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TRIPS: Protecting the Rights of Patent Holders and Addressing Public Health Issues in Developing Countries

By

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Introduction

On April 15, 1994, the world began down an uncertain path that will either lead to greater harmony and prosperity for all or widen the gap between developed and developing countries. On this date, the signatory nations of the General Agreement on Tariffs and Trade (GATT) signed an Agreement of Trade Related Aspects of Intellectual Property (TRIPS).¹ TRIPS is intended to reverse worldwide thinking regarding trade from an anti-protectionist philosophy to one of global competition. TRIPS achieves this transformation by establishing three core commitments: national treatment, most-favored-nation-treatment, and minimum standards.

Although TRIPS establishes a framework for all countries to harmonize their intellectual property law, it does not come without controversy. The TRIPS agreement aims to facilitate stronger protection for intellectual property rights, investments in regulatory agencies to enforce these rights and more consistent

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¹ Agreement on Trade-Related Aspects of Intellectual Property Rights (Apr. 15, 1994), at http://www.wto.org/english/docs_e/legal_e/27-trips.pdf. (Last Visited on Oct. 31, 2004) [hereinafter *TRIPS*]

regimes of protection across international borders.² But these three goals may adversely impact the economic development and overall health of the citizens of developing countries. One issue that has developed since the implementation of TRIPS is the negative effect its patent protection provisions have had on developing and least developed countries and their ability to access pharmaceuticals. As a result of the patent protection, millions of people cannot access drugs necessary to treat their conditions. This forces developing countries to choose between allocating their limited resources to treat their citizens or letting them die.

One concern is that the increased patent protection that TRIPS provides will likely lead to higher pharmaceutical prices. TRIPS does contain provisions that offer safeguards from patent abuse and the negative effects of patent protection, but it is unclear how countries are to implement these safeguards to their benefit. Members of the WTO found this issue to be of such a high level of importance that the Fourth Ministerial Conference in Doha, Qatar was devoted exclusively to this issue.³

This paper will address the following issues: first, an analysis of the TRIPS provisions that potentially could be interpreted to allow developing

² Keith E. Maskus, *Intellectual Property Challenges for Developing Countries: An Economic Perspective*, 2001 U. ILL. L. REV. 457, 457 (2001).

³ *Declaration on the TRIPS Agreement and Public Health* (Nov. 14, 2001), at http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.pdf. (Last Visited on Oct. 31, 2004) [hereinafter *Doha Declaration*]

countries to access pharmaceuticals absent a direct sale or license from the patent-holder; second, an examination of the Doha Declaration of November 2001 and its effect on the potential interpretation of the aforementioned TRIPS provisions; third, a discussion on the current developments that have occurred with regard to the Doha Declaration; and finally, a discussion of the conflicts between the United States and developing countries over compulsory licensing. This paper concludes with commentator's view on the matter and possible solutions.

I. The Availability of Compulsory Licensing Under TRIPS Articles 30 and 31

Developing countries have interpreted Articles 30 and 31 to allow countries to grant compulsory licenses to third parties to manufacture the necessary pharmaceuticals that would be able to address public health issues such as, for example, HIV/AIDS.⁴ Compulsory licensing permits the manufacture and use of generic drugs without the agreement of the patent holder.⁵ Developed countries generally disfavor compulsory licenses since a government of another country can strip a patent-holder of his rights while reducing the amount spent on research and development ("R&D"). The patent-holder is entitled to receive a reasonable compensation for the compulsory license, determined by the country granting the

⁴ Samantha Shoell, *Why Can't the Poor Access Lifesaving Medicines? An Exploration of Solving the Patent Issue*, 4 MINN. INTELL. PROP. REV. 151, 180 (2002).

⁵ Review of TRIPS, Int'l Trade Daily News (BNA) (Int'l Trade Rep.) note 4, at D7 (June 9, 1999) (highlighting the recent controversy surrounding the interpretation of compulsory licensing in TRIPs).

license.⁶ The rationale behind developed countries' granting compulsory licenses is their belief that strong intellectual property protection will adversely affect the public health by denying citizens access to life-saving, brand-name, prescription drugs that they cannot afford.⁷ Developing countries also argue that public health concerns are paramount to commercial profits, which puts developed countries in the awkward position of being portrayed as profit conscious tyrants.

It is difficult to find a common interpretation of TRIPS Articles amongst the WTO Members. There are different Articles within TRIPS, that when read in conjunction with others, can lead a WTO Member to make a good faith interpretation of the Article that may conflict with the interpretation of other WTO Members. Although this would seem to be grounds for the Dispute Resolution Unit of the WTO to address, the WTO has decided to address these issues at the Fourth Ministerial Conference in Doha, Qatar to bring the WTO Members to remedy this issue using more diplomatic means.

A. TRIPS Article 30

Article 30 is seen as a means to allow countries that do not have the ability to manufacture pharmaceuticals to access them without violating TRIPS. It could allow drug-producing countries to issue compulsory licenses without the Article

⁶ TRIPS, *supra* note 1, at Part II, sec. 5, art. 31(h).

⁷ *The WHO Model List of Essential Drugs*, at <http://www.who.int/medicines/organization/par/edl/infedlmain.shtml> (last visited Nov. 8, 2004).

31(f) requirement that the drugs be used exclusively in the domestic arena.⁸

Article 30 eliminates this requirement through a broad interpretation that provides exceptions to exclusive patent rights under three conditions: (1) the exception must be limited; (2) it must not unreasonably conflict with the normal use of the patent; and (3) the legitimate interests of the patent-holder must be protected, while also taking into account the legitimate interests of third parties.⁹

When TRIPS was originally negotiated Article 30 was seen as a mechanism similar to “fair-use” of copyrighted materials.¹⁰ This analogy was made due to the similarity in language between Article 30 and Article 13, which deals with exceptions to copyright rights.¹¹ The United States has interpreted its copyright “fair-use” doctrine as being consistent with Article 13 of TRIPS, but has had trouble reading this into Article 30.

B. TRIPS Article 31

Article 31 provides a detailed means for a WTO Member state to grant use of the subject matter of a patent without the consent of the patent-holder. Article 31 does not expressly refer to the term “compulsory license,” but when read along with Article 2(1) of TRIPS and Article 5(A)(2) of the Paris Convention; the

⁸ Andrea M. Curti, *The WTO Dispute Settlement Understanding: An Unlikely Weapon in the Fight Against AIDS*, 27 AM. J.L. & MED. 469, 481 (2001).

⁹ TRIPS Agreement, *supra* note 1, Part II, sec. 5, art. 30.

¹⁰ Donna M. Gitter, *International Conflicts over Patenting Human DNA Sequences in the United States and the European Union: An Argument for Compulsory Licensing and a Fair Use Exception*, 76 N.Y.U.L. REV. 1623, 1690 (2001).

allowance of compulsory licensing is implied.¹² Article 2(1) of TRIPS states that WTO Members must comply with specific articles of the Paris Convention, including Article 5, which permits the use of compulsory licensing.¹³

Section (b) of Article 31 provides three exceptions for countries to compromise a patent-holder's rights under certain circumstances, including a "national emergency" exception.¹⁴ The problem with the "national emergency" exception under this Article is that there is no definition in TRIPS that specifies what a national emergency is and reading the other Articles of TRIPS do not shed any light on the subject. Even if Article 31(b) is interpreted broadly Article 31(f) presents a problem to countries that do not have the ability to manufacture pharmaceuticals. Article 31(f) can be interpreted as limiting the distribution of goods produced under a compulsory license to "the domestic market."¹⁵ This makes it impossible for developing countries that do not have the ability to produce drugs to obtain them from countries that do. Article 31 would help

¹¹ *See id.* ("TRIPS Article 13 provides that "Members shall confine limitations or exceptions to exclusive rights to certain special cases which do not conflict with a normal exploitation of the work and do not unreasonably prejudice the legitimate interests of the right holder.")

¹² Grace K. Avedissian, *Global Implications of a Potential U.S. Policy Shift Toward Compulsory Licensing of Medical Inventions In a New Era of "Super Terrorism"*, 18 AM. U. INT'L L. REV. 237, 263 (2002).

¹³ TRIPS, *supra* note 1, at Part I, art. 2.

¹⁴ TRIPS, *supra* note 1, at Part II, sec. 5, art. 31(b). ("...such use may only be permitted if, prior to such use, the proposed uses has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be waived by a Member in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. In situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable....")

¹⁵ *See id.* at Part II, sec. 5, art. 31(f).

developed and developing countries that have the ability to produce pharmaceuticals in the case of a “national emergency,” but makes pharmaceuticals unobtainable for the countries that would need to import them to address their national emergency.

II. The Doha Declaration

A. Background

In November 2001, the TRIPS Council convened a special session to discuss the interpretation of the TRIPS Agreement and define the relationship between intellectual property rights and access to essential medicines under the Agreement. This session was necessary because there were several plausible divergent interpretations of TRIPS that could be made in good faith that theoretically would be consistent with TRIPS. The goal of the session was to give legal clarification to issues that are ambiguous if left standing alone in the text of TRIPS.

There were several events that lead to the developing countries calling for the Fourth Ministerial Conference in Doha, Qatar to convene and to discuss how TRIPS should be interpreted with respect to pharmaceutical patents. The most pressing issue that the developing countries faced was the rising number of people in their countries that were suffering due to a lack of access to drugs that combat HIV/AIDS. In sub-Saharan Africa, for example, over 29.4 million people are

currently living with HIV/AIDS; 3.5 million people contracted¹⁶ the virus in 2002.¹⁷ In China, medical experts have predicted that 10 million people could be infected with the virus by 2010.¹⁸

Developed and developing countries presented two conflicting points of view at the special Conference. On the one hand, the congregation of developing countries, lead by the Africa Group, the Association of South-East Asian Nations, and Brazil, sought to clarify the TRIPS Articles that allow Members to promote and protect public health and other overarching public policy objectives.¹⁹ The draft proposal of the developing countries addressed political principals to ensure that TRIPS did not undermine the legitimate right of WTO Members to establish their own domestic public health policies, including provisions related to compulsory licenses, parallel imports, and countries that do not have the ability to produce pharmaceuticals.²⁰

The developed countries, lead by the United States, argued that a strong patent regime would produce benefits for all countries, while acknowledging the

¹⁶ Review of TRIPs, Int'l Trade Daily News (BNA) (Int'l Trade Rep.) note 4, at D7 (June 9, 1999) (highlighting the recent controversy surrounding the interpretation of compulsory licensing in TRIPs).

¹⁷ WHO/UNAIDS, *AIDS Epidemic Updated*, at http://www.unaids.org/html/pub/publications/irc-pub03/epiupdate2002_en_pdf.htm. (Last Visited on Nov. 11, 2004)

¹⁸ People's Daily, *China, US launch cooperation in fighting AIDS*, *Xinhua's China Economic Information Service*, (Last updated on Nov. 8, 2004), at http://english.peopledaily.com.cn/200310/21/eng20031021_126464.shtml.

¹⁹ TRIPS and Public Health, submission of the Africa Group and other developing countries to the Special TRIPS Council Meeting of June 2001, ¶5, at <http://www.twinside.org.sg/title/twr131e.htm>. (Last Visited on Nov. 11, 2004).

interests of developing countries in access to essential medicines.²¹ The proposed draft presented by these countries stressed the importance of the protection of intellectual property since doing so would allow further research and development (“R&D”) of new treatments, which would contribute to global health objectives.²² The events of September 11, 2001 and the subsequent bio-terrorism scare in the United States, not only changed the face of the world, but also placed the United States in an awkward position in terms of their trade policy. The anthrax scare forced the United States and Canada to consider issuing a compulsory license on Ciproflaxin (Cipro), the antibiotic used to treat anthrax, if the disease turned out to be more wide-spread than it did.²³ The two countries consideration of producing these drugs generically to address a “national emergency” (22 reported cases of anthrax, resulting in five deaths)²⁴ puts them at a disadvantage when negotiating the scope of TRIPS. The disadvantage stems from the U.S. almost declaring a “national emergency” for the anthrax scare when in the past the U.S. has questioned countries declaring a national emergency where thousands of

²⁰ Ellen ‘t Hoen, *TRIPS, Pharmaceutical Patents, and Access to Essential Medicines: A Long Way From Seattle to Doha*, 3 CHI. J. INT’L L. 27, 39 (Spring 2002).

²¹ James Thuo Gathii, *The Legal Status of the Doha Declaration on TRIPS and PUBLIC Health Under the Vienna Convention on the Law of Treaties*, 15 HARV. J.L. & TECH. 291, 296 (Spring 2002).

²² *Supra* note 20.

²³ Susan K. Sell, *TRIPS and the Access to Medicines Campaign*, 20 WIS. INT’L L.J. 481, 515 (Summer 2002).

²⁴ James Hughes and Julie Gerberding, *Emerging Infectious Diseases. Anthrax Bioterrorism: Lessons Learned and Future Directions*, at <http://www.cdc.gov/ncidod/EID/vol8no10/02-0466.htm> (Last Visited on November 8, 2004).

people die everyday from treatable diseases.²⁵ The United States eventually negotiated with Bayer to obtain Cipro at a reduced price.²⁶ This also put the United States in an awkward position since this was exactly the tactic the U.S. criticized and prosecuted when Brazil used the threat of granting a compulsory license to obtain cheaper HIV/AIDS drugs.²⁷ These circumstances allowed the developing countries to proffer a successful opposition to the U.S. when negotiating the Doha Declaration, as is evident in the final draft.

The final draft of the unanimously adopted Doha Declaration addressed the pharmaceuticals concerns of the WTO Member with insufficient or no manufacturing capacities.²⁸ The Declaration starts with the Members recognizing the gravity of the public health problems afflicting many developing countries.²⁹ Further the Members agreed that the TRIPS Agreement “does not and should not prevent Members from taking measures to protect public health” and should be interpreted in a manner that promotes access to medicines for all.³⁰ The Declaration also recognized the potential problem that Members with insufficient or no manufacturing capacities to produce pharmaceuticals might face in making effective use of the compulsory licensing provisions of the TRIPS Agreement and therefore instructed the TRIPS Council to come up with a solution before 2002

²⁵ *Supra* note 23 at 516.

²⁶ *Supra* note 23 at 515-16.

²⁷ *Supra* note 23 at 516.

²⁸ Doha Declaration, *supra* note 4 at ¶6.

²⁹ *See id.* at ¶ 1.

ended.³¹ It appeared that the only thing that came out of the Doha Declaration was the Members acknowledgment of the existence of a problem. However, recent developments have shown that the Members are now addressing the problem consistent with the wishes of the developing world.

Current Developments In Conjunction With the Doha Declaration

The December 31, 2002 deadline to address the difficulties that WTO Members with insufficient or no manufacturing capacities could face, as addressed in ¶ 6 of the Doha Declaration passed without the parties reaching an agreement. The U.S. caused the division between parties after its initial objection of the solutions offered by the rest of the membership. The U.S. wanted the list of epidemics eligible for compulsory licenses to be limited and specific.³² Eventually, the U.S. backed down from this position and on August 30th, 2003 the WTO announced its decision to implement Paragraph 6 of the Doha Declaration (“Decision”), essentially establishing a waiver on Article 31(f)’s “domestic market” restriction.^{33,34} The Decision allows any Member country to export pharmaceuticals made under compulsory licenses as long as the export to

³⁰ *See id.* at ¶ 4.

³¹ Doha Declaration, *supra* note 4, at ¶ 6.

³² Datuck Seri Rafidah Aziz, *Cancun Conference: The Malaysian perspective*, Ministry of International Trade and Industry of Malaysia, at <http://www.miti.gov.my/wto-cancun.html>. (Last Visited Nov. 8, 2004).

³³ *Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health* (Aug. 30, 2003), http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm. (Last Visited Nov. 8, 2004).

³⁴ TRIPS, *supra* note 1, at Part II, sec. 5, art. 31(f). (compulsory licensing must be “predominately for the supply of the domestic market”)

an eligible importing Member satisfies the requirements of Paragraphs 2 of the Decision.^{35,36} While the Decision allows all Member countries to take advantage of the waiver, 23 countries stated in the Decision that they will not import pharmaceuticals under the Decision, and another 11 countries stated they would only use the waiver provision if an emergency or extremely urgent situation arose.³⁷

On the face of the Decision, it seems as if the humanitarian objectives that were defined in the Doha Declaration are being achieved. Upon further analysis, however, it becomes apparent that the developing countries have to go through a lot of red tape to purchase drugs from the developed countries, which goes against the main goal of the Doha Declaration: to provide easy access to pharmaceuticals for developed and developing countries. In looking at the Decision, there are 10 possible steps that least developed and developing countries must go through

³⁵ *Supra* note 33, at ¶2(a). (A compulsory license can be used to import a pharmaceutical product if the importing country “(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...; and (iii) confirms that, where a pharmaceutical product is patented in its territory, it has granted or intends to grant a compulsory license in accordance with Article 31 of the TRIPS Agreement...”)

³⁶ *Supra* note 33, at ¶2(b). (Compulsory licenses issued by the exporting Member shall be issued if “(i) only the amount necessary to meet the needs of the eligible importing Member(s) may be manufactured under the license 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 license shall be clearly identified as being produced under the system set out in this Decision through specific labeling or marketing. Suppliers should distinguish such products through 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...”)

³⁷ *Supra* note 33, at ¶1(b).

before the drugs would be available to them.³⁸ A country where the drug has been patented that is seeking to import a drug through a compulsory license would first have to seek a voluntary license on commercially reasonable terms for a reasonable period of time.³⁹ Second, if the importing country was unsuccessful in obtaining a voluntary license, they would have to apply to the WTO for a compulsory license.⁴⁰ Third, if the compulsory license is for import, the importing country must assess its generic industry's capacity to produce the medicine locally.⁴¹ Fourth, if the capacity is insufficient, it must notify and explain to the WTO the reason for its decision.⁴² Fifth, the importing country must notify a potential exporter.⁴³ Sixth, that exporter must in turn seek a voluntary license on commercially reasonable terms for a reasonable period of time.⁴⁴ Seventh, that exporter must seek a compulsory license from its own government on a single-country basis.⁴⁵ Eighth, compensation by royalty must be set based on standards of reasonableness in the importing country.⁴⁶ Ninth, if a license is granted to a generic producer, the exporter must investigate pill size,

³⁸ Importing countries that do not have the capacity to manufacture pharmaceuticals would have to go through more steps than countries that have the ability to produce the drug in question generically.

³⁹ Brook Baker, *Vows of Poverty, Shrunken Markets, Burdensome Manufacturing and Other Nonsense at the WTO* (Sept. 27, 2003), at http://www.healthgap.org/press_releases/03/092703_HGAP_BP_WTO_Cancun.html. (Last Visited Nov. 8, 2004)

⁴⁰ *Id.*

⁴¹ *Id.*

⁴² *Id.*

⁴³ *Id.*

⁴⁴ *Id.*

shape, color, labeling, and packaging of the patent-holder's product in the importing country and differentiate its new product in all respects, regardless of cost.⁴⁷ And finally, the generic producer would need to seek product registration and prove bio-equivalence based on a pill of different size and shape. This process is complicated further because each step must be followed each time a drug is exported, even if the same drug is being exported to another country. This added procedural nightmare is not in the spirit of the Doha Declaration for it will further complicate matters for countries trying to provide relief for their citizens. Citizens that are in desperate need of live-saving pharmaceuticals.

Five major parties are involved in fulfilling developing or least developed country's pharmaceutical needs via compulsory licenses: the importing country; the exporter; the exporting country; the patent-holder in the importing country; and the WTO. The most interesting relationships exist between the importer and exporter and between the exporting country and patent-holder. The exporting country is in a very influential position in terms of affecting the global marketplace for pharmaceuticals of all varieties, especially the generic market. If an importing country specifically targets exporters who concentrate in the generic market, an exporting country that believes in strong patent rights may decline to grant compulsory license to such parties and instead insist that any request to

⁴⁵ *Id.*

⁴⁶ *Id.*

⁴⁷ *Id.*

export pharmaceuticals via a compulsory license from a developing or least developed country be fulfilled by the actual patent-holder. If the exporting country were to grant licenses to the patent-holder of the drug that is the subject of a compulsory license from a developing country, this would only drive the prices of the drug higher because there would be little or no incentive for these parties to lower prices without the outside threat to its stronghold on the market for the particular drug. If the exporting country were to grant the compulsory license to a generic manufacturer, raising competition by making generics more available, the patent-holder would lower prices. This decision appears to rest with the exporting country, but the ramifications of their decision will no doubt affect the worldwide market for pharmaceuticals. One would fear that the U.S. and its allegiance with the large pharmaceutical companies and lobbyists, would lead the U.S. to exclusively grant licenses to these parties in order to protect their patent rights. Not only would this go against the spirit of TRIPS, but it would cause other problems since the intention of the Decision was to lessen the burden on the world, especially developing countries.

A more positive outcome results if countries with the ability to manufacture drugs recognize and respond to the needs of developing and developed countries by becoming a haven for the activity described in the Decision. Canada took steps to do just that on November 6, 2003 by introducing legislation to amend its current Patent Act to facilitate access to pharmaceuticals and to address public

health problems in developing and least developed countries.⁴⁸ The stated purpose of the legislation is to facilitate access to pharmaceutical products to address public health problems afflicting developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria, and other epidemics.⁴⁹ Just as some parties were critical of the scope of the WTO Doha Declaration, some parties are also concerned that the proposed Canadian bill is not as noble as it makes itself out to be. Some civil societies are critical that the bill only includes a limited list of pharmaceuticals since restricting the list conflicts with the non-specific approach that the Declaration was trying to advance.⁵⁰ Limiting the list of pharmaceuticals in the negotiation of the Declaration was one of the major points of contention that was keeping the parties from reaching an agreement.⁵¹ Only once the US agreed not to require such a list did the parties agree to enact the Declaration.⁵² Another point of contention is that the proposed bill only allows its benefits to apply to WTO Members while other non-WTO Members would be excluded.⁵³ There seems to be no rational basis for this in the proposed legislation and some parties are urging Parliament to

⁴⁸ *An Act to Amend the Patent Act and the Food and Drug Act*, Bill C-56, 51-52 Elizabeth II (2002/2003), available at http://www.parl.gc.ca/37/2/parlbus/chambus/house/bills/government/c-56/c-56_1/90247bE.html. (Last Visited on Nov. 8, 2004).

⁴⁹ *Id.*

⁵⁰ Anso Thom, *Canada to Lift Patents on ARVs* (Nov. 7, 2003), at <http://www.journ-aid.org/reports/07112003e.htm>. (Last Visited on Nov. 8, 2004)

⁵¹ *Supra* note 32.

⁵² *Supra* note 33.

⁵³ *Supra* note 50.

amend accordingly.⁵⁴ The proposed legislation also does not allow NGOs to contract with a Canadian generic manufacturer to procure drugs under a compulsory license; it only allows governments or its agents of developing countries to do so.⁵⁵ Some of the least developed countries may not even know what is afflicting their citizens and must rely on outside sources to assist in the treatment of their ill. In addressing a large-scale epidemic within a country, the government may not have the capacity or knowledge of an NGO to administer the drugs or handle the situation in the best manner. Allowing NGOs access to the benefits of the proposed legislation would comport with the general objectives of the legislation and provisions to facilitate such activity could easily be implemented. Finally the proposed legislation provided a right of “first refusal,” allowing patent holders to block licenses for generic manufacturers and to take over the contract with the developing country.⁵⁶ This would discourage a generic market, which is again against the objective of the proposed legislation to promote public health and access to pharmaceuticals for all.⁵⁷ All of these issues will be addressed once the ruling party’s leadership changes take place and the House of Commons reconvenes.⁵⁸

⁵⁴ *Id.*

⁵⁵ *Id.*

⁵⁶ *Id.*

⁵⁷ *Supra* note 50.

⁵⁸ *Id.*

III. The United States, Developing Countries, and Compulsory Licenses

The United States' policy on compulsory licensing has generally favored the brand-name pharmaceutical industry. This has generated many political disputes with foreign nations and special interest groups. But over the years, the United States has sometimes abandoned its alliance with the pharmaceutical industry and even has proposed legislation to address compulsory licensing both in the United States and abroad. Most of these inconsistencies are due to pressure from public and special interest groups and the need for the United States to use the remedy of compulsory licensing to address domestic public health issues.

The United State Patent Act does not contain a provision addressing the issue of compulsory licensing.⁵⁹ There are, however, certain statutory provisions that authorize compulsory licensing for prevention of air pollution, public health emergencies, government use, aerospace, atomic energy, national security and to remedies for anti-competitive practices.⁶⁰ Although these statutory provisions are not seen as vehicles for developing countries to change the United States' position regarding compulsory licensing, some recent events, such as the Anthrax scare, may be showing a shift towards a policy that would be friendlier to developing countries. The first event occurred in 1997 when the South African Parliament

⁵⁹ 35 U.S.C. §§ 1-376 (2004).

⁶⁰ *Supra* note 8, at 254-255.

passed compulsory licensing legislation to reduce the cost of pharmaceuticals.⁶¹ The South African government saw compulsory licensing as the only way to address the growing HIV/AIDS epidemic in their country. Through compulsory licensing, it hoped to give people who have contracted the virus access to affordable treatment. The United States did not support the legislation because it feared that submission to South Africa's intellectual property policy would set a precedent for other countries to implement similar policies.⁶² The United States went as far as to threaten South Africa with trade sanctions if they were to implement this legislation fearing that this could open the door for other countries to break U.S. pharmaceutical patents.⁶³ The pharmaceutical industry also attacked South Africa by filing a lawsuit challenging the law in the South African courts.⁶⁴ This attack on South Africa's compulsory licensing legislation went on for 2 years until the United States completely changed its policy as a result of public and political recognition of the severity of the problem. What is interesting to note is that during the period between 1996 through 2000, South Africa spent \$3 million on AIDS prevention and \$1.3 on arms purchases during the same period.⁶⁵

⁶¹ *Supra* note 13, at 255.

⁶² Frederick M. Abbott, *The TRIPS-Legality of Measures Taken to Address Public Health Crisis: A Synopsis*, 7 WIDENER L. SYMP. J. 71, 72 (Spring 2001).

⁶³ *Supra* note 13, at 25.

⁶⁴ *Id.* at 255-256.

⁶⁵ Daniel Pruzin, *Rewriting TRIPS Could Hurt Research, Pharmaceutical Industry Strongly Warns WTO*, Bureau of National Affairs (Sept. 20, 2001), available at <http://www.cptech.org/ip/wto/bna09202001.html>. (Last visited Nov. 8, 2004).

Another incident involving Brazil is evidence that the U.S. is susceptible to changing its stance when outside pressure is applied. In 1996, the Brazilian government began producing generic equivalents of eight HIV/AIDS medications in state laboratories to address the growing public health crisis by offering free drugs to HIV/AIDS patients within its borders.^{66,67} Brazil requires holders of its patents to manufacture the product in question within Brazil. If this so-called “local working” requirement is not met within 3 years the product shall be subject to compulsory licensing.⁶⁸ The only exception to this “local working” requirement is if a patent-holder can show that it is not economically feasible to produce in Brazil or can otherwise show that the requirement to produce locally is not reasonable; if proven, then the compulsory licensing provision would not be applied.⁶⁹ Also under the Brazilian Patent Law, a company trying to escape the compulsory licensing provision by importing instead of manufacturing in Brazil would not be subject to the compulsory licensing provision, but would then subject its product to parallel importing by others.⁷⁰

⁶⁶ John Zarocostas, *U.S., Brazil Differ on Aids Drug Patent at WTO*, UPI Science News (Feb. 2, 2001), available at <http://www.survivre.usida.net/article3289.html>. (Last Visited on Nov. 8, 2004).

⁶⁷ Paul Champ & Amir Attaran, *Patent Rights and Local Working Under the WTO TRIPS Agreement: An Analysis of the US-Brazil Patent Dispute*, 27 *YALE J. INT’L L.* 365, 380. (Summer 2002).

⁶⁸ Ellen ‘t Hoen, *Public Health and International Law: TRIPS, Pharmaceutical Patents, and Access to Essential Medicines: a Long Way From Seattle to Doha*, 3 *CHI. J. INT’L L.* 27, 32 (Spring 2002).

⁶⁹ *Id.*

⁷⁰ *Id.* at 32-33.

To achieve its goal of providing HIV/AIDS drugs for its infected citizens, the Brazilian government used a three-prong attack. The first prong was to manufacture locally HIV/AIDS drugs that were not subject to patent protection within Brazil.⁷¹ Next, for those drugs that were patented in Brazil, the government would attempt to negotiate a deal with the patent-holder to obtain the drugs at a price that would allow the Brazilian government to provide them to its citizens for free.⁷² When Brazil and the patent-holder could not reach an acceptable deal, Brazil would take a hard-line approach and threaten to issue a compulsory license unless the drug in question was discounted by 50%.⁷³ To further support the first two prongs of its attack on high-priced HIV/AIDS drugs, Brazil used the argument that producing generic versions of these HIV/AIDS medications fell within the TRIPS national emergency exemption which allows the government to override patents in urgent circumstances.⁷⁴ Although the U.S. was against Brazil's activity and legislation enacted to facilitate the production of the generic HIV/AIDS drugs, it was not until January 8th, 2001 that the U.S. finally requested the WTO Dispute Resolution Panel to convene in order to investigate the legality of Article 68 of the Brazilian Patent Law.⁷⁵ The U.S. claimed that the Brazilian law lessening a patent holder's rights violated Article

⁷¹ *Supra* note 66.

⁷² *Supra* note 66, at 380-381.

⁷³ Geoff Dyer, *Brazil Defiant Over Cheap AIDS Drugs*, *Fin Times* (Feb. 9, 2001), at 10

⁷⁴ *Supra* note 65.

27.1 and 28.1 of TRIPS by discriminating against U.S. owners of Brazilian Patents.⁷⁶

On June 23, 2001, Brazil and the U.S. issued a joint statement announcing that the U.S. would withdraw request of the WTO panel against Brazil.⁷⁷ In withdrawing its request for a panel, Brazil agreed to give advance notice to U.S. officials before invoking the “local working” requirement that was implemented in its Patent Law.⁷⁸ The real reason why the U.S. dropped its request for a panel was the public-relations disaster that ensued and the highly effective counter-campaign that Brazil launched against the U.S.⁷⁹ The problem with the stance of the U.S. was not its legality, but the fact that it was threatening the most successful AIDS treatment program in the developing world.⁸⁰ There are an estimated 536,000 Brazilians infected with HIV, with 203,353 cases of AIDS reported from 1980 through December 2000.⁸¹ The success of the Brazilian AIDS program and the enacted patent legislation reduced the AIDS-related mortality rate by more than 50% between 1996 and 1999 and during a two-year span, Brazil saved \$472 million in hospital costs and treatment costs for AIDS-

⁷⁵ Kara M. Bombach, *Can South Africa Fight Aids? Reconciling the South African Medicines and Related Substances Act with the TRIPS Agreement*, 19 B.U. INT’L L.J. 273, 298 (Fall 2001).

⁷⁶ *Brazil Measures Affecting Patent Protection* (Jan. 9, 2001), at <http://docsonline.wto.org/DDFDocuments/t/IP/d/23A1.doc>. (Last Visited Nov. 11, 2004).

⁷⁷ Helene Cooper, *U.S. Drops WTO Complaint Against Brazilian Patent Law*, WALL ST. J., June 26, 2001, at B7.

⁷⁸ *Supra* note 72.

⁷⁹ *Id.*

⁸⁰ *Id.*

⁸¹ *Supra* note 68, at 32.

related infections.⁸² This put the U.S. at an even greater disadvantage for arguing the illegality of the Brazilian Patent legislation since it was public opinion that humanitarian success trumped the U.S.'s plea for patent protection. The Brazilian Health Minister was quick to point out the obvious disparity between the interests that both sides were advancing once it was clear that other Members of the WTO and the NGO community would be more sympathetic to Brazil's plight than that of the U.S's.⁸³

This presents the obvious question that if Brazil and the international community were able to shake-down the U.S. to advance its interest in providing free HIV/AIDS medicines, why don't other developing countries use the same approach? The answer is that although Brazil is considered a developing country, it does have the technological capacity to develop the technology necessary to manufacture pharmaceuticals. Also Brazil's government is concerned more with the immediate welfare of its suffering citizens than protecting the rights of patent holders. This is the argument that has garnered support worldwide in Brazil's successful defense against the U.S. Until August 30, 2003, in order for Brazil to comply with Article 31 of TRIPS, it could only use the generic pharmaceuticals that it produced in the domestic market. It remains to be seen if the waiver agreed to on the "domestic use" requirement in Article 31(f) of TRIPS will be unitized by Brazil to export their generic pharmaceutical to other developing countries. There

⁸² *Id.*

are a couple of factors that Brazil must consider in order for this to be feasible. First, Brazil must determine if exporting of generics can be done without undermining their objective of providing free HIV/AIDS drugs to its citizens. Although exporting generics to other developing countries will undoubtedly help Brazil's fledgling economy, Brazil may not have the manufacturing capacity to satisfy both markets. Also, Brazil must consider if providing generics to developing countries will be as successful as its own battle in diminishing the AIDS-related death rate. Brazil's situation is unique because it has the infrastructure set up to adequately educate patients and properly distribute the drugs. Many other least-developed countries would not be as successful as Brazil since the governmental infrastructure of such countries would not be able to implement a program to ensure that providing its citizens with HIV/AIDS drugs would be effective in combating the public health crisis.

Also, there is an issue as to whether Article 68 of the Brazilian Patent Legislation is actually in the best interest of the country. Although there are the obviously direct and immediate advantages to the system as detailed above, what exactly does this mean for Brazil's intellectual property system and economy in the future? This leads into the drug industry's argument against the granting of compulsory licenses by developing and least-developed countries and the implementation of the Doha Declaration. The drug industry's stance against

⁸³ *Id.* at 33.

compulsory licensing centers on its argument that granting compulsory licenses is a threat to good public health because it would deny patients around the world the future benefits of R&D in the research-based industry from which new therapies arise.⁸⁴ The International Federation of Pharmaceutical Manufacturers Associations (“IFPMA”) advanced its view that uncertainty in TRIPS enforcement is likely to be a disincentive for investors to provide the capital necessary to develop more effective drugs.⁸⁵ Specifically, IFPMA noted that there has been a 30% decline in the number of anti-retroviral drug companies in preclinical and clinical development since 1998, a period that corresponds with the “growing attacks on intellectual property rights linked to AIDS medicines.”⁸⁶ IFPMA’s argument may hold some weight in that further research will provide more effective HIV/AIDS drugs and possibly even a cure, but this prove difficult without the necessary funding due to worldwide patent rights being uncertain. But is the advancement toward a cure worth prolonging the pain and suffering that people currently infected would face without access to the current drugs on the market? The problem with this question is that there is no right answer since weighing the suffering of the few for a potential benefit of the many is such a hard issue to deal with.

⁸⁴ *Supra* note 65.

⁸⁵ *Id.*

⁸⁶ *Id.*

On May 3, 2001, a bill to amend the United States Patent Act called the Affordable Prescription Drugs and Medical Inventions Act, which provides compulsory licensing of certain patented inventions relating to health, was introduced by Representative Sherrod Brown (D-OH).⁸⁷ The bill outlined specific instances in which the Secretary of Health and Human Services or the Federal Trade Commission (FTC) could issue a compulsory license to produce a pharmaceutical or medical invention. The bill also gave the Secretary of Health & Human Services and the FTC the authority to jointly adopt regulations that would implement the purposes of this bill, consistent with TRIPS.⁸⁸ This proposed bill was referred to the Subcommittee on Health where it remained until the 107th Congress adjourned.⁸⁹

On November 6, 2001, Representative Brown introduced the Public Health Emergency Medicines Act.⁹⁰ This bill sought to amend the Patent Act to grant the Secretary of Health and Human Services the authority to authorize use of the subject matter of a patent without the authorization of the patent-holder or to authorize a compulsory license if the Secretary determines that the invention is needed to address a public health emergency.⁹¹ The bill would also allow the Secretary of Health & Human Services to do the same if such medicines are

⁸⁷ H.R. 1708, 107th Cong. (2001)

⁸⁸ *Id.*

⁸⁹ *Id.*

⁹⁰ H.R. 3252, 107th Cong. (2001)

⁹¹ *Id.*

needed to address global public health emergencies, when the legitimate rights of the patent-holder are protected in the export market.⁹² This bill was referred to the Subcommittee on Courts, the Internet, and Intellectual Property, where it eventually died in committee.⁹³

This is the extent to which the U.S. has tried to implement compulsory licensing legislation after the Doha Declaration. Although these bills may have been a quick response resulting from the Declaration, it does not appear as though Congress is going to deviate from its strict protectionist views.

IV. Conclusion

So where does this leave the United States, developed countries that are sympathetic to the “humanitarian” plight of developing countries, and developing countries? No matter what type of legislation is enacted in response to the Declaration in any WTO Member country, there will always be some party that will feel it is not being adequately represented and that the general objectives of the Declaration and TRIPS are not being followed. But the U.S. is now on the defensive to preserve the patent protection that it believed it was going to be afforded when it agreed to the TRIPS agreement. With developed countries such as Canada enacting legislation to provide generic drugs to countries in need and NGOs and developing countries portraying the U.S. as a money-hungry, inhumane mongrel, the U.S. has to work something out that will satisfy the

⁹² *Supra* note 90.

pharmaceutical companies and the rest of the world. If the U.S. is not able to satisfy the interests of its domestic pharmaceutical industry, it is going to be susceptible to being “shaken-down” in the same manner that Brazil was successful in advancing its own interests by enacting its own domestic patent legislation. So what does the U.S. do to improve its image while advancing its own interests in economic growth and technological advancement? Its best option would be to advance further humanitarian efforts through an international agency, such as the U.N. The U.S. has already shown that its policies are capable of being influenced by NGOs and third parties and that it will use some of the TRIPS provisions when it is beneficial to their interests and criticize others when doing the same. To combat this, an international body should be established to ensure that if developing countries are using TRIPS to acquire or manufactures pharmaceuticals that an infrastructure be set up to ensure that the drugs are being used properly and the people that are using them are educated to properly utilize the drugs. This will enable the U.S. to revive its tarnished image, advance the interests of humanity, and place the burden of funding, such an international agency, on the world as a whole.

Patents are a monopoly that an inventor is entitled to for a limited period of time. So what happens when that limited period of time expires? One of the objectives of patent law as a whole is that a patent is a bargain between the

⁹³ *Id.*

inventor and the public for which the inventor is allowed to exploit an invention for a certain amount of time in exchange for disclosing his invention to the public. Most of the pharmaceuticals that address the public health emergencies around the world are not yet in the public domain. When these patents expire, there will likely be more effective drugs on the market to treat the same diseases, but the ones that are on the market right now will still be effective. This will allow developing countries that have the capacity to manufacture pharmaceuticals to produce the drugs for themselves. This ability will not only allow the developing country to address medical emergencies within its own borders, but will also provide the mechanism to advance the developing country into a developed country. This mechanism, assuming that the waiver on TRIPS Article 31(f) is still enforced, will allow a new generic pharmaceutical industry that will make pharmaceuticals available to countries that do not have the capacity to manufacture the drugs themselves. Since the country producing the generic drugs will be sympathetic to the plight of the least-developed country, it will most likely seek a reasonable profit instead of trying to “pad” its pockets for R&D on new drugs. The R&D of new drugs can be left to the developed countries that have been producing drugs that have since fallen out of patent protection. And now, with the developing countries on their way to becoming developed, the R&D cost will be easier to recoup because a U.S. versus Brazil type dispute would be unlikely to result since the developing country would be in a better position,

through its own generic pharmaceutical industry, to purchase the drugs. This will lead to greater economic harmony, foster further R&D, and address grave worldwide public health concerns.