standards over the last decade. It must also be noted that American-owned Riggs Bank was fined for not reporting possible money laundering following the deposit of over $700 million following the discovery of oil. The money was released to Obiang. Obiang and his immediate family also recently owned two multi-million dollar homes in Maryland and the Obiang's son reportedly paid $700,000 to rent Microsoft co-founder Paul Allen's yacht, Tatoosh. Luisa Kroll, Fortunes of Kings, Queens and Dictators, Forbes.com, May 4, 2006, http://www.forbes.com/billionaires/2006/05/04/rich-kings-dictators_cz_lk_0504royals.html. It is also widely believed that former Indonesian President Suharto embezzled more than $10 billion during his 33-year dictatorship; Zaire's (now the Democratic Republic of Congo) former leader Mobutu Sese Seko, overthrown in a 1997 revolt, was reputed to be worth between $4-8 billion; Former Philippine Ferdinand Marcos apparently embezzled $5 billion in government funds during his 20 years in power. Less than $1 billion was ever recovered after his overthrow. See Arik Hesseldahl, How Dictators Manage Their Billions, Forbes.com, June 22, 2000, http://www.forbes.com/2000/06/22/feat.html.

[95] For instance, the IMF has repeatedly recommended that countries limit their health expenditures as a means to combat inflation as a condition to a loan. UN MILLENNIUM PROJECT 2005, *supra* note 1, at 96.

[96] The TRIPS Agreement provides significant flexibilities and wide discretion for determining public health policy and even the conditions of compulsory licensing laws. *See* SISULE MUSUNGU & CECILIA OH, THE USE OF FLEXIBILITIES IN TRIPS BY DEVELOPING COUNTRIES: CAN THEY PROMOTE ACCESS TO MEDICINES (2005), *available at* www.who.int/intellectualproperty/studies/TRIPSFLEXI.pdf.

[97] *See* Mercurio, *supra* note 16, at 246-47.

[98] For statistics on worldwide poverty, see Shaohua Chen & Martin Ravallion, *How Have the World's Poorest Fared Since the Early 1980s?*, 19(2) World Bank Res. Observer 141–70 (2004).

[99] In some countries, the situation is even more dire. For instance, in Cote d'Ivoire, a discounted treatment for AIDS cost $3.48 per day, but in a country where the average GDP per day is $1.94 and donor assistance only adds $0.03 per day, the price still makes the drug unattainable. UN MILLENNIUM PROJECT 2005, *supra* note 1, at 65. WIPO states: "Even reducing the price of HIV/AIDS treatments to cover the costs of basic manufacturing and distribution alone–as was recently done in a number of countries hardest hit by the crisis–still keeps the cost of annual treatments at between $350 and $600 per year. These prices, which are similar to the cost of generic versions of the same drugs and make no provision for recouping the cost of research and development, are still above the annual per capita incomes of some countries with high levels of HIV/AIDS." WIPO No. 491(E), *supra* note 63.

to these countries, these developing countries still cannot afford the storage and administrative costs associated with receiving the drugs.[100]

¶39 The poor level of existing infrastructure in many developing countries is evidenced by inadequate health facilities, lack of hospital beds and laboratories, lack of trained medical and laboratory staff[101] and incomplete or non-existent drug distribution systems.[102] Inefficient use of aid and resources, poor management and little oversight of existing programs is also a large impediment to maintaining a properly functioning public health system.[103] Additionally, it must be noted that in order to see any meaningful progress, significant monetary resources must also be expended to meet the most fundamental of needs for food and clean water to remove some of the conditions leading to illness and disease and to build the necessary medical infrastructure to enable the provision of adequate health services.[104]

¶40 Developing countries do not have the monetary resources to combat these health problems.[105] As illustrated throughout this article, developing countries need assistance in alleviating poverty, minimizing social disruptions, overcoming inconsistent donor aid and encouraging research and development on diseases primarily afflicting the developing world in order to eliminate or at the very least lessen the burden and create a situation more conducive to the provision of health services. Developing countries, however, can help themselves in this process. The first step in finding a long term solution to the problem is for governments in the developing world stricken with health crises to adopt a national medicines policy.[106] The design and implementation of this

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[100] Alan Moran, *Trade Laws and Pharmaceuticals*, 53(4) INST. PUB. AFF. REV. 25, 26 (2001); WHO CMH 2001, *supra* note 91; INTERNATIONAL CHAMBER OF COMMERCE (ICC), FURTHER VIEWS ON CROSS BORDER COMPULSORY LICENSING 8 (2002), *available at* http://www.wto.org/english/forums_e/ngo_e/icc_paper_aug03_e.pdf. There is "increasing international agreement that $30 per capita represents the lower bound [needed to provide health services]." UN MILLENNIUM PROJECT 2005, *supra* note 1, at 63. The price of the cheapest generic triple cocktail to combat HIV/AIDS, on offer by Indian manufacturer Cipla, costs $350 per person per year. *See* PhRMA 2002, *supra* note 75 (PhRMA said the marketing and selling of drugs without any price differential to developing countries is cruel and costs lives. One example of this is the marketing of a Hepatitis C treatment at $30,000 a year. This makes the drug unaffordable to most governments and creates a situation whereby only the wealthy citizens can afford treatment.); MSF 2005, *supra* note 60.

[101] The shortage of trained medical practitioners, nurses, aids, technicians, pharmacists, and pharmacy technicians is "a growing problem that, if unaddressed, threatens to undermine all efforts to strengthen health systems and improve healthcare in much of the developing world." UN MILLENNIUM PROJECT 2005, *supra* note 1, at 30.

[102] *See*, e.g., UN MILLENNIUM PROJECT 2005, *supra* note 1, at 80-81.

[103] Prescription practices in several developing countries have been referred to as wasteful and dangerous. For example, for every $30 of medicine reaching its target (through donations or otherwise), $15 is squandered and $3 more is lost on non-compliance by patients. *See id*. at 86, 88.

[104] *See generally* WORLD BANK, IMPROVING HEALTH, NUTRITION AND POPULATION OUTCOMES IN SUB-SAHARAN AFRICA (2005). In the United Nations Millennium Declaration, the UN set eight goals for development (the Millennium Development Goals or MDGs) and an agenda for improving the human condition by 2015. *See* UN Millennium Declaration, G.A. Res. 55/2, U.N. GAOR, 55th Sess., Supp. No. 49, at 4, U.N. Doc. A/55/49 (2000). More on the MDGs can be found at the UN Millennium Project website, *supra* note 10.

[105] For instance, donations and other aid reportedly account for 52% of Uganda's national budget. *See* UN MILLENNIUM PROJECT 2005, *supra* note 1, at 39.

[106] The Working Group on Access to Essential Medicines calls this a "necessary component of an overall health policy." UN MILLENNIUM PROJECT 2005, *supra* note 1, at 95. The World Bank has defined such policies as existing to ensure that "safe and effective drugs of good quality are available and affordable to the entire population and that they are rationally used." *Id.* at 32 (citing WORLD BANK, WORLD DEVELOPMENT REPORT 1993: INVESTING IN HEALTH (1993), *available at* http://www-

policy should enable the country to meet its national health needs as well as be simplistic enough to enable its realisation.[107] One part of this policy should be a strategy for providing essential medicines to citizens. The importance of such a government policy initiative cannot be understated, as policies and programmes initiated to increase access to essential medicines or to improve the health of a nation can rarely succeed without the support and understanding of all levels of government. For instance, an ambitious health policy without financial support from the government, proper infrastructure and resources for training healthcare workers, sufficiently salaried public servants (including but certainly not limited to healthcare workers), and the implementation of trade, taxation and customs policies creating conditions conducive to smoothly facilitate the improvement of health conditions, is likely to fail.[108] Moreover, institutions such as the police, the judiciary and regulatory bodies must be adequately financed in order to stem rampant corruption. In addition, and importantly, countries must recognize the effect of civil instability on public health (displaced citizenry, lack of and poor quality water, food shortages and a lack of quality medicine and health services). Simply stated, efforts aimed at resolving the problem of access to essential medicines problems will be fruitless if there is a lack of political commitment in the affected developing nation to refocus priorities to the health, or even the public, sector.[109]

¶41 In order to alleviate the situation, governments must also reorientate their priorities and devote more of their scarce resources to meeting the health needs of their citizens. The need for such a reorientation is evidenced by relatively low budgeting for and expenditures on public health[110] which in turn causes shortages of storage facilities, transportation networks, and medical equipment and personnel.[111] In addition, in many

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wds.worldbank.org/servlet/WDS_IBank_Servlet?pcont=details&eid=000009265_3970716142319).

[107] The Working Group on Access to Essential Medicines states that such a policy must be "comprehensive and well-planned" and employ "well-proven principles" based on the essential medicines concept as adopted to the needs of the individual country. Effective monitoring of the system's implementation is also crucial to its success. *Id.* at 95-96. *See also* WHO, *Framework for Action*, 2(1) WHO POLICY PERSPECTIVES ON MEDICINES 2 (2002).

[108] *See* UN MILLENNIUM PROJECT 2005, *supra* note 1, at 32. The Working Group also noted several other crucial factors which impact upon the success of a national health policy, namely: the understanding of local conditions, long-term (local and international) support from the public and private sectors, the prioritization and targeting of access to medicines, and sufficient data and analysis in order to identify and target critical problems and barriers. *Id.* at 95. For a detailed analysis of the problem of healthcare workers see WHO, WORKING TOGETHER FOR HEALTH: THE WORLD HEALTH REPORT 2006 (2006), *available at* http://www.who.int/whr/2006/whr06_en.pdf.

[109] *See* WHO 2004, *supra* note 3. Thus, in many developing countries, wealthy citizens who can afford to be treated privately have access to essential medicines while poorer citizens who rely on the public health system are deprived of essential medicines and treatments. *See* UN MILLENNIUM PROJECT 2005, *supra* note 1, at 95.

[110] *See* MARTIN FOREMAN, BEYOND OUR MEANS? THE COST OF TREATING HIV/AIDS IN THE DEVELOPING WORLD 13 (2000). Compounding the problem is the heavy debt burden of many developing nations. For details and figures, see Jubilee Debt Campaign, http://www.jubileedebtcampaign.org.uk (last visited Jan. 2, 2007).

[111] It has been estimated that over 20,000 health professionals annually emigrate from Africa. UN MILLENNIUM PROJECT 2005, *supra* note 1, at 97. This contributes to the continent spending $4 billion on 100,000 foreign health workers annually. *Id.* The reasons behind the emigration include: doctors being more skilled and advanced than required by local populations (little intellectual stimulation); poor remuneration; lack of incentives to stay or return home; security threats, violence and safety; education for children; poor working conditions; oppressive political climate; persecution of intellectuals, discrimination; lack of research funding and poor facilities; and limited career options. To reverse this trend, the PHP calls for the establishment of full fee-paying universities to train doctors for export, increased training, increased

parts of the developing world, corruption on the part of high level government officials or poorly paid public servants prevents the drugs from reaching the intended beneficiaries.[112] The impact of corruption in the health network of developing countries is significant and costly, both in monetary and human terms, and often prevents even the cheapest of treatments from reaching hospitals and patients.[113] A reorientation of resources could also fund (with the assistance of international aid) increased educational efforts, the dissemination of information and in-service training as well as better retention of skilled workers (and hopefully decrease the incidence of corruption) and compensation schemes for countries that lose health workers.

¶42 Another significant burden to the access of essential medicines is the fact that governments of many developing countries place tariffs, levies, duties and other taxes on pharmaceutical drugs and equipment crossing into their borders, thereby significantly raising the price of the drugs for patients in their own countries.[114] For instance, while the average tariff on medicines is 18%, several developing countries and LDCs levy much higher rates on medicines entering their respective countries.[115] For example, the incredibly poor Democratic Republic of the Congo levies a 30% duty on all drugs crossing its borders, with further taxes adding at least another 13% to the final price at which the drugs can be provided to its citizens.[116] Moreover, other countries in the midst of public health crises such as India, Sierra Leone, Nigeria and Bolivia also impose significant tariffs on the importation of pharmaceuticals at 55%, 40%, 34% and 32% respectively.[117] Examples of governments that charge excessive sales tax on medicines include South Africa (14%), Argentina (21%), Bangladesh (15%), the Dominican Republic (28%), Greece (15%) and Turkey (18%).[118] Perhaps worst of all is India, which, having more than 3 million HIV/AIDS cases and only 17,000 patients being regularly treated, charges at least 25% duty on medicines.[119] In total, large mark-ups are being paid even when tariff rates are low or even zero.[120] Incredibly, Kenya, Morocco

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salaries and support (housing, transport, etc.) and improving and stimulating the working environment (computers, journals, etc.). *Id.*

[112] UN MILLENNIUM PROJECT 2005, *supra* note 1, at 29, 96-98, 148. For instance, a reported 25% of discounted drugs sent to Africa from GlaxoSmithKline between June 2001 and July 2002 failed to reach their intended destination. Carol C. Adelman, et al., *Myths and Realities on Prices of AIDS Drugs*, HUDSON INST. 13 (2004) [hereinafter Adelman, et al., *Myths and Realities*].

[113] *See, e.g.*, FOREMAN, *supra* note 110, at 16.

[114] *See, e.g.*, U.N. Comm. on Econ., Soc. & Cultural Rights, *Report of the High Commissioner, Economic, Social and Cultural Rights: The Impact of the Agreement on Trade-Related Aspects of Intellectual Property on Human Rights*, UN Doc. E/CN.4/Sub.2/2001/13 (2001). Moreover, border delays caused by the facilitation of customs requirements pertaining to tariffs and taxes sometimes result in the medicines expiring during the delays or suffering medicinal degradation due to suboptimal storage facilities (such as heat, cold, humidity or light). *See* UN MILLENNIUM PROJECT 2005, *supra* note 1, at 80.

[115] Adelman et al., *The Full Cost of HIV/AIDS Treatment*, *supra* note 62, at 10.

[116] Adelman et al., *Myths and Realities*, *supra* note 112, at 3.

[117] UN MILLENNIUM PROJECT 2005, *supra* note 1, at 80.

[118] *See* Roger Bate, *The Sick are Taxed to Death in Poor Countries*, FIN. TIMES (LONDON), May 31, 2004, *available at* http://www.fightingmalaria.org/news.php?ID=261 (last visited Jan. 2, 2007).

[119] *See id.*; Roger Bate, *Taxed to Death*, American Enterprise Institute for Public Policy Research: Short Publications, Jul. 5, 2006, http://www.aei.org/publications/filter.all,pubID.24624/pub_detail.asp. For more details and similar statistics on a number of other nations, see Adelman et al., *The Full Cost of HIV/AIDS Treatment*, *supra* note 62, at 10-12.

[120] For instance, pharmaceuticals enter Sri Lanka, Kenya and Armenia duty free, but the final mark-up in those countries due to other taxes and the like is 64%, 54.2% and 87.5%, respectively. *See* Adelman et al., *Myths and Realities*, *supra* note 112, at 11.

and Peru impose such high levels of tariff and taxes on imported medications that the citizens of those countries pay a higher price than the domestic market of the drugs' manufacture – even with price differentiation.[121]

¶43 As a result of the application of tariffs and taxes, the actual price of imported medicines in certain developing countries can be over 50% more than the reported value of the drug. To illustrate, when the Clinton Foundation in October 2003 "brokered" a deal to lower the price of an HIV drug treatment to US$140 a person a year, the final price at which the drugs were provided to citizens was, at its lowest, US$277 in Cameroon.[122] In Mozambique, the price was US$389 and in Honduras it was US$426.[123]

¶44 Quite obviously, a simple step that every government can take to lower the costs of pharmaceutical drugs and equipment is to lower tariffs, levies, duties and other taxes that raise the price, and therefore reduce access of the medicines to its populace.[124] The argument that the countries which levy significant tariffs need the revenues is intellectually shallow, short-sighted and reveals the priority the countries have placed on public health. The unnecessary raising of prices of essential medicines through tariffs and other taxes is without question unconscionable and a continuing cause of the significant loss of life.

¶45 Reducing tariffs and taxes on the importation of pharmaceuticals and related products, as well as improving the distribution of health products and services, and maintaining quality of the pharmaceutical supply through reliable testing facilities are key issues which governments must address in the fight to improve the lives of many in the developing world.[125] While most, if not all, developing countries need financial assistance to meet these standards, it is clear that "some developing countries have aggregate national resources sufficient to meet all the primary healthcare needs of their citizens, yet non-health priorities are … given precedence."[126] Unfortunately, the barrier of lack of political will demonstrated by the governments of several countries to address the public health crises in their countries is a problem for which there is not a clear solution. States cannot generally interfere in the activities of other States and so there is little that the governments of other nations can do to stop the mismanagement and corruption that is prevalent in many developing countries or to change the cultural views that impede access to essential medicines and a proper health infrastructure.[127] If much of the monopoly that funds the lavish exercises of government officials in developing countries is diverted to build medical infrastructure and control the epidemic diseases prevalent, then together with commitment from developed countries and the international

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[121] *See* WORLD HEALTH ORG. & HEALTH ACTION INT'L, MEDICINE PRICES — A NEW APPROACH TO MEASUREMENT 99-100 (2003), *available at* http://whqlibdoc.who.int/hq/2003/WHO_EDM_PAR_2003.2.pdf for the price survey methodology.

[122] Adelman et al., *Myths and Realities*, *supra* note 112, at 4.

[123] *Id.* at 5.

[124] *See* UN MILLENNIUM PROJECT 2005, *supra* note 1, at 81 (stating "[t]axes and tariffs on essential medicines should be eliminated; they negatively affect affordability and competition").

[125] *See id.* at 63-64. For problems of distribution, particularly to rural areas, and the role of NGOs in assisting with their own distribution systems, see *id.* at 80-81.

[126] *Id.* at 39.

[127] For example, since 2000, only two African countries (Uganda and Botswana) have accepted an offer by German pharmaceutical company Boehringer Ingelheim to provide free donations of an anti-retroviral drug designed to prevent pregnant women suffering from HIV/AIDS from infecting their unborn babies. Geoff Dyer, *Only Two African States Take Up Aids Offer*, FIN. TIMES, July 14, 2003, at 8.

community, the suffering of millions may be eased. However, considering that in some developing nations, governments have not been elected democratically, changing the political situation will be difficult. The most that can be done is for the international community to place pressure on these governments to make a commitment to their citizens to alleviate the worsening situation. However, as mentioned above, the lack of commitment from developing country governments may be impeding increased aid from the developed world.

¶46 Another method developing countries can utilize to reduce expenditures on drugs is regional negotiation using potential purchasing power as an advantage. While this strategy may not be appropriate in every setting, regional negotiating efforts have proven to be successful in the eastern Caribbean.[128] It has been noted, however, that such a strategy requires, among other things, significant purchasing power, homogeneity of members, financial stability, prediction of needs, loyalty and monitoring.[129] However, even if countries cannot make use of bargaining strengths, all developing countries can guarantee price transparency when purchasing drugs and medical supplies to ensure, *inter alia*, competition and rational decision making.[130]

¶47 In a perfect world, developing countries would be able to ease the ongoing health crises by simply increasing local production of pharmaceuticals but the reality is that this involves large capital investment, basic infrastructure capable of supporting such a venture, trained technical staff and ongoing costs, *i.e.*, maintaining quality and standards. In addition, competition is fierce in the global pharmaceutical market and a developing country start-up faces many challenges. Thus, despite a World Bank report deeming it technically feasible for a developing country to build a pharmaceutical industry, it is doubtful whether it will be able to compete with the already established industries in India and Brazil, among others.[131]

¶48 That said, numerous benefits can result from having a local industry and establishing such an industry is an option which should be explored by developing countries.[132] For example, native industries have recently been promoting technology

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[128] *See* UN MILLENNIUM PROJECT 2005, *supra* note 1, at 77.

[129] *Id*.

[130] For more on the necessary elements of price transparency, see *id*. at 76*; see also* MSF, UNTANGLING THE WEB OF PRICE REDUCTIONS: A PRICING GUIDE FOR THE PURCHASE OF ARVS FOR DEVELOPING COUNTRIES (8th ed. 2005), *available at* http://www.accessmed-msf.org/documents/untanglingtheweb%208.pdf.

[131] In order for such a plan to succeed, technology transfers, increased research capacity and increased manufacturing capabilities all need to be received or addressed.

[132] It is worth noting that generic and counterfeit drugs manufactured in developing countries are often of substandard quality, dangerous, or even lethal. *See* WHO, MEDICINES STRATEGY: COUNTRIES AT THE CORE 2004-2007 5, 90, 95, 97, 104-06, 143 (2004), *available at* http://whqlibdoc.who.int/hq/2004/WHO_EDM_2004.5.pdf (citing recent WHO assessments that found 50%-90% of samples of antimalarial drugs failed quality control tests and more than half of ARVs assessed did not meet international standards); WHO, WHO Factsheet No. 275, Substandard and Counterfeit Medicines, http://www.who.int/mediacentre/factsheets/2003/fs275/en/ (last visited Jan. 4, 2007); Liza Gibson, *Drug Regulators Study Global Treaty to Tackle Counterfeit Drugs*, 328 BRIT. MED. J. 486 (2004) (reporting that counterfeit drugs account for 40 to 50% of all drugs sold in Nigeria and Pakistan). International standards have been formulated (and supported by the WHO), such as GMP and International Conference on Harmonization (ICH), in an attempt to maintain proper quality and safety standards in the production of drugs in the developing world. While such standards are complex and increase production costs, they save lives. At present, only a minority of manufacturing facilities are in compliance with the standards and the international community must convince manufacturers to meet the standards (for example, by procurement agencies insisting the standards be met before purchasing the drugs and by

transfers and participating more directly in research and development of diseases afflicting the local population.[133] In addition, generic industries in such countries as Brazil have acted to lower the price of drugs in recent years.[134] Brazil also successfully reduced the price of several drugs by threatening to issue a compulsory licence unless the patent holder reduced the price of the drug in question.[135] In each instance, the patent holder eventually succumbed to the threat because Brazil has the technological capacity and well-established generic pharmaceutical industry to manufacture sufficient quantities of the drug in question.[136] Without a native industry, such threats would merely be idle and could not be acted upon.[137]

¶49 Unfortunately, all of the above (as well as international efforts) will be for naught if simple information regarding infectious diseases fails to be effectively communicated to the populace. In this regard, the governments of the developing world have failed and this failure is no more apparent than in South Africa, which until 2002 denied that HIV caused AIDS.[138] More recently, former South African Deputy President Jacob Zuma, in his trial for allegedly raping an AIDS activist, admitted to having unprotected sex with the woman despite knowing that she was infected with HIV.[139] Moreover, Zuma – who

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facility inspections). In addition, the prequalification of producers should be further explored (with a removal process) by the standard-setting bodies and the WHO. The manufacture and sale of substandard and counterfeit medicines is also a large problem in the developing world. Some countries facilitate this problem by having weak governmental regulatory agencies handle procurement and importation schemes. Substandard medicines are sometimes the result of unintentional error. At other times, it is intentional, misleading conduct which produces the inadequate drugs (this is particularly the case in India, where Schedule Y of India's Drug and Cosmetics Act does not even require toxicity or bioequivalence data for drugs being exported). Substandard medicines are a major problem, as they lead to resistance and deaths. Inspection and both civil and criminal penalties are needed to reduce the proliferation of inadequate medicines. In addition, procurement, customs, and regulatory agencies must be provided with adequate resources to enforce laws, and the judicial system needs to be equipped to handle such cases.

[133] For instance, several initiatives have been formed involving developing country research centers/universities, universities in developed countries and pharmaceutical companies (such as one initiative involving the Kenya Medical Research Institutes collaboration with GlaxoSmithKline and the University of Liverpool for an anti-malaria treatment). *See Prescription for Healthy Development: Increasing Access to Medicines*, *supra* note 1, at 11.

[134] *See* MSF 2004, *supra* note 1.

[135] *See, e.g.*, Andrew Pollack, *Defensive Drug Industry Fuels Fight Over Patents*, N.Y. TIMES, April 20, 2001, at A6; Mark Drajem, Brazil Pushes Merck, Pfizer to Cut Drug Costs Amid WTO Talks, BLOOMBERG, Aug. 28, 2003, http://quote.bloomberg.com/apps/news?pid=10000103&sid=a_804W5JtnZc&refer=us; Paulo Prado, *Brazil Again Seeks to Cut Cost of AIDS Drug*, N.Y. TIMES, April 20, 2001, *available at* http://www.nytimes.com/2005/08/19/business/19abbott.html?ex=1165035600&en=07473c1d770ae211&ei=5070. For similar reports and newspaper articles, see http://www.cptech.org/ip/health/c/brazil/. *See also* Paul Vandoren & Jean Charles Van Eeckhaute, *The WTO Decision on Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, 6 J. OF WORLD INTELL. PROP. 779, 793 (2003).

[136] Both South Africa and Kenya have likewise received voluntary licenses for the same reason. UN MILLENNIUM PROJECT 2005, *supra* note 1, at 62.

[137] This strategy does have its limitations, as the voluntary license provides the drugs at a lower cost than previously obtainable, but does not involve any technology transfer or facilitate the development of a technologically improved domestic industry. *Id.*

[138] *AIDS Ignorance*, USA TODAY, May 11, 2006, at 17A, *available at* http://www.usatoday.com/news/opinion/editorials/2006-05-10-aids-edit_x.htm[hereinafter *AIDS Ignorance*].

[139] Manoah Esipisu & Rebecca Harrison, *South Africa's Zuma Acquitted of Rape*, THE BOSTON GLOBE, May 8, 2006, http://www.boston.com/news/world/africa/articles/2006/05/08/safrica_set_for_verdict_in_zuma_rape_trial/?rss_id=Boston.com+%2F+News.

once headed South Africa's anti-AIDS campaign – testified that he "took a shower" after the sexual encounter to diminish the risk of infection.[140] Furthermore, South Africa continues to promote lemons, beetroot, garlic and other traditional medicine as HIV/AIDS preventative medicine while at the same time publicly criticizing the side effects of ARV drugs.[141] Such practices recently drew the ire of the international community at several AIDS conferences, where its policies and drug delivery record were chastised and for embracing theories worthy of the "lunatic fringe."[142] With such ignorance shown by the leaders of South Africa, it is questionable whether any coordinated effort will be effective until domestic knowledge is substantially improved.

C. Innovative financing solutions for new medicines

¶50 In addition to patent protection, the pharmaceutical industry has also often been a scapegoat for the lack of access to life-saving drugs in the developing world, with many asserting that the industry should devote more resources to illnesses and diseases affecting developing countries.[143] This criticism is overly simplistic and does not accurately reflect the situation. For instance, 77% of the WHO Essential Drugs List between 1977 and 2002 originated or were substantially developed by the pharmaceutical industry.[144] In addition, as noted above, pharmaceutical companies routinely sell pharmaceuticals at heavily reduced prices to developing countries in order to promote goodwill and, in all probability, to counter the negative publicity the industry has received in recent years. However, even the most ardent critic should realize that it is unrealistic to ask the industry to incur losses ad infinitum. But the situation of donations and voluntary reductions of pricing is different than one which requires the industry to discount or donate its product or to forgo its patent rights in that such a mandate results in a de facto discriminatory tax on the industry; such a de facto tax would place the pharmaceutical industry at a significant disadvantage in its ability to compete for capital and other resources with other industries.[145] Much like every other industry, one can only expect the pharmaceutical companies to continue researching and developing new drugs to combat health problems associated with the developing world when it can expect a reasonable return on its investment.

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[140] *AIDS Ignorance*, *supra* note 138.

[141] *See, e.g.*, *Beetroot But No Blushes*, ECONOMIST, Aug. 24, 2006, at 40. South Africa's health minister, Manto Tshabalala-Msimang, recently stated: "Raw garlic and a skin of the lemon--not only do they give you a beautiful face and skin but they also protect you from [HIV/AIDS]." Sarah Boseley, *Aids Groups Condemn South Africa's "Dr Garlic*," THE GUARDIAN (London), May 6, 2005, at 16.

[142] *Id.*

[143] While respectable NGOs such as MSF acknowledge other factors relating to a lack of research and development for certain diseases, they still highlight the pharmaceutical industries' spending patterns. *See e.g.*, MSF, R & D SYSTEM IS FAILING TO MEET HEALTH NEEDS IN DEVELOPING COUNTRIES: MSF BRIEFING NOTE FOR MINISTERIAL SUMMIT ON HEALTH RESEARCH, MEXICO CITY, 16-20 NOVEMBER, 2004 (2005), *available at* http://www.accessmed-msf.org/prod/publications.asp?scntid=121120041119152&contenttype=PARA&.

[144] UN MILLENNIUM PROJECT 2005, *supra* note 1, at 137 (industry dissent).

[145] *See* Mercurio, *supra* note 16, at 248-253; *see also* WIPO No. 491(E), *supra* note 63, at 1: ("A robust patent system providing for adequate patent protection is an indispensable incentive to creative and inventive work and is crucial to establishing and maintaining an attractive commercial environment."); DFID, *supra* note 56, at 5-6.

¶51 On the other hand, it is well known that research and development of medicines and vaccines to address health problems of developing countries is inadequate. The main problem with the current system is that patents do not provide sufficient research incentives where the market for the product is insufficient. In such a circumstance, even though the pharmaceutical industry appears to be genuinely making an attempt to develop vaccinations and drugs to treat several developing country diseases,[146] the fact of the matter remains that these vaccines and drugs are either non-existent or no longer effective due to resistance.[147] Quite obviously, the lack of innovation in this area is at least partly responsible for prolonging the public health crises in the developing world.[148] Again, the current incentive structure promoting research and development of medicines and vaccines to address health problems of developing countries is deficient.[149]

¶52 In order to ensure sustained research and development into the afflictions of the developing world and widespread access to the resulting drugs, health priorities must be re-oriented and incentives provided for the industry or pharmaceutical companies will eventually exit the market, thus reducing the number of new drugs to service the developing world.[150] Despite much publicized rhetoric, simply expropriating the intellectual property rights of pharmaceutical companies is not the long-term solution. This point is illustrated by using an analogy to the expropriation of a foreign-owned manufacturing plant or a foreign-owned bank account. Such expropriation would inevitably result in less foreign investment in the country. Likewise, the expropriation of a company's intellectual property results in less research and development into medicines to prevent and treat diseases afflicting the expropriating country.

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[146] *See* UN MILLENNIUM PROJECT 2005, *supra* note 1, at 139 (industry dissent). The pharmaceutical industry states: "[We] continue to play an important role in development of medicines for malaria, TB, and other diseases occurring primarily in developing countries. For example, Novartis recently established a research centre in Singapore for the discovery and development of drugs for tropical diseases, with and initial focus on TB and dengue fever. When drugs are finally produced, they will be sold at no profit. Astra Zeneca has created a new discovery research facility in Bangalore, India, which will focus exclusively on TB. GlaxoSmithKline has a dedicated facility in Tres Cantos, Spain, for drug discovery in diseases of the developing world, including malaria and TB. They currently have two antimalarial drugs in development (phases I and III) as well as vaccines in clinical trials for TB and malaria. Much of this work is in association with public-private partnerships that offer a new and innovative approach to drug and vaccine development—a development barely cited in the report."

[147] For more information, see the WHO webpage on drug resistance. WHO, Drug Resistance, http://www.who.int/drugresistance/en/ (last visited Nov. 26, 2006); *see also*, Carol C. Adelman et al., *Myths and Realities*, *supra* note 112, 13-16.

[148] *See, e.g.*, MSF, ACCESS TO ESSENTIAL MEDICINES CAMPAIGN AND THE DRUG FOR NEGLECTED DISEASES WORKING GROUP, FATAL IMBALANCE: THE CRISIS IN RESEARCH AND DEVELOPMENT FOR DRUGS FOR NEGLECTED DISEASES (2001), *available at* www.msf.org/source/access/2001/fatal/fatalshort.pdf . For more on the cost of combating the AIDS crisis, see UN MILLENNIUM PROJECT , REPORT OF THE TASK FORCE ON HIV/AIDS, MALARIA, TB, AND ACCESS TO ESSENTIAL MEDICINES, WORKING GROUP ON HIV/AIDS: COMBATING AIDS IN THE DEVELOPING WORLD, 129-49 (2005), *available at* http://www.unmillenniumproject.org/documents/HIVAIDS-complete.pdf.

[149] *See* GLOBAL FORUM FOR HEALTH RESEARCH, THE 10/90 REPORT ON HEALTH RESEARCH: 2003-2004 (2004), *available at* http://www.globalforumhealth.org/Site/002__What%20we%20do/005__Publications/001__10%2090%20reports.php (PDF form of THE 10/90 REPORT ON HEALTH RESEARCH: 2003-2004 is available on the right side of the webpage by chapter) (reporting that approximately 90% of the research and development of health research goes to diseases afflicting mainly the developed world); Condon & Sinha, *supra* note 13.

[150] *See* Mercurio, *supra* note 16, at 251; *see also* ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT (OECD), PATENTS AND INNOVATION: TRENDS AND POLICY CHALLENGE 9 (2004), *available at* http://www.oecd.org/dataoecd/48/12/24508541.pdf [hereinafter OECD 2004] (stating "[e]mpirical evidence tends to support the effectiveness of patents in encouraging innovation").

¶53 It is also too simplistic to demand that the pharmaceutical company expend more resources on researching and developing drugs relating to developing country diseases. The pharmaceutical industry is like very few in the world where research and development and trials account for 30% of total production costs and where a rigorous regulatory process is necessary before the products can be marketed and sold.[151] This procedure guarantees the safety and effectiveness of the drugs, but in the process renders much of the research and development expenditure by the industry essentially wasted as the vast majority of drugs fail to reach the market. In fact, only 5 of every 250 compounds that enter preclinical testing make it to clinical trials, with over half failing the clinical trial stage and an additional large number failing the regulatory stage.[152] For those drugs proven to be safe and effective, the process of navigating through the trials and regulatory stage takes years and millions of dollars, and all this takes place while the period of exclusivity granted by the patent is dwindling.[153] Pharmaceutical companies can only ever hope to generate modest profits in the developing world, but it may be that modest profit is vital to ensure that research and development continues for certain diseases.[154] Therefore, a period of restricted competition is required for the recoupment of research and development and regulatory costs, as well as for the making of small profits in order to encourage future creation and ensure that some suppliers do not exit the market entirely.[155] However, where a market is incapable of paying for the treatment, patents do not provide the necessary impetus to encourage research and development. In such a circumstance, incentives must be provided to the pharmaceutical industry or directly funded by governments, international organizations or from other sources.

¶54 In this regard, the problem with access to medicines in the developing world is two-fold: (1) developing countries either cannot afford to purchase existing drugs or do not have the infrastructure to safely store, transport and administer the drugs; and (2) there are no existing drugs to prevent or treat diseases mainly afflicting the developing world.

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[151] *See* Moran, *supra* note 100, at 25. The industry estimates that it spends approximately 17% or more of sales on research and development, a figure three times more than the next highest-spending industry (telecommunications), and four times more than the defence industry and all other industries. *See* PHRMA, PHARMACEUTICAL INDUSTRY PROFILE 2003 (2003), *available at* http://www.phrma-jp.org/publication/pdf/industry/2003/2003FRONT.pdf.

[152] PHRMA, PHARMACEUTICAL INDUSTRY PROFILE 2006, 2, 5-6 (2006), *available at* http://www.phrma.org/files/2006%20Industry%20Profile.pdf.

[153] The pharmaceutical industry reports the average effective life of a patent as being 11.5 years. *Id*. at 8.

[154] The OECD referred to patents as an "essential factor" in the development of new medicines. More specifically, an OECD report stated that patents were important to start-ups and university spin-offs in the biomedical field for the protection and raising of capital. The report did warn, however, that patent protection could lead to overly strong regulatory positions. *See* OECD 2004, *supra* note 150; *see also* John P. Walsh et al., *Science and the Law: Working Through the Patent Problem*, 299 SCI. 1021 (2003) (finding that although IPRs create complexities, they are a necessary stimulus, have never caused research to halt midstream and can be effectively managed).

[155] *See* Alan O. Sykes, *TRIPS, Pharmaceuticals, Developing Countries, and the Doha "Solution"*, 3 CHI. J. INT'L L. 47, 57 (2002). A survey of "executives in a range of industries were asked to estimate what percentage of inventions . . . in the early-1980s would not have been developed without [adequate] patent protection." *Id*. The survey revealed that 14% of all products would not have been invented, but that 60% of pharmaceutical products would not have been developed without patent protection. *Id*. at 60-61 (citation omitted). *See also* Roy Widdus, *Product Development Partnerships on "Neglected Diseases": How They Handle Intellectual Property and How This May Contribute to Improving Access to Pharmaceuticals for HIV/AIDS, TB and Malaria*, ICTSD-INCTAD DIALOGUE ON ENSURING POLICY OPTIONS FOR AFFORDABLE ACCESS TO ESSENTIAL MEDICINES (2004), *available at* http://www.iprsonline.org/unctadictsd/bellagio/docs/Widdus_Bellagio3_revised.pdf.

¶55 An example of developing countries not being able to afford existing treatment options can be seen from the recent advances of ARV drugs in the treatment of HIV/AIDS. Thus, while there is still no cure for the disease, it has been effectively controlled in the developed world largely due to the availability of modern ARV drugs.[156] Studies have shown that the mortality rate in the United States has declined by over 75% over three years through the use of ARV drug cocktails.[157] Patients in developing countries, however, can neither afford the wide range of drugs available on the developed country market, nor do they have the facilities or the means to effectively administer the few drugs that they do have access to. For these reasons, the epidemic remains uncontrolled in the developing world and sub-Saharan Africa alone must contend with over 25 million people infected with HIV/AIDS (which account for more than 70% of all HIV/AIDS cases globally).[158]

¶56 In this regard, while the efforts of the pharmaceutical industry[159] and aid agencies in either reducing the price,[160] donating drugs or facilitating delivery to developing countries,[161] are beneficial, ad hoc arrangements are not sufficient.[162] Instead, scale coordinated, targeted aid and large scale equity pricing schemes must be implemented in order to guarantee the long-term supply of affordable, quality drugs to the developing world.[163] Under equity pricing, countries and regions would only pay what they can afford while continuing to make use of voluntary and compulsory licences, negotiating and transparency in order to ensure the procurement of low cost drugs.[164] In essence,

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[156] IIPI, *supra* note 76, at 9.

[157] *Id*.

[158] *Id*. at 4.

[159] Credit must be given to the pharmaceutical industry for their efforts at promoting global healthcare. For instance, the industry spends between $1.4-2.1 billion dollars annually for global healthcare – a figure that represents more than a third of the United States' total healthcare assistance to the developing world. *See* PHRMA, GLOBAL PARTNERSHIPS: HUMANITARIAN PROGRAMS OF THE PHARMACEUTICAL INDUSTRY IN DEVELOPING NATIONS 1 (2004), *available at* http://www.phrma.org/files/Global_Partnerships_2004.pdf [hereinafter PHRMA 2004]. In addition, in 2003, industry members of the Partnership for Quality Medical Donation provided more than $1.4 billion in donated drugs, and in 2002, pharmaceutical companies' select humanitarian programs totalled $810 million. *See* PHRMA, IMPROVING HEALTH IN THE DEVELOPING WORLD (2004) (on file with author). More specific donation programs can be seen throughout PHRMA 2004. *Id*. Overall, the industry provides almost the same, if not more, total aid than most governments and international health organizations. UN MILLENNIUM PROJECT 2005, *supra* note 1, app. 2, at 138.

[160] At least one commentator believes that the reduction in price is, for the most part, not low enough to be efficiently utilized. *See* Kevin Outterson, *Pharmaceutical Arbitrage: Balancing Access and Innovation in International Prescription Drug Markets*, 5 YALE J. HEALTH POL'Y L. & ETHICS 193, 225-27 (2005). For statistics on the health budget of some developing countries, see *supra* text accompanying notes 99 and 100.

[161] For instance, UNICEF and the Rockefeller Foundation secure lower prices for drugs and vaccines due to their procurement practices, warehousing and delivery networks. UN MILLENNIUM PROJECT 2005, *supra* note 1, at 78. In fact, UNICEF claims it supplies 40% of the vaccine market for AIDS covering 5% of market in financial terms. *Id*. The Stop TB Partnership and Global TB Drug Facility supply the vaccine market at similar rates for those afflictions. *Id*.

[162] Several studies have shown that small scale donations are, for the most part, not appropriate or unsustainable for meeting local needs. *See, e.g.*, Phillippe Autier et al., Drug Donations in Post-emergency Situations, *in* WORLD BANK HEALTH, NUTRITION & POPULATION FAMILY (HNP) DISCUSSION PAPER SERIES (2002), *available at* http://siteresources.worldbank.org/HEALTHNUTRITIONANDPOPULATION/Resources/281627-1095698140167/Nassery-DrugDonation-whole.pdf.

[163] The WHO successfully initiated equity pricing in the 1980s for vaccines and reproductive health. UN MILLENNIUM PROJECT 2005, *supra* note 1, at 68.

[164] *See, e.g*., WHO Secretariat, *More Equitable Pricing for Essential Drugs: What do we Mean and*

equity pricing would allow developing countries to procure drugs without having to pay for development costs, marketing or shareholder returns. More specifically, sales to lower-income developing countries would be at a "no profit, no loss."[165] Middle-income countries would pay a higher rate for the drugs while the burden on developed countries would be even greater in order to cover the development costs, marketing and shareholder returns.[166]

¶57 The second, and perhaps more difficult, problem is that a number of diseases primarily affecting the developing world, *i.e.*, African trypanosomiasis, Chagas disease, leishmaniasis, and dengue fever, have been neglected by the pharmaceutical industry and there is either no cure, vaccine or treatment or new medicines available to "address [the] shortcomings of existing treatments, such as safety, efficacy, appropriate dosing, length of treatment, and the ongoing threat of drug resistance."[167] While the international community (most notably, philanthropic foundations, certain governments and the pharmaceutical industry) has improved its response and has provided needed resources to fund research and development for new medicines, more financial resources are needed on an ongoing basis to "create a strong and sustainable pipeline of new products".[168] In this regard, "[n]ew thinking, different means of financing and organizing medicines development, and other reforms are needed. For example, the WHO Commission on Intellectual Property Rights, Innovation, and Public Health should examine alternative international models to the current patent-based system for priority setting and financing of health R&D."[169]

¶58 In the current climate, for-profit pharmaceutical companies will not reorientate research priorities. Therefore, incentives in the form of subsidies and other support need to be given to all those involved in the research and development of essential medicines, including pharmaceutical manufacturers, academia, government researchers and national organisations. Industrialized countries must bear the cost of these subsidies.[170] In addition, alternative intellectual property strategies, such as placing medical innovations in the public domain, sharing bundles on IPRs, patent pools, patent clearinghouses, public

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What are the Issues?, *in* WHO-WTO SECRETARIAT WORKSHOP ON DIFFERENTIAL PRICING AND FINANCING OF ESSENTIAL DRUGS, NORWAY, APR. 8-11, 2001 (2001), *available at* http://www.wto.org/english/tratop_e/trips_e/who_background_e.doc.

[165] *See* UN MILLENNIUM PROJECT 2005, *supra* note 1, at 18, 68, 115.

[166] The extraction of profits from developing countries have been called "both cruel and unnecessary: cruel because people will die because a life-saving treatment is possible, but unaffordable; unnecessary because low-income populations would never have contributed much towards global R&D cost recovery in any case." Kevin Outterson, Nonrival Access to Pharmaceutical Knowledge (2005), *available at* http://www.who.int/intellectualproperty/submissions/KevinOutterson3january.pdf.

[167] UN MILLENNIUM PROJECT 2005, *supra* note 1, at 31. MSF states that while over 1200 new chemical entities have been registered in the world over the past 20 years, only 13 were for tropical diseases. MARIE BYSTRÖM & PETER EINARSSON, TRIPS: CONSEQUENCES FOR DEVELOPING COUNTRIES: IMPLICATIONS FOR SWEDISH DEVELOPMENT COOPERATION, CONSULTANCY REPORT TO THE SWEDISH INTERNATIONAL DEVELOPMENT COOPERATION AGENCY 37 (2001), *available at* http://ww.grain.org/docs/sida-trips-2001-en.pdf. For similar statistics, see Gavin Yamey, *Public Sector Must Develop Drugs for Neglected Diseases*, 324 BRIT. MED. J. 698 (2002); Troullier et al., *supra* note 91; Ellen't Hoen, Statement by MSF at WIPO General Assembly (Sept. 30, 2004), http://www.cptech.org/ip/wipo/msf09302004.html (last visited July 18, 2006).

[168] UN MILLENNIUM PROJECT 2005, *supra* note 1, at 31.

[169] *Id.; see also* PRIMO BRAGA & CARLOS CORREA, INTELLECTUAL PROPERTY RIGHTS, THE WTO AND DEVELOPING COUNTRIES: THE TRIPS AGREEMENT AND POLICY OPTIONS (2000).

[170] Several studies conclude that current levels of donor assistance are inadequate and must be substantially raised. *See, e.g.*, WHO CMH 2001, *supra* note 91; Troullier et al., *supra* note 91.

databases and non-rival access to knowledge must be further studied and implemented.[171] Moreover, complete alternatives to the current scheme must be further studied to provide the needed incentives to increase research and development of neglected diseases. Such efforts include compulsory licensing or patent buy-outs,[172] employer-based payroll taxes,[173] patent auctions[174] and well-funded research centers.[175]

¶59 Currently, the development of public and private partnerships (PPPs) is one of the most encouraging developments in the area.[176] PPPs are an innovative way to finance creative solutions and encourage innovation.[177] More specifically, successful PPPs:

- deliver critical funding;
- draw attention to health threats that may not be widely known;
- share knowledge and resources;
- build the numbers needed to facilitate volume-related discounts; and
- achieve specific public health disease management objectives.[178]

¶60 In addition, it is widely believed that the probability of the success of PPPs is enhanced when:

- common performance measures are developed;
- clinical trial capacity development is coordinated;
- the potential of disease endemic countries is harnessed;
- the financial stability of the PPPs is ensured;
- the research, development and access components are communicated and

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[171] OECD 2004, *supra* note 150, at 23; DFID 2004, *supra* note 4; Outterson, *supra* note 166. Moreover, the OECD has embraced economic-based reforms of patent regimes including "introducing a more differentiated approach to patent protection that depends on specific characteristics of the inventions, such as their life cycle or their value (as opposed to the current uniform system); making patent fees commensurate to the degree of protection provided; and, developing alternatives to patenting such as the public domain." OECD 2004, *supra* note 150, at 6. For more analysis and alternatives, see John Barton, *Integrating IPR Policies in Development Strategies*, *in* TRADING IN KNOWLEDGE: DEVELOPMENT PERSPECTIVES ON TRIPS, TRADE AND SUSTAINABILITY 5-64 (Christophe Bellmann et al. eds., 2003); Carlos Correa, *Formulating Effective Pro-development National Intellectual Property Policies*, *in* TRADING IN KNOWLEDGE: DEVELOPMENT PERSPECTIVES ON TRIPS, TRADE AND SUSTAINABILITY 209-18 (Christophe Bellmann et al. eds., 2003); *see also* UN MILLENNIUM PROJECT 2005, *supra* note 1, at 59-60; WHO, PUBLIC HEALTH, INNOVATION AND INTELLECTUAL PROPERTY RIGHTS, REPORT OF THE COMMISSION ON INTELLECTUAL PROPERTY RIGHTS, INNOVATION AND PUBLIC HEALTH 161-92 (2006), *available at* http://www.who.int/intellectualproperty/documents/thereport/CIPIHReport23032006.pdf. It must be recalled that alternatives are not likely to have much impact on the pharmaceutical industry (for instance, Africa as a whole comprises only 1% of the world pharmaceuticals market). Moran, *supra* note 100, at 26.

[172] *See, e.g.*, Mattias Ganslandt et al., *Developing and Distributing Essential Medicines to Poor Countries: The DEFEND Proposal*, 24 WORLD ECON. 779 (2001).

[173] *See, e.g.*, Tim Hubbard & James Love, *A New Trade Framework for Global Healthcare R & D*, 2(2) PLOS BIOLOGY e52 (2004), http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=340954 (last visited Jan. 3, 2007); Thomas W. Pogge, *Human Rights and Global Health: A Research Program*, 36 METAPHILOSOPHY 182, 182-209 (2005).

[174] *See, e.g.*, Michael Kremer, *Patent Buyouts: A Mechanism for Encouraging Innovation*, 113 Q. J. ECON. 1137 (1998).

[175] *See, e.g.*, The Free Market Drug Act of 2004, H.R. 5155, 108th Cong. (2004). For more information, see Congressman Kucinich's website, Congressman Dennis J. Kucinich, http://kucinich.house.gov/news/DocumentSingle.aspx?DocumentID=28571 (last visited Jan. 3, 2007).

[176] See, for example, the research by the Medicines for Malaria Venture, THE NEW LANDSCAPE OF NEGLECTED DISEASE DRUG DEVELOPMENT (2005), *available at* http://mmv.org/IMG/pdf/Chapter_2.pdf.

[177] For basic information and stimulating questions, see WORLD ECONOMIC FORUM AND THE UNITED NATIONS FOUNDATION, PUBLIC-PRIVATE PARTNERSHIPS: MEETING IN THE MIDDLE (2003), *available at* http://www.weforum.org/pdf/Initiatives/GHI_2003_Meeting_in_the_middle.pdf.

[178] UN MILLENNIUM PROJECT 2005, *supra* note 1, at 54-55.

coordinated; and
- industry contributions are fully recruited and involved.[179]

¶61 While it is beyond the scope of this article to develop a model for increasing research and development into these diseases, several useful models already exist and all stress the need for cooperation between public, private, academic, philanthropic foundations, government and international organisations.[180] All of these models stress that increased financing, clear priorities, effective management and meaningful technology and knowledge transfers are all necessary components to the equation.[181]

¶62 Importantly, PPPs provide a viable solution to improving the public health crises without the need to tackle the reform of intellectual property systems. Moreover, PPPs address both the underlying problems of affordability and development by providing an alternative to dependence on donations from governments and other organisations or access to essential medicines from pharmaceutical companies.[182] Under the PPP model, private companies provide technology as well as development and distribution expertise, while the public sector partners fund development costs and help ensure the medicines reach those who are most in need.[183] There is thus no set formula for PPPs and different groups tend to focus on different (or multiple) access and development aspects; for instance, some promote leadership and capacity building, others focus on educating the public on intellectual property laws and promoting access to medicines and still others focus on increasing regulatory bodies in the developing world to ensure safe and quality medicines and increased registration.[184]

¶63 By far, the Bill and Melinda Gates Foundation is one of if not the largest donors to PPPs, supporting, among others, the Global Fund, WHO efforts and US agencies providing access to medicines.[185] Significantly, the Gates Foundation provides grants and rewards for discovery of new medicines to prevent, alleviate or treat developing county illnesses and diseases.[186] The Gates Foundation also excels in the promotion of research and development (such as clinical trials) currently lacking existing vaccines or medicines.[187]

¶64 By working together, the public and private sector, aid organisations and governments have demonstrated the ability to positively influence the course of the developing world. One example of a potential PPP success is the partnership initiative between the pharmaceutical company GlaxoSmithKlein, the University of Liverpool and

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[179] *See* ROY WIDDUS & KATHERINE WHITE, COMBATING DISEASES ASSOCIATED WITH POVERTY: FINANCING STRATEGIES FOR PRODUCT DEVELOPMENT AND THE POTENTIAL ROLE OF PUBLIC-PRIVATE PARTNERSHIPS 23 (Abr. ver. 2004), *available at* http://www.globalforumhealth.org/filesupld/ippph/CombatingDiseases.pdf.

[180] *See, e.g., id.* For some of the pharmaceutical industries' contributions to these efforts, see UN MILLENNIUM PROJECT 2005, *supra* note 1, at 138-39 (industry dissent).

[181] *Id.*

[182] For a more complete definition and illustration of PPPs, see PUBLIC-PRIVATE PARTNERSHIPS FOR PUBLIC HEALTH 1-18 (Michael R. Reich ed., 2002).

[183] For more detail, see Adetokunbo O. Lucas, *Public-Private Partnerships: Illustrative Examples, in* PUBLIC-PRIVATE PARTNERSHIPS FOR PUBLIC HEALTH 1-18 (Michael R. Reich ed., 2002).

[184] *See e.g.*, Widdus & White, *supra* note 89, at 5.

[185] See *id.* at 4-5; UN MILLENNIUM PROJECT 2005, *supra* note 1, at 46, 54-55, 60, 138.

[186] Interestingly, the first grant provided under this scheme was to a non-profit pharmaceutical company. For more information, see Bill & Melinda Gates Foundation, http://www.gatesfoundation.org/default.htm (last visited Jan. 3, 2007).

[187] *Id.*

the London School of Hygiene and Tropical Medicine, and a £2.5 million grant from the UK Government's Department of International Development to research and launch the malaria-treatment drug Lapdap.[188] This initiative highlights two important points, namely that public funding can be used on a range of public policy initiatives to control and relieve the overall health crisis, and second, that resources and attention do not need to be predominantly placed on amending the current IP regulation which allow for viable solutions to the lack of access to medicine problem.[189]

¶65 Both the quantity of PPPs and funding to PPPs is increasing, but the majority of initiatives – including the Global Fund and WHO efforts – remain under-funded.[190] This is especially the case for the traditionally neglected diseases such as African trypanosomiasis, Chagas and leishmaniasis.[191] While funding for these diseases is improving,[192] a critical shortage remains. However, it cannot be stressed enough that in order to be effective, aid programs must be coordinated and address issues surrounding the governance, participation, procurement, prioritization and best practices of PPPs.[193] Sporadic, ad hoc, diffuse or uncoordinated aid or PPPs will not help alleviate the suffering.

D. Differential pricing and the prevention of trade diversion

¶66 Parallel importation occurs when the patent holder sells a product to a buyer who exports the product to a second buyer in another country.[194] Parallel importing of products is an attractive option when the price of the imported product, taking into account transportation and tariffs, is lower than the price of the same product legally made or imported into the country. Parallel importation undercuts the ability of a patent holder to engage in price discrimination, *i.e.*, tiered pricing, across national borders and can severely reduce profit levels of international companies. Importantly, the Doha Declaration confirmed the existing right available under TRIPS that each WTO Member may establish its own regime of exhaustion of intellectual property rights.[195] Parallel importing is therefore not in and of itself a violation of TRIPS and many countries (both

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[188] *See* Press Release, WHO, Glaxosmithkline and World Health Organization Sign Agreement to Develop a New Treatment For Malaria (Mar. 2, 2001), *available at* http://www.who.int/inf-pr-2001/en/pr2001-10.html. The initiative was established following the DFID's release of its report on intellectual property rights. *See* THE DEPARTMENT FOR INTERNATIONAL DEVELOPMENT, UK GOVERNMENT RESPONSE TO THE REPORT OF THE COMMISSION ON INTELLECTUAL PROPERTY RIGHTS: "INTEGRATING INTELLECTUAL PROPERTY RIGHTS AND DEVELOPMENT POLICY" 5-6 (2003), *available at* http://www.iprcommission.org/papers/pdfs/govt_response/govt_response.pdf.

[189] *See* Press Release, WHO, *supra* note 188.

[190] UN MILLENNIUM PROJECT 2005, *supra* note 1, at 148.

[191] *Id.* at 59.

[192] For instance, the pharmaceutical company Roche donated technology to the Brazilian government to manufacture effective medicines. *Id*.

[193] *See, e.g.*, UN MILLENNIUM PROJECT 2005, *supra* note 1, at 46, 107-08. For issues of governance, see Kate Buse, *Governing Public-Private Infectious Disease Partnerships*, 10 BROWN J. WORLD AFF. 225 (2004) (highlighting "design" faults and lack of developing country participation in many PPPs); *see also* THE BILL & MELINDA GATES FOUNDATION, DEVELOPING SUCCESSFUL GLOBAL HEALTH ALLIANCES (2002), *available at* http://www.gatesfoundation.org/nr/downloads/globalhealth/GlobalHealthAlliances.pdf.

[194] For more information, see Consumer Project on Technology, Health Care and Intellectual Property: Parallel Imports, http://www.cptech.org/ip/fsd/health-pi.html (last visited Jan. 3, 2007).

[195] *See* Doha Declaration, *supra* note 22, at para. 5(d).

developed and developing) take advantage of this flexibility to import products such as books and CDs.[196]

¶67 The problem for the parallel importation of pharmaceuticals and related products is that they are being distributed to developing countries at reduced prices or donated, which also allows companies to charge a high price in developed countries able and willing to meet the higher price.[197] This enables the companies to recoup the costs of offering a lower price to those markets unable or unwilling to meet that same price, but there is nothing to prevent the importing nation from exporting the drugs back to the original market or any other market for profit. Of course, such conduct on the part of developing countries would be against the spirit of the Doha Declaration and prevent the goal of facilitating access to medicines from being reached.[198] Paragraph 4 of the Implementation Agreement attempts to resolve the uncertainty, but it is a compromise provision fraught with uncertainty.[199] Paragraph 4 attempts to balance the concerns of both developed and developing countries by instructing importing countries to take measures to prevent re-exportation, but leaves unclear the issue of to what extent an importing country must act.[200] Instead, Paragraph 4 merely states that the measures must be "reasonable," "within their means," and "proportionate to their administrative capacities and to the risk of trade diversion."[201]

¶68 In order to maintain price discrimination between developed countries that can afford the medicines and developing countries that need the medicines, the supply of pharmaceuticals at reduced prices must be conditioned on the fact that the drugs will be used to ease their health crisis, not simply re-exported to a market willing to pay a higher price for the drugs. While the Implementation Agreement is designed to avoid imposing conditions that developing countries cannot meet while also encouraging them to take responsibility to ensure that medicines reach their intended destinations, the ambiguity of their responsibilities and the lack of repercussions following a breach could potentially unsettle the system. Whether the risk is real or imagined, it is clear that the pharmaceutical industry is concerned about the implications of pharmaceutical arbitrage/diversion from low income markets to high income markets.[202] This fear, in turn, impacts upon the willingness of the industry to donate or sell drugs at a reduced price to the developing world.[203]

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[196] In fact, the parties effectively did not reach agreement on the issue. In the end, the decision to allow its operation resulted because the parties could not agree on how to govern its use or otherwise restrict its use. *See* Peggy B. Sherman & Ellwood F. Oakley, III, *Pandemics and Panaceas: The World Trade Organization's Efforts to Balance Pharmaceutical Patents and Access to AIDS Drugs*, 41 AM. BUS. L.J. 353 (2004).

[197] For examples of pharmaceutical companies voluntarily licensing products to companies in developing countries, see Adelman et al., *Myths and Realities*, *supra* note 112, at 5-6.

[198] *See Implementation Agreement*, *supra* note 45.

[199] For criticism, see Mercurio, *supra* note 16, at 244-45.

[200] *Id*.

[201] See *Implementation Agreement*, *supra* note 45, at para. 4.

[202] Matthews, *supra* note 54, at 100.

[203] One commentator claims that, "Empirically, such arbitrage is rarely observed, and need not be a significant threat…" Outterson, *supra* note 160, at 257-60; but see HIV Drugs for Africa Diverted to Europe, Wash. Post, Oct. 3, 2002, at A10 (detailing how only ten percent of over $18 million dollars worth of HIV/AIDS medication (sold to Africa at a discount of up to 90%) sent from GlaxoSmithKline in Europe reached its intended destination due to a sophisticated regime of diverting, relabelling and re-shipping the medication back to Europe).

¶69 In addition, while Paragraph 4 envisions developed countries assisting those developing countries and LDCs that "experience[] difficulty" in preventing diversion, its conditions and guidance are inadequate, only allowing developed countries to provide technical and financial cooperation to prevent diversion "on request and on mutually agreed terms and conditions" of the importing Member.[204] Therefore, if an importing Member does nothing to prevent or encourages or even brokers a deal for the diversion of medicines away from its citizens and into another market, other Members and/or the patent holder cannot prevent the diversion (other than through their domestic institutions). Such a system invites abuse and provides no stop mechanism. It would seem appropriate for Members to have the ability to become involved in an effort to prevent diversion, particularly if the importing Member is actively participating in such diversion. At the very least, one would expect that the Implementation Agreement would include a provision allowing aggrieved Members the right to complain to and refer the matter to the Council for TRIPS. But the Implementation Agreement does not provide for redress of diversion, instead viewing the measure's only purpose to ensure medicines reach their destination, and fails to provide property holders with any mechanism to enforce their rights.[205]

¶70 In not taking a stronger stand in the Implementation Agreement, WTO Members missed an opportunity to effectively monitor the sale of pharmaceuticals to developing countries (whether by compulsory or voluntary licensing or through price discrimination).[206] For instance, the Council for TRIPS could monitor transactions and better ensure not only that the drugs do not get re-exported but also that only minimal economic, legal, and bureaucratic burdens are placed on the importing country. Such a system, if properly designed, could have been workable and agreeable to all concerned parties.[207] On the other hand, while preventing re-importation is the goal, any potential solution cannot unduly raise developing country compliance costs.[208] In this regard, the implementation concerns of developing countries are well-founded.

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[204] See *Implementation Agreement*, *supra* note 45, at para. 4.

[205] *See generally id.*

[206] This may have the effect of limiting or reducing donations/furthering price discrimination in developing country markets. *See*, *e.g.*, Keith E. Maskus, Parallel Imports In Pharmaceuticals: Implications For Competition And Prices In Developing Countries (2001), http://www.wipo.int/about-ip/en/studies/pdf/ssa_maskus_pi.pdf.

[207] In such a circumstance, the US and other nations have sought to impose strict standards on other nations via FTAs providing for the restriction and/or prohibition on parallel importation. This development is regrettable, as it fragments trade and prevents large scale price discrimination and donation. For example, US FTAs with Morocco (art. 15.9.4) and Australia (art. 17.9.4) prohibit parallel importation; however, both agreements provide that the prohibition may be limited to cases where the patent owner has placed restrictions by contract or other means. Notwithstanding this footnote, the provision may effectively prohibit parallel importation and essentially allow patent holders, through contract law, to segment markets and maintain price discrimination. Furthermore, the US-Singapore FTA (art. 16.7.2) also restricts parallel importation by allowing patent holders to block parallel importation into either country when the same is done in violation of a distribution agreement anywhere in the world. Interestingly, a number of US FTAs with developing countries, including Chile, Jordan and CAFTA, are silent on the exhaustion of patent rights; thus, these countries have retained the flexibility granted by TRIPS. On the other hand, the draft text of the Free Trade of the Americas (FTAA) only partially allows for the retention of the TRIPS flexibility, allowing each country to determine its own rules on parallel importation but then obliging them to set up regional exhaustion under their domestic laws within five years. In effect, this would allow parallel importation within the FTAA zone, while keeping the world market segmented.

[208] *See* UN MILLENNIUM PROJECT 2005, *supra* note 1, at 67-68.

¶71 Therefore, while patent protection and TRIPS is not the cause of or even a significant factor in worsening the public health crisis in the developing world, it is not a perfect agreement and – if the pharmaceutical industry is to be believed – can be amended to facilitate increased donations of essential medicines. Two possible solutions are suggested for dealing with the shortcomings of TRIPS and the accompanying agreements. First, TRIPS could be amended so as to allow for redress of diversion through dispute settlement. This suggestion concededly has many flaws, but a possible solution to halting existing and preventing further trade diversion may lie in setting up an effective dispute settlement scheme or allowing the existing system to hear cases where Members who have acquired drugs under a license or through price discrimination/donation based on their economic and public health needs are exporting the drugs for profit. It must be acknowledged, however, that Articles 28 and 5 of TRIPS and Paragraph 5(d) of the Doha Declaration may perhaps impede such a solution as they do not permit Members from challenging schemes dealing with the exhaustion of intellectual property rights.

¶72 Of course, even if TRIPS was amended to allow dispute settlement over diversionary issues, an additional barrier exists on the practical matter of how to monitor such trade diversionary practices. One possibility would be for a body to be established to monitor possible trade diversions,[209] but this would be a costly endeavor as considerable funding would be required to set up such an international watchdog. It would seem more practical for that funding to be diverted into more essential areas such as building infrastructure and alternative solutions to the trade diversion problem.

¶73 A more practical solution to the problem would seem to be through simple amendments to TRIPS. For example, Sykes suggests that amendments to TRIPS could be made which permit sectoral agreements on the exhaustion issue depending on the product in order to discourage or prohibit parallel imports of pharmaceuticals.[210] However, it is well known that consensus decision making in the WTO significantly impedes progress or amendments of any kind.[211] For instance, one must remember that Members negotiated for over two years to reach a consensus to a solution on the Paragraph 6 issue of the Doha Declaration and it seems unlikely that any revision of TRIPS will be any easier.[212]

¶74 That being said, there may be potential in the future to adopt a regime which is similar to the system currently operating in the EU. The EU uses its own regional exhaustion of rights doctrine to prohibit imports of cheaper patented drugs from outside the EU.[213] The EU arrangements differ from the system agreed by the WTO in the Implementation Agreement in that the EU scheme protects the interests of patent holding proprietary pharmaceutical companies by deterring trade diversion of low-cost drugs they

[209] The packaging and labelling requirements imposed by the Implementation Agreement will allow generic drugs to be easily identifiable.

[210] Sykes, *supra* note 155, at 67.

[211] *See, e.g.*, Jeffrey J. Schott & Jayashree Watal, *Decision-Making in the WTO*, 00-2 INT'L ECON. POL'Y BRIEFS 2 (2000); Mary E. Footer, *The Role of Consensus in GATT/WTO Decision-Making*, 17 NW. J. INT'L L. & BUS. 653, 661 (1996-97).

[212] The "expeditious" solution to paragraph 6 of the Doha Declaration on Public Health of 2001 was not resolved until August 30, 2003.

[213] *See* Council Regulation No. 953/2003, 2003 O.J. (L 135) 5 (EC), *available at* http://trade-info.cec.eu.int/antitradediversion_html/en.pdf.

have made available.[214] Under the EU arrangements, exporting drug companies may apply to the Commission for permission to put their medicines onto a tiered price list, selling them to developing countries at a fraction of the factory price.[215] Re-importation of these drugs is prohibited from 76 least-developed and developing countries. In order to facilitate the agreement, the drugs listed carry a logo so that they are identifiable by customs authorities examining imports at the EU borders.[216]

¶75 Practically, the EU approach is more favorable than the current multinational approach for several reasons. First, it protects the patent-holding pharmaceutical companies directly and provides incentives, through the safeguards imposed, for these companies to provide discounted drugs to the developing world.[217] Second, the cost of the EU approach may prove to be significantly less than the current administrative and procedural costs under the WTO scheme as the EU scheme only requires that the products listed carry a particular logo.[218] Perhaps on the global scale, each region of the developed world participating in such a scheme, for example, North America, Australasia, etc., may have its own logo to identify that particular region. If the EU scheme proves both effective at encouraging the export of discounted pharmaceuticals to the developing world while also preventing diversion back into the market, or into another market, it may provide the evidence needed to amend Article 6 of TRIPS and sanction a uniform and non-discretionary scheme to prevent the diversion of trade.

V. CONCLUSION

¶76 This article demonstrates that the TRIPS regime of patent protection does not fully explain why one-third of the world's poor lack access to essential medicines. The public health crises plaguing much of the developing world are a large-scale global problem, but it is a problem for which there is a global solution.[219] The developed world has a duty to the countries suffering public health problems and, in doing so, must address several factors, including funding, medical infrastructure, education, and intellectual property regulations. Although seemingly forgotten, it is important to realize that the issue of global access to medicine requires measures and policies much broader than simply amending global intellectual property protection. In the current situation, many of the developing countries experiencing public health crisis cannot even afford to buy and distribute pharmaceutical products that are off-patent, let alone warehouse, store and

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[214] *See id*. The WTO scheme, on the other hand, is designed to deter trade diversion in circumstances where generic drug producers manufacture and export low-cost drugs to developing countries under compulsory licensing conditions. *See Implementation Agreement*, *supra* note 45, at paras. 4 and 5.

[215] Council Regulation No. 953/2003, *supra* note 213.

[216] The logo is depicted in Annex V of the Regulation as the winged staff of Aesculapius with a coiled serpent in the centre of a circle formed by twelve stars. *See id*. at Annex V. As mentioned earlier, however, some argue that marking drugs exported to developing countries adds an unnecessary cost to the process. *See id*.

[217] *See generally id*.

[218] Although both the WTO and EU schemes have packaging requirements, the WTO scheme seems more burdensome with regard to the extent of the labelling and packaging requirements, as well as the procedural requirements.

[219] *See* Jonathan D. Quick, *Ensuring Access to Essential Medicines in the Developing Countries: A Framework for Action*, 73(4) CLIN. PHARMACOL. THER. 279 (2003); *see generally*, JEFFREY D. SACHS, THE END OF POVERTY: ECONOMIC POSSIBILITIES FOR OUR TIME (2005).

administer the drugs and vaccines donated by the pharmaceutical companies.[220] This is the reality they face and in this reality we must ask if the issuance of compulsory licenses, or otherwise allowing access to patented pharmaceutical products, will do any good.

¶77 Numerous diseases, such as HIV/AIDS, malaria, and tuberculosis, are at an epidemic level in many developing countries, and yet commercial research and development of essential medicines to prevent or treat these ailments (less HIV/AIDS) is almost non-existent.[221] The reason for this is simple: it does not make good economic sense for any industry to pour money into a product that does not have at least a promise of return and the countries afflicting with these diseases do not have the ability to pay for any new medical and treatment options. Thus, under the current structure, incentives to research into the area of diseases afflicting the developing world are almost non-existent. Therefore, while TRIPS allows for countries to issue a compulsory license to acquire needed drugs, there is sometimes no drug on the market to alleviate the problem due to lack of research and development.[222]

¶78 Developing countries themselves do not, in the main, have the incentives or ability to fund, develop and distribute new drugs. Thus, patent protection must ensure that the pharmaceutical industry's incentive to create remains strong. If properly administered, a system of intellectual property rights, combined with a compulsory licensing regime could strike the appropriate balance.[223] On the other hand, a system of intellectual property that guarantees no return on investment and allows for the expropriation of intellectual property rights without proper compensation or enforceable limits will reduce the incentive to research and invest into the area and exacerbate the relative dearth in medicines for "third world" diseases. Such a situation must be avoided. But another, possibly larger, problem is that the current system of patent protection does not create the incentives necessary to encourage research and development into diseases for which there is little or no possibility for return. Instead, diseases primarily afflicting the developing world – including but not limited to malaria and tuberculosis – remain under-funded.[224] It is, therefore, incumbent upon the governments of the developed world to provide incentives to the pharmaceutical industry to research and develop treatments and vaccines for these neglected diseases, directly fund the research and develop treatments and

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[220] *See* discussion *supra* Section IV(b), and text accompanying footnotes 99 and 100.

[221] *See supra* text accompanying notes 1-8 and discussion Section IV(c).

[222] *See supra* text accompanying notes 161-70.

[223] The right to health has long been recognized as an international human right. *See, e.g.*, The Charter of WHO Constitution (1946), *available at* http://www.who.int/about/en/; The United Nations Universal Declaration of Human Rights (1948), *available at* http://www.un.org/Overview/rights.html; The International Convention of Economic, Social and Cultural Rights (1966), *available at* http://www.unhchr.ch/html/menu3/b/a_cescr.htm; The United Nations Commission Human Rights (UNCHR), Main Themes, http://www.unhchr.ch/html/menu2/2/chrintro.htm (last visited Jan. 4, 2007); The Office of the High Commissioner for Human Rights (OHCHR), Human Rights Issues, http://www.ohchr.org/english/issues/index.htm(last visited Jan. 4, 2007); The Joint United Nations Programme on HIV/AIDS (UNAIDS), Uniting the World Against AIDS, http://www.unaids.org/en/ (last visited Jan. 4, 2007). However, these rights are not necessarily contradictory to IPRs. For instance, while art. 25 of the United Nations Universal Declaration of Human Rights protects the right to a standard of living that affords adequate health and medical care, art. 27 allows individuals the right to enjoy the material and moral benefits as a creator. These provisions can be viewed as complimentary as the former affords the enjoyment of the latter through progress and innovation. *See* the United Nations Universal Declaration of Human Rights.

[224] *See generally*, STEVENS, *supra* note 2.

vaccines themselves, or totally recalibrate the patent system for traditionally neglected diseases.

¶79 Simply stated, the current system does not provide incentives to research developing country diseases.[225] But the patent system alone is not the problem, as pharmaceutical companies have in recent years expended significant resources to combat diseases which afflict both the developed and developing world (such as HIV/AIDS) and the disparity between the two groups of nations has increased in recent years.[226] Even more important than the current system of IPRs to the lack of access to medicines and corresponding health crises in the developing world is one of funding: developing countries do not have adequate resources, developing countries misallocate resources, international support is inadequate and the levels of research and development into diseases afflicting the developing world is insufficient.[227] As Attaran and Gillespie-White conclude:

> "[A] variety of de facto barriers are more responsible for impeding access to antiretroviral treatment, including but not limited to the poverty of African countries, the high cost of antiretroviral treatment, national regulatory requirements for medicines, tariffs and sales taxes, and, above all, a lack of sufficient international financial aid to fund antiretroviral treatment."[228]

¶80 Therefore, while a solution to alleviating the public health crises currently tormenting much of the developing world is achievable, such a solution cannot be attained by merely amending, or even abandoning, TRIPS and patent laws or by implementing only one of the initiatives outlined above. This is especially the case given that while over 95% of the WHO Essential Drugs List is off-patent, these inflictions and diseases continue to decimate much of the developing world.[229] The initiatives suggested in this article must be explored in combination to tackle the twin problems of inadequate development of vaccines and drugs and access to existing vaccines and drugs facing developing countries. Developed countries and the international community must increase both the amount as well as the coordination of funding and aid activities, developing countries must prioritize public health, improve infrastructure and work towards creating an environment conducive to growth and sustainability, and alternatives to current research and development schemes (such as alternatives to patents, the further development of PPPs and the provision of research incentives/subsidies to the pharmaceutical industry) must be studied and implemented. It is only then when, through global commitment from the entire international community, that the public health crises may be alleviated and suffering end.

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[225] *Id.*

[226] INTERNATIONAL CHAMBER OF COMMERCE, COMMISSION ON INTELLECTUAL PROPERTY, FURTHER VIEWS ON CROSS BORDER COMPULSORY LICENSING (2002), *available at* http://www.wto.org/english/forums_e/ngo_e/icc_trips_28_e.doc.

[227] Attaran & Gillespie-White, *supra* note 77.

[228] *Id.*

[229] *See* WORLD INTELL. PROP. ORG., STRIKING A BALANCE: THE PATENT SYSTEM AND ACCESS TO DRUGS AND HEALTH CARE (2005), *available at* http://www.wipo.int/freepublications/en/patents/491/wipo_pub_491.pdf.