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ANALYSIS OF INTERNATIONAL PATENT PROTECTION AND GLOBAL PUBLIC HEALTH

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The Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS), governed by the World Trade Organization, provides for stringent patent protection in the name of intellectual property rights. This international agreement has elicited public health concerns in developing countries, worried that they will be unable to access essential medicines as a result of increasing patented drug costs. This paper confirms legitimate attempts to promote global public health and, more specifically, ready access to medicines through ‘flexibilities’ including compulsory licensing and parallel importation, outlined in TRIPS, and reaffirmed in the Doha Declaration on TRIPS and Public Health. However, it is determined that, in practice, barriers exist which erode or have the potential to erode the implementation of these flexibilities in developing countries. These include a lack of local production capabilities and technological know-how, lack of economies of scale, needed legislative reform, and pressure from TRIPS-plus bi-lateral and regional agreements. Policy recommendations highlight the need for developing countries to cooperate on regional levels, developed countries to focus foreign aid strategies on building capacity, and for non-state institutions to create more proactive policies to assist implementation and information sharing amongst developing countries.

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BACKGROUND

The World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) was added under the General Agreement on Tariffs and Trade (GATT) at the close of the 1994 Uruguay Round. TRIPS, an internationally binding agreement for all 149 signatory members of the WTO, provides a minimum standard of protection for intellectual property in the form of copyright, patents, geographical indicia, trade secrets, industrial designs, trademarks, and integrated circuit layouts (WTO 2005a).

Interpreting the scope and application of specific policy flexibilities laid out in the 1994 TRIPS Agreement intended to improve access to essential drugs in developing countries remained challenging to those countries wishing to exercise them. The Doha Declaration on TRIPS and Public Health, developed in November 2001 by WTO members, centers on the use of flexibilities including compulsory licensing and parallel imports intended to prioritize global public health over commercial patent rights, and confirms the rights that the members of the TRIPS Agreement hold. It acknowledges the global outcry regarding the negative impacts of patent protections on the affordability of drugs for preventable and treatable diseases in developing countries, reaffirming the spirit of the agreement. It asserts that “TRIPS can and should be interpreted and implemented in a manner supportive of WTO members’ right to protect public health and, in particular, to ensure access to medicines for all” (WTO 2001a, par. 4).

PROBLEM: INTELLECTUAL PROPERTY AND INNOVATION PROTECTION VS. GLOBAL HEALTH AND ACCESS TO MEDICINES

Despite the presence of TRIPS flexibilities in the form of special provisions and safeguards for developing countries, widespread apprehension and skepticism remains over the feasibility of their implementation given the economic and political pressure to protect intellectual property (IP) over and above global health. The heart of the debate is striking a balance between the right to IP protection, championed by multinationals and developed countries, and the developing world’s right to health via affordable drugs in the face of extreme disease and poverty. An overview of the debate is presented below.

The Right to IP Protection

Arguments in favor of global patent protection are rooted in the financial commercialization rewards sought and secured through successful research and development (R&D) and innovation (Foreman 2002, 7). Without patents, as argued under economic theory, research would decrease as innovators would be hard pressed to recoup preliminary investments in light of forgery, knock offs and reverse engineered generics.¹ As such, this theory suggests that without patent protection pharmaceutical industries will invest less in research and be less likely to discover drugs that could potentially alleviate widespread diseases such as HIV/AIDS (Girvan 2002). As the political philosopher Michael Novak put it, “What is distinctive about the capitalist economy is the original discovery that the primary cause of economic development is the mind. The cause of wealth is invention, discovery, enterprise” (2000, 103). In sum, TRIPS is said to promote discovery, which will benefit society, without reducing market incentives.

The Right to Affordable Drugs

Societies are said to benefit from patent protection in the longer-term through new inventions from R&D, at the expense of possible short-term costs tied to monopoly pricing (Commission On Intellectual Property Rights 2002, 14). These costs, for example, are reflected in an estimated one-year supply of patented HIV antiviral drug treatment which can range from several hundred dollars to several thousand USD depending on the stage of treatment (Clinton 2005),² distribution networks, infrastructure capacity, etc. High prices such as these put essential drugs,³ out of reach for one third of the world’s population (Foreman 2002, 2). The governments of developing countries simply do not have the resources to support public health care and, more specifically, the distribution of medicines. Thus, their respective citizens personally bear a high portion of drug expenditures—67 percent in Africa and 81 percent in Asia and the Pacific—more than double that of most developed states (Foreman 2002, 2). As a result, 18 million deaths per year—50 thousand daily—are due to preventable poverty related causes (Reality of Aid Networks 2004, 2).

Prior to the introduction of TRIPS, countries formulated their own intellectual property right (IPR) policies. Over fifty countries (including developed countries) did not award patent protection on pharmaceuticals (Human Development Report 2001, 106). Many developing countries deemed this to be absolutely necessary to provide accessibility to medicines. At present, however, most developing countries are official parties to the TRIPS agreement; least developed countries (LDCs) are scheduled to become official parties by 2016 (WTO 2001a, par. 6).

Violation of stringent patent laws underlined in TRIPS which, for example, includes a twenty-year patent protection provision (Duckett 1999), could result in harsh recourse on developing states. This recourse could occur through threat of unilateral or multilateral action overseen by a Dispute Settlement Board (DSB) at the WTO, notably in the form of trade related sanctions. The ability of developed countries to wield TRIPS sanctions over developing states can be threatening to any country relying heavily on export profits and essential imports. Keeping in mind that one-third of the world's population subsists on less than U.S.\$2 per day (Millennium Project 2005), and half of the population in some of the poorest countries in Asia and Africa lack access to essential medicines (Foreman 2002, 2), forced compliance with TRIPS raises great concern regarding developing country access to essential medicines at domestically affordable prices.

PURPOSE OF PAPER

Controversies involving the right to protect IP for commercial gain persistently clash with arguments supporting access to drugs in poorer nations. Despite this ongoing debate, the governing body of international patent protection, namely the WTO, has attempted, with the implementation of TRIPS flexibilities and the recent Doha Declaration, to balance global health needs and international patent rights. It remains to be seen whether these attempts will elicit real benefits to the world's poor. This paper will conduct an analysis, in principle and in practice, of the TRIPS flexibilities and their subsequent interpretation and clarification within the Doha Declaration. This analysis will determine whether the TRIPS flexibilities and the Doha Declaration adequately protect developing country rights to public health by promoting access to medicines.

It will be shown that despite legitimate attempts to promote global public health and, more specifically, ready access to medicines through the flexibilities outlined in TRIPS and reaffirmed in the Doha Declaration on TRIPS and Public Health, in practice there are many constraints to implementing these flexibilities. Thus, the TRIPS provisions and Declaration together do not adequately protect developing countries' right to public health or promote access to medicines. For the purpose of this paper, access is defined as both affordability and availability of medicines, and developing countries include LDCs unless otherwise indicated.

FRAMEWORK: GLOBAL RIGHTS WITH PRIORITIES

Today, the right to health is firmly embedded in international,⁴ regional and national human rights declarations. This right was first introduced

in the 1946 World Health Organization's Constitution and was later followed in Art. 25 of the Universal Declaration on Human Rights (UDHR)⁵ (Faracik 2002, 25). The WHO Constitution stated that "the enjoyment of the highest attainable standard of health" is "a fundamental right of every human being without distinction of race, religion, political belief, economic or social condition" (WHO 1946, 2). Two regional agreements with similarly embedded rights include the European Social Charter (Art. 11) and the African Charter on Human and Peoples' Rights (Art. 16) (Musungu, et al. 2004, 1). These declarations legitimize the basic right to access medical care and affordable drugs.

Similarly, IP rights are defined under the UDHR agreement as a human right, in so far as they provide the basis or preconditions for essential participation, cultural freedoms, and innovation (Faracik 2002, 41). This right to IP is seen to induce future creation by protecting both the moral and material right to intangible property.⁶ This right was further condoned by the European Community in their statement purporting "that intellectual property and public health can and should be mutually supportive because without effective medicines, public health policies would be hampered" (European Commission 2001, par.2).

Positioning

It is the position of this paper that IP rights and the protection of public health are pertinent to the sustainable growth of nations. However, it is understood that international binding agreements, such as TRIPS, must delineate special protection for human life over and above that of IP rewards in circumstances where the latter erodes the attainment of former—when they cannot mutually support each other. The movement to protect IP and patents is rooted in the fundamental commoditization rewards that established the global pharmaceutical market as the second largest by market value in 2002 (Dyer 2002). Cristina Laurell focuses on the privatization of key health sectors in her criticisms of World Bank policies, identifying that pushing to "recommodify" health care turns it into "a terrain for capital accumulation and rejects health as a human need and social right" (1996, 1). In order to respect the basic health rights of individuals who cannot access medicines within the market due to high cost, it is necessary to de-commodify drugs by way of removing the onus on poorer nations to abide by international global patent standards. Access to essential medicines is critical to the fulfillment of the right to health and thus cannot be left in the hands of the market alone.

This analysis respects the right of poorer nations to develop by focus-

ing on the human health requirements needed to sustain productive and efficient economies. As Amartya Sen (2002) argues, justice is served when equal opportunities are granted to individuals and their capabilities are equalized. Presently, developing country capabilities are significantly lower than developed nations. Developing countries face added disadvantages due to a suppressed labor force caused by illness and death. This vast divide illustrates the need for developing countries to be supported so as to catch up to the more prosperous and healthy industrialized global economies of the West. Sen's emphasis on cosmopolitanism and global justice resonates throughout this paper, as does the important and enabling role that developed nations play in improving global health rights and access to medicines.

METHODOLOGY

The methodology supporting this thesis encompasses a two-step process. First, the basic framework of the Doha Declarations on TRIPS and Public Health will be explored to establish an understanding of the declaration's intent, and to identify and evaluate any special flexibilities within TRIPS that protect developing countries' right to health. Specifically, in order to focus this discussion, concentration will be placed on Art. 6, parallel importation (PI), and Art. 31, compulsory licensing (CL). Second, the paper will analyze the adequacy and applicability of the TRIPS special provisions in achieving the spirit of their intent in the global arena. On the basis of available studies and evidence, the analysis in this section will detail proposed theoretical roadblocks yet to be seen, as well as practical examples which evolved in developing countries after TRIPS came into force. To date, the flexibilities have been well defined but little practical evidence of their use exists, primarily due to the newness of the agreement as developing countries only became liable under TRIPS in 2005. As such, this paper will focus predominantly on foreseeable problems and potential alternatives.

Generalizing the barriers to TRIPS implementation is difficult due to the variations in implementing countries' profiles in terms of per capita income, production capacity, IPR legislation and overall degrees of development (Correa 1998). However, this analysis will present the prevalent and overarching concerns affecting the majority of poorer nations. Constraints to implementing TRIPS flexibilities discussed include: (1) the effects of market size attractiveness and lost profit incentives, (2) bureaucratic red tape, (3) drug registration impediments, (4) political coercion and TRIPS-plus pressures, (5) price inflation and R&D incentives, (6) misaligned national legislation, and (7) overall underdeveloped capacity. Policy alternatives

and recommendations are integrated throughout with a comprehensive summary in the concluding remarks.

ARGUMENT

This section introduces the Doha Declaration, followed by an explicit breakdown of TRIPS flexibilities and a feasibility assessment of their implementation and practical use by developing countries. Analysis of the flexibilities' advantages and disadvantages is viewed from the perspective of global health rights and access to medicines, centering on political realities, administrative and economic barriers, and legal interpretations.

Fair Vision: The Preamble to the Doha Declaration on TRIPS and Public Health

The 2001 Doha Declaration on TRIPS and Public Health is a political statement and ministerial decision that carries legal bearing on WTO members and bodies, including the DSB and Council for TRIPS (Correa 2002a, 44). Although a declaration has no clear legal status in WTO law, it can be seen as a subsequent agreement⁷ and binding precedent⁸ between members regarding the interpretation of the TRIPS Agreement and its applications. As such, the Declaration is a clear platform from which developing countries can raise concerns and structure domestic public health policies. The first four paragraphs of the Declaration delineate how TRIPS rules, active provisions, and extensions should be interpreted and utilized. Paragraph one of the document states: “We recognize 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” (WTO 2001a, par. 1)

After much controversy in its discussion, this preamble was written to include the most troublesome epidemics as reference, but does not limit its application to crisis or certain diseases alone (as some developed countries preferred). The Declaration refers to the effect of TRIPS on public health in general. Furthermore, despite the fact that the initial push for the Declaration to promote drug access, Doha also includes products and methods for health care. Clearly, the more inclusive approach to the Declaration proves positive for developing country governments.

Paragraph two and three of the declaration are as follows:

2. We stress the need for the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) to be part of the wider national and international action to address these problems.

3. We recognize that intellectual property protection is important for the development of new medicines. We also recognize the concerns about its effects on prices. (WTO 2001a, par. 2 & 3).

The recognition by WTO members of the difficulties developing countries face in addressing their domestic health needs due to protected markets and exorbitantly high drug prices is noteworthy. The TRIPS active resolutions, if put in place, could theoretically address the 89 percent of HIV/AIDS-infected individuals worldwide who reside in countries that make up less than 10 percent of world gross national product (Duckett 1999).

Paragraph four states:

4. ... should not prevent members from taking measures to protect public health. ... we affirm 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. ... we reaffirm the right of WTO members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose. (WTO 2001a, par. 4).

Providing access to medicines for all is a very strong statement indicating the belief that the right to health is an outcome by which TRIPS can be measured. This statement further solidifies the notion that countries can draw upon the flexibilities provided for within TRIPS to protect themselves. Attempts to impede the use of such flexibilities are contrary to the purpose of TRIPS itself (Correa 2002a, vii).

Paragraph five of the Declaration includes a non-exhaustive list of flexible measures, including CL (Article 31) and PI (Article 6). The following are not mentioned directly in the Declaration but remain key flexibilities in TRIPS itself: data protection provisions (Article 39); patentable subject matter provisions (Article 27); provision regarding exceptions to patent rights (Articles 25 and 30); abuse of patent rights (Articles 16 and 9); and provisions relating to anti-competitive practices and competition (Articles 40, 8:1 and 8:2). In order to focus the paper, an analysis of the two primary provisions, CL and PI will be presented.⁹

Two Primary Flexibilities Intended to Enforce the Declarations Vision

Compulsory Licensing (Art. 31)

Compulsory licensing allows governments to grant licenses under na-

tional law to manufacture and distribute generic drugs without obtaining agreement from the patent holder. This is normally undertaken after the original patent holder has denied the issuance of a voluntary license (VL) to produce the drug (Correa 2003, 3). CLs are accounted for in paragraph 5b of the Declaration. Under this provision each country has the right to grant CLs and further determine the grounds by which such a license is granted (Correa 2002a, 15). Possible grounds for granting a license, outlined in the agreement, include: national emergencies; anti-competitive practices by pharmaceutical companies; the need to establish a pharmaceutical base; and high prices (Musungu et al. 2004, 13). While countries retain the right to determine what constitutes these situations, TRIPS Art. 31 outlines granting conditions including remuneration and patent holder negotiation discerned on a case-by-case basis (Correa 2002a, 15). These provisions allow developing countries to stimulate domestic pharmaceutical manufacturing capacities by permitting the use of incentives and preferential procurement to domestic entities as well as generic subsidiaries.¹⁰

Though very few compulsory licenses have been granted to date,¹¹ this particular TRIPS flexibility appears to offer developing countries considerable capacity to obtain desired drugs at manageable costs. The number of CLs issued, owing to the fact that the threat of utilizing the CL provision can spur voluntary negotiations instead, does not necessarily measure the actual value of compulsory licenses in international law (Correa 2000, 97). This flexibility exists insofar as adequate generic manufacturers are present and willing to produce for modest returns, and the country in question has not negotiated away its use of flexibilities in more explicit TRIPS-plus agreements.¹²

Barriers to Compulsory Licensing

When the real costs and manufacturing capabilities required for local production are considered, potential problems with the issuance of CLs or VLs can arise. Generic manufacturers will likely rely on the importation of primary or active pharmaceutical ingredients, which constitute a large portion of the value of the final product and, subsequently, the revenues collected (Baker 2004, 35). Various factors can play into the actual capabilities of a developing country to manufacture pharmaceuticals successfully, including the size of the economy, the ratio of domestic R&D to GDP, income levels, local infrastructure and competitive inputs, and national policies governing production (Kaplan et al. 2003 as cited in Musungu et al. 2004, 27).

Additionally, invoking CLs or VLs may place too much emphasis on

the success of the generic producers and developing countries may, in turn, forgo their right to import drugs produced on a compulsory license defined under the waiver to the paragraph 6 provision. This waiver allows for cheaper generics, which are produced on a compulsory license in developed or developing countries, to be imported into a country deemed unable to manufacture the drug domestically.

It is beneficial for some developing countries to build capacity by producing generics at home, as South Africa has done (Musungu et al. 2004, 49). Domestic manufacturing, under certain conditions, can create employment, increase technological know-how, provide secure drug access and indirectly raise awareness with the hopes of reducing prices and augmenting access to medicines for the poor (WTO 2001b, par. 20). However, the pharmaceutical industry relies heavily on skilled workers, high-tech machinery and access to economies of scale. Countries must remain wary of its efficiencies relative to other generic producers. The extent to which the domestic cost of drugs exceeds more competitive producers, thus inhibiting drug access to those in need, must be considered when decisions of domestic investment and long-term efficiency are made. To that end, developing countries should be provided with assistance from the WTO to discern actual manufacturing capacities based on cost-effective measurements.

Parallel Importing (Art. 6)

Parallel importing refers to products that are imported into a country without consent by the patent holder and have been made available in the exporting country through a license from the patent holder, a process also known as comparison-shopping. Specifically, TRIPS allows the right to PI on the principle that the patent holder has been remunerated on the first sale of the drug and further compensation on subsequent sale would exhaust their rights. By parallel importing of generic pharmaceuticals, members of Kenya's non-profit sector successfully lowered the cost of anti-retroviral triple therapy drugs by 40%-65% (Lewis-Lettington and Munyi 2004, 17). Thus, this provision endorses price equity in the market and reaffirms the right of countries to use their own regime of exhaustion of rights in paragraph 5d of the Declaration. European Union policies have long-since included PIs of patented products, regarded as effective tools to temper costs (Duckett 1999).

Specific waivers have also been taken to TRIPS, allowing for the exportation of generics from nations, which have been granted CLs predominantly for the domestic market, to poorer nations lacking the manufacturing capacity to produce their own generic medicines. The WTO General Council

granted this process after much deliberation and added it to paragraph 6 of the Declaration in 2003 (Bonita de Boer 2005). This interim waiver became a permanent amendment to the TRIPS agreement on 6 December 2005. However, it will remain an interim waiver until such time as two-thirds of the WTO members ratify the change. Members have until 1 December 2007 to do so (WTO 2005b). This is a positive move for the extremely high number of non-producing countries (NPCs), which have no domestic pharmaceutical industry and thus cannot benefit from compulsory licensing.

Barriers to Parallel Importing

Despite the promise of the paragraph 6 provisions, no country to date has utilized it (as of December 2005, as cited in Cohen et al. 2005, 4). Explicit problems with the usage of paragraph 6 have been linked to the immaturity and extremely low numbers of qualified generic manufacturers producing the newest drugs, a lack of incentives, and the complexity of the system (Baker 2004, 35-36). Any WTO member can serve as an exporter of generics to NPCs, but they must then abide by the premise outlined by the chairperson that this provision must be used “in good faith to protect public health, without prejudice to paragraph 6 of the Decision, and not be used as an instrument to pursue industrial or commercial policy objectives” (WTO 2003, par. 29). This premise tries but fails to understand the basic monetary interests that drive marketplace incentives and entice commercial manufacturers to undertake highly procedural exportation processes.

Generic manufacturers tend to focus on the supply of non-patented medicines and have utilized the compulsory licensing provisions to a very limited degree (Correa 2002a, 33). As such, when small importing countries draw on the paragraph 6 waiver, they are required to identify a manufacturer willing to develop a production method at a low-cost for non-commercial objectives. Generic manufacturers may have little motivation to incur these cumbersome costs for minimal returns and lost economies of scale. As a result, generic manufacturers rarely begin producing the drug in question or preparing for its registration until very near to its expiry such that developed countries can be included in its accessible market base. For example, there is a minimal number of generic producers supplying the latest antiretroviral (ARV), Efavirenz, which is unlikely to change until numerous economic, technical and procedural barriers are eliminated (Baker 2004, 37).

One progressive solution proposed by Engelberg (2002) has been to encourage multiple poorer countries to pool their buying power, as pres-

ently done in the Caribbean region, to entice investors with newly created economies of scale. The Caribbean cooperative of seven different countries has enabled the overall reduction of drug prices by roughly 50 percent and stimulated the growth of more concentrated drug knowledge (Duckett 1999). Thus, for the TRIPS flexibilities, and specifically paragraph 6, to have real impact on the world's poor, smaller NPCs may wish to consider working together, pooling resources to drive up their collective demand of specific patented and even non-patented drugs. The premise of this collective would be to induce supply interest and market entrants, thus creating a more competitive pricing environment and more ready access to medicines (Baker 2004, 38).

The creation of large-scale demand, through grouping smaller importing countries' buying power, has been exemplified by the Clinton Foundation's HIV/AIDS Initiative (CHAI). In 2003, the Foundation successfully negotiated ARVs at the low cost of U.S.\$150 per year for over 50 developing countries. The foundation uses this momentum to provide technical assistance, mobilize human and financial resources and share best practices. In addition to creating a stronger buying and capacity building network, the Clinton Foundation targeted several generic producers and active ingredient manufactures so as to create competitive pricing and spread industry capacity (Clinton 2005).

Overarching Complications with TRIPS Flexibilities

Excessive Bureaucracy

Sovereign decisions taken by developing countries to draw on flexible provisions do not require pre-approval by the WTO, but do demand notifying the WTO and ad hoc consultations (Baker 2004, 16). Complications and time lags are introduced by the negotiations between the licensee and patent holder regarding the length of license to be granted and terms of commerciality. VLS are excluded due to their rapid applicability with little administration requirements and no judicial requirements (Baker 2004, 36). Bureaucratic procedures may deter implementation as delineated in the eleven-step procedure of the paragraph 6 waiver. Exporting members are required to issue different licenses for each drug being distributed to each country with specific quantities defined according to importer needs. Exporters are also required to alter the original packaging and labeling of generic drugs before distribution to avoid re-importation for profit. Further, exporters must provide notification when changes to packaging, quantities and receiving countries occur (Baker 2004, 17). In order to alleviate some of these procedural roadblocks, provisions should be stipulated to allow

for continuous exportation, an aspect missing in the TRIPS Agreement and Doha Declaration.

Carlos M. Correa speaks to this cumbersome process in his article, "Recent International Development in IPRs," noting that "Such a complex and burdensome system does not create a serious risk to the patent owners' position; hence, they will have little or no incentive to lower their prices or to negotiate voluntary licenses" (2003, 4). As evidenced in a recent study undertaken by the Health Systems Resource Centre (HSRC),¹³ Malawi, an NPC, is currently experiencing considerable technical difficulties in meeting the bureaucratic requirements to draw upon TRIPS flexibilities (Lewis-Lettington and Banda 2004).

Furthermore, generic exporters such as Canada have faced significant limitations on their efforts to produce drugs for the developing world. The list of eligible receiving countries and suitable drugs, prepared and maintained by the WTO, places limitations on exporters and is not necessarily reflective of an exporting country's position. For example, Canada challenged the absence of fixed-dose AIDS combinations on the list, which was recommended by the WHO as vital to improving care for this disease. Although the WTO leaves room for the alteration of the list of drugs and countries, Canada's efforts to add new drugs has been resisted through vigorous lobbying by pharmaceutical firms. For instance, Bayer was successful in its efforts to restrain one of its latest pneumonia therapy drugs, moxifloxacin, from appearing on the list (t Hoen 2005).

Restrictions on Drug Registration

In practice, patents are registered with the importing and producing country before hitting the market. Countries either rely on collective regional registration, individual registration or acceptance based on some previous registration made by another domestic drug authority. Typically, developing countries lack sufficient expertise and facilities to assess drug efficiency, safety, and quality, and thus rely on external authorities (Musungu et al. 2004, 28). A discussion paper written by the WHO in 1999 suggested that less than one in six WHO members had well-developed drug regulation of which all were industrialized states (WHO 1999, 13).¹⁴

This lack of domestic capacity can have the effect of slowing the process of regulatory approval on generics and hamper the rate with which TRIPS flexibilities can be implemented. An example of such flexibilities is the early working exceptions,¹⁵ one of which—Art. 39—is described below. Lack of regulation in the home market also impedes the ability of developing countries to issue CLs owing to fierce defensive behavior by patent holders, such as anti-competitive post-marketing practices (Musungu et al.

2004, 29). Lack of information and fear of being fined deters investment by local manufacturers in developing countries.

Art. 39 (Limiting the Protection on Test Data) of TRIPS has made special provisions to ease the process of bringing generics to market. TRIPS enables this by permitting a follow-on review of generic data against the original patent's data so as to grant a bio-equivalency or a standard mark of similarity, thereby avoiding tedious procedures demanded for original patent review. Bio-equivalency serves to eliminate duplicate costs incurred by time-consuming trial runs. Barriers to use include the cost incurred by generic firms to obtain bio-equivalency. This cost deters applications by generic companies unless a fair-sized market demands their goods, which most individual developing countries do not offer. Furthermore, as mentioned, many of the poorest developing countries lack sufficient regulatory resources required to readily register generics, thus making the process inefficient and uninviting for generic producers, who must be registered in the importing country.

One proposed solution is to have countries facing this predicament rely on an external, more stringent regulatory agency, instead of doing the registration internally (Baker 2004, 41). Under this scenario, generic manufacturers could apply for bio-equivalency with an external body and avoid having to make individual application to each nation requiring access. It may be beneficial to rely on a non-partisan third party rather than a developed country's approval process. The WHO, for instance, has introduced a pre-qualification program that will serve to eliminate some of the difficulties tied to complicated registration procedures and the data exclusivity provisions. This program is intended to qualify generics in a more timely fashion for developing countries in the absence of domestic capacity (WHO 2004), as seen in the several pre-qualified ARV generics and the short-list of fixed dose combination generics passed by the WHO to date.¹⁶ In addition to identifying quality products in a timely fashion, this program serves to introduce good manufacturing practice and inspection capacity to developing countries by teaming up a qualified inspector from a developed country with an individual from a developing country agency. Together they view each application submitted to the WHO (Hill et al. 2004, 39). Furthermore, this forum for approval could potentially serve as a medium by which developing countries collaborate on generic drug purchases so as to entice generic producers to register these countries' goods.

Alternatively, developing countries may wish to concentrate expertise and build a regional registration network to alleviate the onus of imple-

mentation and recognition on individual countries. Countries may wish to work toward this option over the long-term while relying on the WHO program for pertinent drug access in the interim.

National Legislation Requirements

The Doha Declaration is not self-executing and requires countries to implement proper domestic legislation so as to utilize the flexibilities (Correa 2002a, 45). As case studies undertaken in 2004 by the United Kingdom's Department for International Development's (DFID) Health System Resource Centre (HSRC) which focus on the absence of appropriate legislation in both Malawi and Kenya show, these countries were unable to draw upon the flexible mechanisms provided for in TRIPS (Lewis-Lettington and Banda 2004). Many developing countries share this same predicament primarily due to lack of technical expertise.

Despite the clear mandate of the Doha Declaration, its intent is difficult to realize in the developing world where legislative capacity and IP know-how is lacking. Expertise in the area needs to be offered to assist the appropriate implementation and execution of the TRIPS provisions. As Love (2001) notes, most patent systems in developing countries are modeled on EU or U.S. patent laws. Furthermore, the issuing of compulsory licensing has been commonplace in regions of the world such as North America, Europe and Japan, which presents an opportunity for knowledge sharing and best practice guidelines to poorer states (Love 2001). However, most of the assistance granted to the developing world to date has centered on compliance with patent protection rather than the appropriate usage of flexibilities within TRIPS.

As Correa identified, and was reaffirmed by the United Nations Conference on Trade and Development (UNCTAD) study entitled "The TRIPS Agreement and Developing Countries," developing countries which have made amendments to substantive laws in an effort to adapt TRIPS continue to face a division between law and enforcement primarily due to increased budgets required to control for policing at borders, administrative procedures as well as civil and criminal procedures in court (Correa 1998). Lack of legislative reform can hamper the abilities of countries to adequately utilize these special provisions.

Regional coordination efforts by developing countries in an attempt to pool resources relating to IP legislative experience and expertise could help mitigate such problems. This method is currently being undertaken in the Association of Southeast Asian Nations (ASEAN) region, which has pooled IP and policy experts to meet and discuss potential changes and adaptable legislative templates (Baker 2004, 84).¹⁷ Stronger political

support is required from the developed world with a greater emphasis on supplying technical expertise and technology transfer. Capacity building activities that are currently provided to developing countries lack focus on the flexibilities themselves and are primarily concerned with compliance of those provisions affecting patent holders (Balasubramaniam 2002, 17). Best practice guidelines pertaining to the proper implementation of TRIPS flexibilities are not readily available despite extensive exposure to CL and antitrust legislation in some developed states (Musungu et al. 2004, 25).

Political Pressure: TRIPS-plus

Flexibilities such as CLs and PIs may prove to be effective and feasible by overcoming technical barricades, however controversies surrounding IPRs and health will persist. This is due to the continued political and economic pressure placed on developing countries by industrialized states to avoid utilizing TRIPS flexibilities or to adopt TRIPS-plus provisions, which go beyond and effectively supersede the minimum requirements in TRIPS.

For instance, recent external extensions and heightened IP protection have arisen from developed country pressure in bilateral and regional trade agreements. The United States, for example, has concluded such trade agreements with Chile, Morocco, Jordan, Singapore and Australia. It continues to negotiate with Thailand and regionally with the Andes Region, Central America and Southern Africa. The ‘plus’¹⁸ in these agreements is the added IP protection originating from U.S. law—potentially eroding paragraph 6 and the Doha Declarations’ usage (Baker 2004, 41). These additions or changes can effectively negate much of the mobility afforded to developing countries through TRIPS flexibilities to protect the right to health and promote access to medicines. It has not been reported that the U.S. has pursued limitations on CLs or PI in low and middle-income countries. However, the refined CL standard remains part of the text of the Free Trade Area of the Americas negotiations and appears in the U.S.–Singapore agreement; the more stringent PI standard is reflected in U.S.–Singapore and U.S.–Australia Free Trade Agreements (FTA) (Baker 2004, 69-70).

Unilateral trade pressure by the United States can persuade countries from acting in a manner harmful to U.S. industry. This was seen in the case of Thailand when it attempted to produce a generic HIV/AIDS drug still under patent in the United States for the sole purpose of providing AIDS patients drugs at affordable prices. Thailand abandoned its production plans when faced with U.S. trade sanctions targeting its primary exports (Correa 2002b, 270). The ongoing threat of TRIPS-plus provisions and lack of political support for TRIPS flexibilities further constrain the intent

of the Doha Declaration. Developing countries should remain wary of these pressures and fight for special limitations in regional and bilateral agreements so as to ensure the ready access of medicine to those in need. When the Declaration does not supersede negotiated bilateral and regional agreements, stipulations should be included within the framework of these side agreements that respect the application of Doha's flexible measures and exclude the specific use identified constraints.

Developing countries will be hard pressed to obtain these special limitations without collective backing; thus, they should continue to work together to protect the practical use of the Declaration. This is exemplified in the case of South Africa, Brazil and India, which recently joined forces and collectively committed to resist increased IP protection from powerful trading partners (Department of Foreign Affairs, Republic of South Africa 2003, par. 45). A common approach to improve access to essential medicines will only strengthen the abilities of these countries to resist powerful industrialized pressures (Musungu et al. 2004, 76) and fight for improved rights in multilateral WTO negotiations.

TRIPS Agreement: Additional Considerations

Overall Price Impediments

With TRIPS, drugs will increase in cost as a direct result of the correlation between patents and the creation of monopolies, which augment prices (Correa 2002b, 261). The onus is on developing countries to proactively draw upon flexible measures to reduce costs to promote domestic access to medicines by bypassing patents in times of need. Mass generic drug producing countries, namely India and China, have long neglected to enforce patent laws. As of 2005, industries in such countries face new regulation and controls that will undoubtedly increase market costs. In the case of India, 5000 patent applications were made during the WTO transition period, effective in 2005, thereby increasing prices on existing drugs (The North South Institute & CCIC 2004, 2-3). One such example is Zantac, an ulcer treatment for pain, which in 1996, according to the Indian National Working Group on Patent Law, sold for U.S.\$0.42 in India (un-patented at the time). In patent countries such as the United Kingdom it sold for U.S.\$10.89, in the United States for U.S.\$23.78, and in Pakistan for U.S. \$5.89 (Faracik 2002, 66).¹⁹ Obtaining CLs for drugs that are less prevalent, but no less critical, like Zantac, is likely to face opposition from developed country patent holders and will receive less attention from generic producing governments concerned with higher profile malaria and AIDS drugs. While the first paragraph in the Doha

Declaration “recognizes the gravity of health problems” in the developing world, it does not define a universal and explicit list of accessible drugs. Therefore it is naive to believe that less popular drugs required by a smaller proportion of individuals in poorer nations will be prioritized. With the recent adoption of TRIPS by developing countries, and specifically India, the extent of this phenomena remains to be seen. However, it is unavoidable that lesser known drugs will become less accessible to the poor whose health remains dependent upon them.

Again, this becomes a numbers game. If developing countries collaborate at a regional level on efforts to collect fair drug prices, this will ease the registration costs of generics and entice generic manufacturers to pursue production for a smaller percent of individuals suffering from some medical ailment in each country as they collectively represent a much more enticing market.

Disproportionate Spending on Research & Development

Another important question to be asked relates to the focus of R&D by pharmaceutical companies. While patent protection clearly defines the rights of the holder, it does not speak as vehemently to obligations. As a result, a clear imbalance has developed between patent protections as an incentive for innovation, given that no real vehicle exists to direct such innovation other than monetary incentives (‘t Hoen 2005). While developing countries form 80 percent of the market, new research is predominantly spent on rich country concerns. From 1975-1999, 1,393 new chemical entities were introduced of which 379 were defined for therapeutic use and 13 for tropic diseases—of which 4 made it to market (Muddassir 2005). Tuberculosis, malaria, pneumonia and diarrhea account for 20 percent of world disease and are rampant in underdeveloped regions of the world but obtained less than 1 percent of the funds allocated to health research in 2002 (Singh 2002). This phenomena is exacerbated by the market flooding of ‘me too’²⁰ drugs which are much less valuable, modified imitations of existing medications sold with a new or extended patent. While patent protection has increased over the last twenty years, the mean innovation rate has declined (‘t Hoen 2005). While some of these patents may reflect very weak or even illegitimate extensions, it is increasingly difficult for smaller generic firms to litigate against bigger multinational enterprises for unfair practice due to the sheer costs of litigation (Correa 2002b, 265). If developing countries are asked to abide by more stringent patent laws and pay higher prices for drugs whenever feasible, a more equitable proportion of these funds should be allocated toward those diseases plaguing the developing world. Developed country governments should recognize

the role they have in ensuring that all individuals can exercise the right to public health no matter their geographical or economic location. Signatories to the UDHR declaration have an obligation to protect those beyond their own borders. A global movement to shift the R&D focus beyond bottom line figures is necessary so as to incorporate neglected developing world diseases.

To stimulate such a shift, it has been proposed that developed countries introduce public-private partnerships between governments and biotechnological firms to encourage research into developing world diseases. These partnerships would be based on mechanisms of incentives where governments agree to purchase developed vaccines from firms at a pre-negotiated price upon development, focusing on medicines in developing countries such as malaria vaccines (Sachs 1999). Prospects such as these are worth further investigation.

CONCLUSION: PROTECTION AND PROMOTION IN PRINCIPLE

The Doha Declaration on TRIPS and Public Health has set a firm foundation upon which developing countries can protect their public health needs against the WTO's intellectual property policies. The preamble of this declaration addresses the fundamental concerns purported by developing member states, including a need for broad recognition of medical goods and diseases where the circumvention of patent protection rules for matters of public health is expected and necessary. The Declaration clarifies the right of poorer nations to act outside the market to avoid higher commodified drug prices by way of drawing on pertinent flexible mechanisms, including compulsory licensing and parallel imports. Therefore, it is concluded, in principle, that developing countries are adequately equipped with special provisions to protect their right to public health and promote access to medicines.

Practical Barriers

While the TRIPS flexibilities denoted in the Doha Declaration have well-guided intent, the abilities of developing countries to utilize these flexibilities for public health concerns face onerous internal and external barriers. Many developing countries continue to lack local production capabilities and experience difficulties in achieving economies of scale. There is also a lack of efficient technical expertise to create the needed legislative reform to implement TRIPS flexibilities, as well as a lack of regulatory and registration capacity for drug patents and generics. The lengthy procedural and bureaucratic processes for importers or exporters of

generics, under both the CL and PI provisions, can be discouraging from a technical and economic perspective. Beyond barriers to implementing TRIPS flexibilities, bilateral and regional FTA agreements impose new negative pressures for developing countries to adopt TRIPS-plus provisions, potentially eroding protection provided for in Doha. Despite the Declaration's broad approach, higher prices of less popular drugs may cause more inaccessibility. Concerns also remain over the minimal R&D spending on diseases plaguing poorer regions.

It is evident that, despite legitimate attempts, the TRIPS provisions and Declaration together do not adequately protect the right of developing countries to public health and access to medicines. The aforementioned internal and external barriers erode, or have the potential to erode, the practical implementation of the flexibilities themselves.

Policy Recommendations

Extensive work is needed at both the regional and international level to ensure the successful implementation of the TRIPS flexibilities to actualize real global health benefits. The series of recommendations detailed by this paper reflect three distinct trends. First, there is a need for developing country governments to cooperate at the regional level in order to alleviate economic and bureaucratic constraints. Poorer nations should pool their drug demand so as to reduce high drug prices and eliminate the lack of investment incentives for generic producers. Collaboration and participation in regional registration networks and forums on legislative reform would help minimize the absence of technological know-how by improving content knowledge and expertise. Developing countries should also collectively commit to work together to protect the Declaration's practical use by joining forces to resist increased IP protection from powerful trading partners and pressure patent holders to issue VLs, which are less time consuming and cumbersome than CLs.

A second trend centers on the need for the developed countries governments to play a more proactive role in providing aid in ways that offer best practice principles and encourage technology transfers and strategic R&D spending. Most importantly, the developed world needs to respect the rights of poorer nations to implement flexibilities without pressure from more restrictive bilateral and regional trading arrangements, or blatant unilateral pressure.

Finally, non-state institutions must be reformed to address some of the aforementioned constraints. The WTO should continue to expand its technical assistance and training plan in the coming years as to provide expertise to developing countries regarding their manufacturing capabilities,

adapting legislation and disseminating information on successful regional cooperatives.²¹ Furthermore, the Doha Declaration should be considered a living and breathing document, one that is formally reviewed and iteratively improved. One such improvement would be to streamline the arduous and redundant processes tied to CLs and PI.

The WHO should continue to encourage the usage of the pre-qualification program for generics to countries lacking capacity and consider utilizing this forum to assist in regional collaboration aimed at achieving economies of scale. Additionally, international NGOs should remain conscious of these constraints and focus projects on building capacity in relevant areas, as seen in the activities of organizations such as *Médecins Sans Frontières* and Oxfam.

Eight thousand people will die in the next twenty-four hours from AIDS in the developing world, most without ever having had adequate access to antiviral drugs or a real right to life (t Hoen 2005). The recommendations made here all but scratch the surface of the major global reforms that must take place so as to properly address and acknowledge the rights of individuals' to access medicines. TRIPS flexibilities and the Doha Declaration have set the stage; however, a greater effort is needed to overcome internal and external constraints. Without such an effort, the health of the developing world will continue to suffer at the hands of economic concerns.

NOTES

- ¹ Reverse engineering is usually undertaken to produce a duplicate of a system without access to the original prints. It requires one to break down the model from big to small so as to see a system in all its separate parts and discern their interrelations in an effort to build a replacement model.
- ² Second-line treatment for HIV/AIDS cost at least 10 times that of first-line therapies (Clinton 2005).
- ³ Essential drugs: "Those drugs that satisfy the health care needs of the majority of the population; they should therefore be available at all times in adequate amounts and in appropriate dosage form. The WHO Model List of Essential Drugs is intended to be flexible and adaptable to many different situations; exactly which drugs are regarded as essential remains a national responsibility" (Duckett 1999, 10).
- ⁴ Similar declarations are included in conventions including the 1966 International Covenant on Economic Social and Cultural Rights (Art. 12), the Elimination of All Forms of Discrimination Against Women (Art. 10, 12, 14), the Convention on the Elimination of All Forms of Racial Discrimination (Art. 5) and the Convention on the Rights of the Child (Art. 24) (Faracik 2002, 25).

- ⁵ [25(1)] “Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care and necessary social services, and the right to security in the event of unemployment, sickness, disability, widowhood, old age or other lack of livelihood in circumstances beyond his control” (United Nations Department of Public Information 2005).
- ⁶ Article 27 of the UDHR notes that: “1. Everyone has the right freely to participate in the cultural life of the community, to enjoy the arts and to share in scientific advancement and its benefits. 2. Everyone has the right to the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author” (United Nations Department of Public Information 2005)
- ⁷ Under article 31.3 (a) of the Vienna Convention on the Law of the Treaties, a declaration can be used for this purpose.
- ⁸ According to the European Commission
- ⁹ For a complete analysis of flexibilities see article Musungu, et al., 2004.
- ¹⁰ See paragraph 2C of the Declaration.
- ¹¹ “The largest number of compulsory licenses has probably been granted in Canada, under the 1969 law amendment that authorized automatic licenses on pharmaceuticals, and in the USA, under antitrust laws” (Correa 2000, 97).
- ¹² TRIPS-plus: Regional Trade Agreements & Free Trade Agreements with more stringent IP protection stipulations. To be discussed further on in the paper.
- ¹³ The British Government Department for International Development (DFID) receives advice from HSRC, which is managed by several international organizations. These include the Aga Khan Health Services Community Health Department, Kenya; CREDES-International, France; Curatio International Foundation, Georgia; Institute of Development Studies University of Sussex, UK; International Health Systems Group - Harvard School of Public Health, U.S.A.; and the Institute of Policy Studies, Sri Lanka.
- ¹⁴ For more information see World Health Organization. 1999. *Status of Drug Regulation and Drug Quality Assurance in WHO African Region and Selected Countries*, as cited in Love 2001.
- ¹⁵ This early working exception allows generic companies to obtain marketing approval of a drug before its patent expires. This speeds up the introduction of the generic to market once the patented drug expires.
- ¹⁶ For more information on the Pre-Qualification program see the WHO website: <http://mednet3.who.int/prequal/> (accessed February 25, 2006).
- ¹⁷ For more information see ASEAN. 2003. *Cooperation on Intellectual Property*. <http://www.aseansec.org/10109.htm> (accessed on March 6, 2005).
- ¹⁸ According to recent research under taken by the DFID HSRC, the re-occurring

more stringent standards within the aforementioned agreements include: (1) supporting the exclusive use of compulsory licenses for national emergencies by governments for non-commercial use only, (2) precluding production for export, (3) forbidding parallel trade, (4) extending patent granting to new uses and ease patent standards, (5) granting data exclusivity, and (6) linking drug registration to patent rights (Baker 2004, 41).

¹⁹ Value expressed in terms of American dollars. Conversion performed by author from Indian Rupees to U.S. Dollars using March 3, 2006 exchange rates.

²⁰ Drugs, which are very similar but not completely identical to one another.

²¹ At present, under the WTO 2006 technical assistance and training plan, a TRIPS seminar is to be held in 5 separate regions of the World, of which one, in Africa, focuses entirely on TRIPS and Public Health. (WTO 2005c).

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