



WHAT A LONG, STRANGE “TRIPS” IT’S BEEN:
COMPULSORY LICENSING FROM THE ADOPTION OF TRIPS TO
THE AGREEMENT ON IMPLEMENTATION OF THE DOHA DECLARATION

MARK C. LANG

ABSTRACT

Startling numbers of people die every day because they do not have access to essential medicines and treatment for diseases such as HIV/AIDS, particularly in Africa and Asia. The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) was established by the World Trade Organization (WTO) to set a minimum level of protection of intellectual property rights across international borders, as well as promote and protect the welfare of humanity. This Comment reviews the history of the TRIPS Agreement, including the most recent adoption of the WTO relating to the issuance of compulsory licenses. Specifically, this Comment suggests that the WTO look to United States case law on the topic of governmental use of patents without authorization, in addition to the spirit and goals of the TRIPS Agreement, and amend TRIPS by setting adequate remuneration at a very modest royalty rate when a compulsory license is utilized. Implementation of such an amendment will prevent further delay to the access to critical medicines in developing countries and advance the objectives of TRIPS.

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MARK C. LANG*

INTRODUCTION

Infectious and parasitic diseases killed over ten million people worldwide in 2001, with over five million deaths resulting from HIV/AIDS, tuberculosis, and malaria.¹ In 2002, HIV/AIDS alone caused the life expectancy to drop in fifty-one countries, with some disturbing discrepancies in sub-Saharan Africa.²

One of the main reasons for these alarming statistics is that the access to adequate health care to prevent and treat these diseases is almost non-existent in developing countries.³ These problems arise mostly due to the high prices of pharmaceutical products produced by Western companies.⁴ In order to support research and development for further products, pharmaceutical companies maintain that prices must remain high while they have enforceable rights to their patents.⁵ While these companies are making money off the high prices of their products, people

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¹ World Health Organization, *The World Health Report 2002*, Annex Table 2 (WHO 2002).

² U.S. Agency for International Development, *Life Expectancy Will Drop Worldwide Due to AIDS*, at <http://www.usaid.gov/press/releases/2002/pr020708.html> (Oct. 2, 2002) (noting that in Botswana the average life expectancy is 39 years, whereas without the AIDS caused deaths it would have been 72). See also *AIDS to Decimate Life Expectancy*, available at <http://www.cnn.com/2003/WORLD/africa/03/06/southafricalife.ap> (last visited Oct. 2, 2002) (predicting that in the next six years the life expectancy of blacks in South Africa will drop by fifteen years; also noting the projected low life expectancies in other sub-Saharan countries in ten years, such as Malawi and Mozambique (below thirty years), Swaziland (forty years), Lesotho (thirty-three years), and Zambia (thirty-four years)); *AIDS to Cut Life Span to 27 Years*, available at <http://new.hst.org.za/news/index.php/20010615/> (last visited Apr. 14, 2004) (predicting that in ten years in Zimbabwe, life expectancy will plummet seventeen years).

³ Ellen ‘t Hoen, *PUBLIC HEALTH AND INTERNATIONAL LAW: TRIPS, Pharmaceutical Patents, and Access to Essential Medicines: a Long Way From Seattle to Doha*, 3 CHI. J. INT’L L. 27, 28 (2002) (commenting that one third, one half in the case of Africa and Asia, of the world does not have access to essential drugs because they are unaffordable or are not adapted to local conditions).

⁴ Jean O. Lanjouw, *A New Global Patent Regime for Diseases: U.S. and International Legal Issues*, 16 HARV. J. LAW & TEC. 85, 90 (2002) (showing through tables that over forty-five percent of the world population accounts only four percent of all drug sales).

⁵ See David B. Resnik & Kenneth A. De Ville, *Bioterrorism and Patent Rights: “Compulsory Licensure” and the Case of Cipro*, AM. J. BIOETHICS, Summer, 2002, at 29 (discussing that it can cost hundreds of millions of dollars to bring a drug from conception to the market with only approximately a ten year window of enforceable rights on the patent). See generally U.S. CONST. art. I, § 8, cl. 8. The Constitution gives Congress the power “[t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.” *Id.* (emphasis added).

in poor countries are dying at alarming rates because they cannot afford a simple vaccine for malaria, or the \$15,000 a year needed to stay alive with HIV/AIDS.⁶

Pressure from the international community to help developing countries combat disease and increase access to essential medical treatment has forced action by world governments. Starting with the formation of the World Trade Organization (“WTO”) in 1994, the international community recognized the importance of intellectual property protection and adopted the Agreement on Trade-Related Aspects of Intellectual Property (“TRIPS Agreement”).⁷ However, ambiguities in the TRIPS Agreement led to the Doha Declaration in November 2001, which declared that these ambiguities must be resolved immediately.⁸

After almost two years of waiting and political positioning, WTO member countries finally came to an agreement on how to implement the Doha Declaration.⁹ This agreement recognizes that compulsory licensing is necessary to serve the public health in developing countries.¹⁰ A compulsory license with respect to a patent is defined as granting the use of a patent to a third party without the authorization of the patent holder.¹¹

Section I of this Comment will discuss the history and events leading up to the agreement adopted on August 30, 2003 (“Implementation Agreement”), specifically how countries interpreted and implemented TRIPS articles without a formal interpretation. Section II will briefly analyze the new agreement to see what it did and did not accomplish and will discuss issues that may arise. It will also look at the issue of “adequate remuneration” from the perspectives of the world’s developed and least developed countries. Additionally, possible interpretations of this ambiguous phrase will be analyzed through a review of U.S. court decisions. Finally, Section III of this Comment will propose that an amendment to TRIPS be made which interprets

⁶ Samantha Shoell, *Why Can't the Poor Access Lifesaving Medicines? An Exploration of Solving the Patent Issue*, 4 MINN. INTEL. PROP. REV. 151, 152–53 (2002) (noting that the standard of care for treating an AIDS patient is a triple drug therapy, which can cost between \$11,000 and \$15,000 per year; also mentioning that keeping an AIDS patient alive in Zimbabwe for one year is twenty-four times the average annual income and that doctors do not even mention these remedies to patients because they know patients cannot afford them).

⁷ See Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, LEGAL INSTRUMENTS – RESULTS OF THE URUGUAY ROUND vol. 31, 33 I.L.M. 81 (1994) (setting minimal standards of protection of intellectual property rights to be recognized by all Member countries of the WTO).

⁸ See 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. LAW & TEC. 291, 292 (2002) (noting that the Doha Declaration was necessitated in part by the divergent purposes attached by developing and developed countries to the TRIPS Agreement).

⁹ World Trade Organization – Council for Trade-Related Aspects of Intellectual Property Rights, *Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, IP/C/W/405 (Aug. 30, 2003) (discussing the availability of compulsory licensing under Article 31 of the TRIPS agreement).

¹⁰ *Id.* at 2 (stating that a Member’s obligation under Article 31(f) of TRIPS is waived by grant of a compulsory license to the extent necessary for the purposes of production of pharmaceutical products).

¹¹ BLACK’S LAW DICTIONARY 931 (7th ed. 1999) (defining compulsory license as “a statutorily created license that allows certain parties to use copyrighted material without the explicit permission of the copyright owner in exchange for a specified royalty”).

adequate remuneration in a manner that promotes the objectives of the Doha Declaration, while also favoring the grantor of the compulsory license.

I. BACKGROUND

This section will discuss the basis of interpretation issues with TRIPS and how some countries, such as South Africa, Brazil and India, have instituted laws and practices that allow compulsory licensing in accordance with their interpretation of Article 31. It will then proceed to briefly analyze the new Implementation Agreement reached on August 30, 2003.

A. The TRIPS Agreement and its Interpretation

Through the adoption of the TRIPS Agreement in 1994, the Member countries of the WTO sought to implement uniform international protection of intellectual property rights.¹² The objectives of TRIPS are to promote innovation and the sharing of the information necessary to understand the innovations, while balancing the rights of patentees and obligations of patent users in a way beneficial to these respective groups.¹³ The TRIPS Agreement allows Members to “adopt measures necessary to protect public health and nutrition” so long as they coincide with the provisional foundations set forth in the Agreement.¹⁴

However, the TRIPS Agreement created a great deal of confusion as to when a member could grant a compulsory license.¹⁵ The specific provisions that were mainly in question were Articles 27, 30 and 31 when read separately and in conjunction with one another. Article 30 provides Members with the opportunity to override a patent holder’s rights in their country as long as this deprivation does not negatively affect

¹² TRIPS Agreement, *supra* note 7 (recognizing the need for new rules concerning “the provision of adequate standards and principles concerning the availability, scope and use of trade-related intellectual property rights” and “of effective and appropriate means for the enforcement of trade-related intellectual property rights, taking into account differences in national legal systems”).

¹³ *See* TRIPS Agreement, *supra* note 7, art. 7.

The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.

Id.

¹⁴ *See* TRIPS Agreement, *supra* note 7, art. 8 (1). “Members may, in formulating or amending their laws and regulation, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.”

Id.

¹⁵ *See* Gathii, *supra* note 8, at 292 (noting that developing countries believed that the TRIPS Agreement applied to the HIV/AIDS crisis, while the developed countries, such as the United States, believed that the Agreement only was to apply during the provisional time period until full compliance with the Agreement was attained).

the patent holder or his rights.¹⁶ Article 27¹⁷ allows exclusions from patentability “to protect *ordre public* or morality, including to protect human . . . life.” Article 31¹⁸ provides that unauthorized use of a patent will be permitted in the “case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use.” Developing nations would argue that Articles 27 and 31 allow a country to grant compulsory licenses to license HIV/AIDS drugs because it is saving or preserving human life.¹⁹

B. The Doha Declaration

In 2001, the WTO addressed the confusion over the extent to which TRIPS allowed compulsory licensing²⁰ at the Fourth Ministerial Conference in Doha, Qatar.²¹ Prior to the Conference, two groups of countries submitted proposals on how to interpret the scope of the TRIPS Agreement to the Council for Trade-Related Aspects for Intellectual Property Rights (“Council”).²² However, due to its own recent actions threatening to issue a compulsory license for Cipro®, the United States’

¹⁶ See TRIPS Agreement, *supra* note 7, art. 30. “Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.” *Id.*

¹⁷ See TRIPS Agreement, *supra* note 7, art. 27 (2).

Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by law.

Id.

¹⁸ See TRIPS Agreement, *supra* note 7, art. 31. When the subject matter of a patent is used without the authorization of the patent holder, a number of conditions must be met. *Id.* See Article 31 for a list of these conditions.

¹⁹ Sara M. Ford, *Compulsory Licensing Provisions Under the TRIPs Agreement: Balancing Pills and Patents*, 15 AM. U. INT’L L. REV. 941, 965 (2000). “The justification for the developing nation’s perspective would likely arise out of the exclusions noted in Article 27 of TRIPS.” *Id.*

²⁰ *Id.* at 964–66 (explaining the wide range of interpretations that developing and developed nations can attach to the language in Article 31).

²¹ Divya Murthy, *The Future of Compulsory Licensing: Deciphering the Doha Declaration on the TRIPs Agreement and Public Health*, 17 AM. U. INT’L L. REV. 1299, 1305 (2002) (noting that the ministerial text of the Doha Declaration intended to address two issues: the scope of the term “public health” and the ability of Members without adequate manufacturing capacities to seek the benefits of compulsory licensing).

²² See World Trade Organization – Council for Trade-Related Aspects of Intellectual Property Rights, *Draft Ministerial Declaration, Proposal From a Group of Developing Countries*, IP/C/W/312, WT/GC/W/450 (Oct. 4, 2001) (proposing broad use of compulsory licenses to protect public health). The group of developing countries consisted of The African Group, Bangladesh, Barbados, Bolivia, Brazil, Cuba, the Dominican Republic, Ecuador, Haiti, Honduras, India, Indonesia, Jamaica, Pakistan, Philippines, Peru, Sri Lanka, Thailand, and Venezuela. *Id.* See also World Trade Organization, *Draft Ministerial Declaration, Proposal From a Group of Developed Countries*, IP/C/W/313 (Oct. 4, 2001) (proposing a different version without use of the term “compulsory licensing”). This group comprised of Australia, Canada, Japan, Switzerland and the United States. *Id.*

arguments against compulsory licensing under TRIPS were weakened.²³ Ultimately, Members reached two general agreements (“Ministerial Declaration” and “Doha Declaration”), although neither specifically resolved the issues of interpretation with TRIPS.

The main Ministerial Declaration stressed once again the severe disadvantage that developing countries face in the global trade environment.²⁴ Specifically, a portion of this declaration recognized the importance of interpreting and implementing TRIPS in a manner supportive of public health.²⁵

In the Doha Declaration, the Members reiterated the need to address public health problems facing developing and least-developed countries.²⁶ The Doha Declaration also reaffirmed the right of WTO Members to interpret and implement TRIPS in a manner consistent with the protection of public health and to promote access to medicines for all.²⁷ However, one question was left up in the air—what are countries with no manufacturing capacity to do?²⁸ The Doha Declaration gave an instruction to the Council for TRIPS to “find an expeditious solution to this problem . . . before the end of 2002.”²⁹ In the meantime, many countries had to take immediate action to protect their citizens.

²³ See 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, 260 (2002) (discussing the reluctance of the Bush administration to change its anti-compulsory licensing policy although it threatened to use such a measure to obtain patent rights to Cipro in light of the anthrax attack on the United States).

²⁴ World Trade Organization, *Ministerial Declaration*, WT/MIN(01)/DEC/1, ¶ 3 (Nov. 20, 2001) (recalling the commitments made at meetings in Marrakesh to help least developed countries secure beneficial integration into the international trading system and the global economy in general).

²⁵ *Id.* ¶ 17 (stressing the importance of interpreting and implementing TRIPS in a way beneficial to the public health, by way of promoting and increasing access to essential medicines).

²⁶ See World Trade Organization, *Declaration on the TRIPS Agreement and Public Health*, WT/MIN(01)/DEC/2 (Nov. 20, 2001) (recognizing the gravity of public health problems afflicting developing countries and the need for international action to help combat these problems).

²⁷ *Id.* ¶¶ 4-5 (affirming the right of Members to interpret and implement TRIPS to protect and promote public health; also, recognizing the right of each member to grant compulsory licenses).

²⁸ See TRIPS Agreement, *supra* note 7, art. 31. Under the TRIPS Agreement, art. 31(f), unauthorized use of a patent “shall be . . . predominantly for the supply of the domestic market of the Member authorizing such use.” *Id.* This poses a serious problem for those countries that desperately need patented drugs but have no manufacturing capacity of their own; therefore, they cannot issue a compulsory license under Article 31. *Id.*

²⁹ Doha Declaration, *supra* note 26, at ¶ 6 [hereinafter “Paragraph 6”].

We recognize that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002.

Id.

1. *The South Africa Lawsuit*

South Africa currently has nearly five million citizens infected with HIV/AIDS.³⁰ Faced with this unsettling figure and believing that TRIPS permitted them to do so because it was a national crisis, the South African government proposed an amendment to the Medicines and Related Substances Act, which allowed compulsory licensing.³¹ While the United States government (as well as the European Commission) heavily criticized the decision to enact this amendment,³² it produced beneficial results for the people of South Africa.³³ However, this occurred only after representatives of various South African pharmaceutical companies filed a lawsuit against the South African government, which eventually settled.³⁴ Other countries sought to achieve similar results by following in the footsteps of the South African government and its interpretation of the TRIPS Agreement.

2. *Brazil Industrial Property Law, Article 68*

Brazil is encountering a national health crisis similar to that of South Africa.³⁵ Accordingly, Brazil took comparable actions by enacting a law that permits compulsory licenses to generic producers of antiretroviral drugs to combat HIV/AIDS.³⁶ Use of compulsory licenses was, as Brazil believed, within the context of TRIPS.³⁷ As in South Africa, this interpretation of TRIPS received great attention from developed countries and beneficiaries of their patent protection systems, this

³⁰ See *AIDS to Decimate Life Expectancy*, *supra* note 2 (reporting that eleven percent of the population of South Africa, roughly 4.7 million, are infected with HIV).

³¹ See Ford, *supra* note 19, at 951 (discussing the Medicines and Related Substances Control Amendment Act which permits the South African government to override patents to allow compulsory licensing for the protection of the public health).

³² See 't Hoen, *supra* note 3, at 30 (discussing United States pressure put on the South African government by withholding trade benefits and threatening further trade sanctions unless the Medicines Act is repealed; also, noting pressure from the European Commission to do the same).

³³ See *South Africa: Drug Firms Drop Patent Suit*, Facts on File World News Digest, April 19, 2001, 297E3 (noting that the Pharmaceutical Manufacturers Association, which represented thirty-nine South African drug manufacturers, had begun to negotiate price reductions with fifty countries for AIDS drugs).

³⁴ See 't Hoen, *supra* note 3, at 30 (noting that in February 1998 the South African Pharmaceutical Manufacturers Association and forty multinational pharmaceutical manufacturers brought suit against the government of South Africa alleging that the Medicines and Related Substances Control Amendment Act was unconstitutional and violated TRIPS).

³⁵ See 't Hoen, *supra* note 3, at 32 (stating that approximately 500,000 people in Brazil are infected with HIV, only twenty percent of whom are receiving treatment).

³⁶ World Trade Organization, *Request for the Establishment of a Panel by the United States, Brazil Measure Affecting Protection*, WT/DS199/3 (Jan. 9, 2001). The United States complained that Article 68 of Brazil's 1996 industrial property law (Law No. 9,279 of 14 May 1996; effective May 1997), requires that a patented product be produced in Brazil, otherwise it can be the subject of a compulsory license, which the United States believed was violative of WTO agreements. *Id.*

³⁷ See 't Hoen, *supra* note 3, at 33 (stating that Brazil believed its Article 68 and compulsory licensing are in line with TRIPS and Article 5.4 of the Paris Convention).

time in the form of an action before the WTO³⁸ by the United States government.³⁹ However, the United States ultimately dropped its action against Brazil due to widespread criticism from various groups⁴⁰ advocating the increase of access to drugs in developing countries.⁴¹

Although the WTO never had the opportunity to clarify the scope of compulsory licensing under TRIPS because the United States dropped the suit, the Brazilian government nevertheless benefited from enacting the law⁴² and maintained their successful HIV/AIDS treatment programs.⁴³

3. Other Countries' Responses to Issues of Public Health

Other countries also have implemented legislative acts to allow compulsory licenses of pharmaceutical products, including India.⁴⁴ However, these actions by the Indian government came under heavy criticism from the United States and the European Community, and the WTO ultimately chastised India's actions.⁴⁵

³⁸ See World Trade Organization: Settling Disputes, at http://www.wto.org/English/thewto_e/whatis_e/tif_e/displ_e.htm (last visited Sept. 21, 2003). Dispute settlement is used if one member believes fellow members are violating trade rules by adopting a trade policy, e.g. compulsory licensing, that one member considers to be breaking WTO agreements. *Id.*

³⁹ See *Request for the Establishment of a Panel by the United States*, *supra* note 36 (charging that Article 68 of Brazil's industrial property law, *supra* note 35, discriminates against U.S. owners of Brazilian patents and is therefore in violation of TRIPS).

⁴⁰ See Treatment Action Campaign, *TAC Statement on US Complaint Against Brazil at WTO*, at <http://www.tac.org.za/Documents/Statements/usvsbrzl.html> (last visited Apr. 15, 2004) (calling the United States' action against Brazil "the continuation of bullying weaker nations in pursuit of narrowly defined US commercial interests"); Consumer Project on Technology, *Statement on the Trade Dispute Between the United States and Brazil*, at <http://www.cptech.org/ip/health/c/brazil/CPTstatement.html> (last visited Apr. 15, 2004) (setting forth several reasons why the United States should not have filed a WTO action against Brazil).

⁴¹ Peng Jiang, *Fighting the AIDS Epidemic: China's Options Under the WTO TRIPS Agreement*, 13 ALB. L.J. SCI. & TECH. 223, 239 (2002) (suggesting that the United States dropped its suit against Brazil before the WTO due to widespread criticism from various groups advocating better access to AIDS drugs in developing countries in exchange for Brazil's agreement to hold talks with the United States government before granting compulsory licenses on patents owned by United States companies).

⁴² See John Donnelly, *Brazil Wins Big Price Cut in AIDS Drug Trade-Law Tactic Could Be Model, Health Chiefs Says*, THE BOSTON GLOBE, Sept. 1, 2001, at A1 (discussing the fact that Brazil threatened to issue a compulsory license of a Swiss drug, which forced the company to lower prices, saving Brazil \$35.4 million a year).

⁴³ Jiang, *supra* note 41, at 238–39 (stating that as a result of generic competition, the prices of AIDS drugs fell by seventy-nine percent over five years; that the Brazil AIDS program reduced AIDS-related mortality rates by more than fifty percent in three years; and that Brazil continues to negotiate lower prices for drugs through the threat of compulsory licenses).

⁴⁴ Andrea M. Curti, *The WTO Dispute Settlement Understanding: An Unlikely Weapon in the Fight Against AIDS*, 27 AM. J.L. AND MED. 469, 477–78 (2001) (noting that India has numerous generic producers of products patented in Western countries because it allows for compulsory licensing due to its designation as a developing country).

⁴⁵ *Id.* (discussing that both the United States and the European Community brought claims against India before a WTO panel for failing to meet its transitional obligations, both actions resulted in decisions against India).

Thailand also sought to battle its HIV/AIDS problem through a provision that permitted the granting of compulsory licenses.⁴⁶ However, it never used this provision out of a fear that the United States would impose trade sanctions against Thailand.⁴⁷ Due to mounting international pressure⁴⁸, the United States announced that it would not impose trade sanctions if the Thai government chose to utilize compulsory licenses to produce generic HIV/AIDS drugs.⁴⁹

The implementation of laws allowing compulsory licensing in these countries made it necessary for the WTO to consider formally interpreting or amending TRIPS to ensure that its purposes would be carried out regardless of the uncertain outcome of any possible disputes.

C. Implementation of Paragraph 6 – Content of August 30 Agreement

Due to these actions of various governments, there was an implicit call to the Council on TRIPS to make changes to facilitate developing and least-developed countries in their quest to obtain access to drugs for their citizens. The Council attempted to answer these requests on a number of occasions, but to no avail.⁵⁰ However, almost two years after the Doha Declaration urged the Council to find an “expeditious solution” to the problem of implementation of TRIPS, Members adopted an agreement on the interpretation of ambiguous TRIPS Articles (“Implementation Agreement”).⁵¹

⁴⁶ See Jiang, *supra* note 41, at 240 (discussing an amendment that gave a Pharmaceutical Patents Board authority to grant compulsory licenses).

⁴⁷ See Jiang, *supra* note 41, at 240.

⁴⁸ See Third World Network, *NGOs Denounce Northern Pressures Against Compulsory Licensing*, at <http://www.twinside.org.sg/title/1879-cn.htm> (last visited Apr. 15, 2004) (noting that leading non-governmental organizations, such as Medicins Sans Frontieres, Health Action International and Consumer Project on Technology, denounced threats and pressures by the United States and other governments for trade disputes with Thailand and South Africa involving compulsory licensing).

⁴⁹ See Jiang, *supra* note 41, at 240 n.128 (noting that the Thai government was still awaiting assurances from the United States before it issued a compulsory license).

⁵⁰ Daniel Pruzin, *NGOs Say WTO TRIPS/Medicine Formula No Cure for Drug Dearth in Poor Countries*, PAT., TRADEMARK & COPYRIGHT DAILY (BNA), Sept. 2, 2003 (noting that WTO Members were to finalize an agreement on December 16, 2002, but the United States opposed it because the United States believed the range of diseases to be covered was too open-ended). See also World Trade Organization, *Trips and Public Health: the Situation Before Cancun* available at http://www.wto.int/English/tratop_e/trips_e/health_background_e.htm (last visited Sep. 21, 2003) (pointing out that the TRIPS Council attempted to resolve this issue in January and February 2003, but failed).

⁵¹ See Implementation Agreement, *supra* note 9. This agreement recognizes the charge set forth in the Doha Declaration to find an expeditious solution to the problem of compulsory licensing for countries with little or no manufacturing capacity. *Id.* It goes on to define pertinent terms and obligations imposed on Members who use the compulsory licensing provisions, including that the “importing Member” notify the Council when such a license is granted and the requirements of a compulsory license for an “exporting Member”. *Id.* at 2.

The General Council Chairperson issued a separate statement to clarify certain points of the Implementation Agreement.⁵² These two documents comprise the agreement that Members adopted on August 30, 2003.

Developing and developed countries alike reacted positively to the Implementation Agreement,⁵³ however, some countries permanently opted out of utilizing the provisions of the agreement.⁵⁴ Pharmaceutical companies around the world also welcomed the Implementation Agreement with open arms, hoping that it would increase access to essential drugs for impoverished people, as well as improve their public image.⁵⁵ However, non-governmental organizations were not as content with the Implementation Agreement, quickly pointing out the problems that it contained,⁵⁶ as well as other problems that developing countries still faced in getting access to essential drugs.⁵⁷

⁵² World Trade Organization, *The General Council Chairperson's Statement*, (Aug. 30, 2003) available at http://www.wto.org/English/news_e/news03_e/trips_stat_28aug03_e.htm. Advising Members that (1) the agreement should be used in good faith to protect public health and that in order for it to work; (2) importing countries must implement adequate measure to prevent diversion of generic drugs to other markets; (3) members should resolve any disputes as quickly and smoothly as possible; and (4) that the TRIPS Council will review the implementation of this agreement annually.

⁵³ See European Trade Commission, *Access to Essential Medicines: EU Strongly Welcomes WTO Deal on Generic Medicines*, at http://europa.eu.int/comm/trade/issues/global/medicine/medic010903_en.htm (Oct. 2, 2003) (proclaiming that the EU welcomes the August 30 agreement to improve access to medicines for developing countries); *TRIPS and Public Health STATEMENT OF INDIA*, at <http://www.cptech.org/ip/wto/p6/india092003.html> (Oct. 2, 2003) (stating that India is delighted to join in with other Members in adoption of the August 30 agreement).

⁵⁴ *Implementation Agreement*, *supra* note 9, at 2. Within the meaning of "exporting member," the agreement notes that certain countries will not use the system in this Decision. These countries consist of Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Japan, Luxembourg, Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland, the United Kingdom, and the United States. *Id.* at 2, n.3; Espicom Business Intelligence, *WTO reaches agreement on pharmaceutical IP issues* (Sept. 1, 2003) (adding that until their accession to the European Union ("EU"), the Czech Republic, Cyprus, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, the Slovak Republic and Slovenia would only utilize the benefit of the decision in the event of a national emergency; and after their accession to the EU, they will opt out of using the system as the twenty-three countries mentioned above; also other countries announced that they would use the system only in urgent emergency situations, including Chinese Hong Kong, Israel, Korea, Kuwait, Chinese Macao, Mexico, Qatar, Singapore, Taiwan, Turkey, and United Arab Emirates).

⁵⁵ See European Federation of Pharmaceutical Industries and Associations, *EFPIA Statement on Compulsory License for Export ("Paragraph 6" of Doha Declaration on TRIPs & Public Health)*, available at http://www.efpia.org/3_press/20030830.htm (Aug. 30, 2003) (stating that the conclusion of the negotiations should be "welcomed by all committed to the success of the Doha Development Agenda"); see also Pharmaceutical Research and Manufacturers of America, *Statement from Senior Vice President, International Affairs in Reaction to the Successful Conclusion of the Negotiations on TRIPS and Public Health*, available at <http://www.phrma.org/mediaroom/press/releases/30.08.2003.841.cfm> (Aug. 30, 2003) (expressing its pleasure that Members were able to find common ground in clarifying past issues in TRIPS).

⁵⁶ See *Joint NGO Statement of TRIPS and Public Health WTO Deal on Medicines: A "Gift" Bound in Red Tape*, at <http://www.cptech.org/ip/wto/p6/ngos09102003.html> (Oct. 2, 2003) (suggesting that the August 30 agreement was nothing more than a public relations exercise that created many problems, including: requiring issuance of two compulsory licenses; constraints on generic drug manufacturers; creating uncertainty as to the role that generic drug manufacturers are

The journey of TRIPS appears to have hit some smooth pavement during an otherwise bumpy trip. As this trip continues, are there still holes in the road ahead, or is it a road that developing countries must pave for themselves?

II. ANALYSIS

This section will briefly analyze the accomplishments and pitfalls of the Implementation Agreement. Under the Implementation Agreement and TRIPS, use of compulsory licensing to protect the public health mandates that the licensee pay adequate remuneration for use of the patent, among many other conditions.⁵⁸ It will then look at adequate remuneration and review decisions from U.S. courts on analogous topics. Finally, this section will evaluate the policy concerns underlying the developed and developing countries' different interpretations of adequate remuneration.

A. Decision of August 30, 2003 – The Implementation Agreement plus the Chairperson's Statement

Again recognizing the gravity of the public health problems affecting developing and least developed countries and the importance of the protection of intellectual property rights, Members of the WTO adopted the Implementation Agreement.

1. What did the Implementation Agreement do?

The Implementation Agreement defines numerous terms, including "pharmaceutical product," "eligible importing Member," and "exporting Member."⁵⁹

playing; and, whether economic problems constitute a ground for finding that a country lacks manufacturing capacity).

⁵⁷ See Oxfam International, *Flawed WTO Drugs Deal Will Do Little to Secure Future Access to Medicines in Developing Countries*, available at http://www.oxfam.org/eng/pr030830_wto_final.htm (Sept. 21, 2003) (commenting that the new system is burdensome and does nothing to ensure that generic production will happen in the future; developing countries will have no alternative to high prices of brand-name pharmaceuticals).

⁵⁸ See Implementation Agreement, *supra* note 9, at 3. Requiring that where a compulsory license is granted by a Member, "adequate remuneration pursuant to Article 31(h) of the TRIPS Agreement shall be paid . . . taking into account the economic value to the importing Member of the use of that has been authorized in the exporting Member." *Id.* See also *TRIPS Agreement*, *supra* note 7, art. 31(h). Similarly requiring that when the subject matter of a patent is used without authorization of the patent holder, "the right[s] holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of authorization." *Id.*

⁵⁹ See Implementation Agreement, *supra* note 9, at 1–2.

For the purposes of this Decision:

"pharmaceutical product" means any patented product, or product manufactured through a patented process, of the pharmaceutical sector needed to address the public health problems as recognized in paragraph 1 of the

First, the Implementation Agreement makes compulsory licensing easily accessible to least developed countries by defining an eligible importing Member as “any least developed country Member,”⁶⁰ without any further requirements.

Second, it waives the requirement of Article 31(f) of the TRIPS Agreement that when a compulsory license is used, it must be predominantly for supply of the domestic market.⁶¹ For this waiver to occur, both the eligible importing Member⁶² and the exporting Member⁶³ must meet a number of conditions. Furthermore, the

Declaration. It is understood that active ingredients necessary for its manufacture and diagnostic kits needed for its use would be included;

“eligible importing Member” means any least developed country Member, and any other Member that has made a notification to the Council for TRIPS of its intention to use the system as an importer, it being understood that a Member may notify at any time that it will use the system in whole or in a limited way, for example only in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use.[remainder not included]

“exporting Member” means a Member using the system set out in this Decision to produce pharmaceutical products for, and export them to, and eligible importing Member.

Id.

⁶⁰ See World Trade Organization, *Least Developed Countries* (Nov. 2003) at http://www.wto.org/english/thewto_e/whatis_e/tif_e/org7_e.htm (last visited Nov. 8, 2003). Listing the least developed countries that are Members of the WTO as Angola, Bangladesh, Benin, Burkina Faso, Burundi, the Central African Republic, Chad, the Democratic Republic of the Congo, Djibouti, Gambia, Guinea, Guinea Bissau, Haiti, Lesotho, Madagascar, Malawi, Maldives, Mali, Mauritania, Mozambique, Myanmar, Niger, Rwanda, Senegal, Sierra Leone, Solomon Islands, Tanzania, Togo, Uganda and Zambia. *Id.* The following countries are in the process of accession to the WTO: Bhutan, Cambodia, Cape Verde, Ethiopia, Laos, Nepal, Samoa, Sudan, Vanuatu and Yemen. *Id.*

⁶¹ See Implementation Agreement, *supra* note 9, at 2. “The obligations of an exporting Member under Article 31(f) of the TRIPS Agreement shall be waived with respect to the grant by it of a compulsory license . . .” *Id.*

⁶² See Implementation Agreement, *supra* note 9, at 2. The Decision sets out conditions to be met by the eligible importing Member, including that it:

- (i) specifies the names and expected quantities of the product(s) needed;
- (ii) confirms that the eligible importing Member in question, other than a least-developed country Member, has established that it has insufficient or no manufacturing capacities in the pharmaceutical sector for the product(s) in question in one of the ways set out in the Annex of this Decision; and
- (iii) confirms that, where a pharmaceutical product is patented in its territory, it has granted or intends to grant a compulsory licence in accordance with Article 31 of the TRIPS Agreement and the provisions of this Decision.

Id.

⁶³ See Implementation Agreement, *supra* note 9, at 3.

[T]he exporting Member shall notify the Council for TRIPS of the grant of the licence, including the conditions attached to it. The information provided shall include the name and address of licensee, the product(s) for which the licence has been granted, the quantity(ies) for which it has been granted, the country(ies) to which the product(s) is (are) to be supplied and the duration of licence. The notification shall also indicate the address of the website referred to in subparagraph (b)(iii) above.

Id.

Implementation Agreement sets out numerous conditions that the compulsory license itself must incorporate.⁶⁴

The Implementation Agreement also clears up some prior concerns of double compensation to the patent holder that a Member would encounter under the requirement of adequate remuneration in Article 31(h).⁶⁵ In addition, the Implementation Agreement states that importing Members are to take reasonable measures to prevent re-exportation of the products that they have imported under a compulsory license.⁶⁶ It also provides that Members shall assist one another in preventing re-exportation from occurring; and, if a Member has a problem with another Members' compliance with this requirement, that Member may bring the issue before the Council for TRIPS for review.⁶⁷

Further, the General Council Chairperson's Statement clarifies that Members are to implement the Decision in good faith to protect the public health.⁶⁸

⁶⁴ See Implementation Agreement, *supra* note 9, at 2.

[T]he compulsory licence issued by the exporting Member under this Decision shall contain the following conditions:

(i) only the amount necessary to meet the needs of eligible importing Member(s) may be manufactured under the licence and the entirety of this production shall be exported to the Member(s) which has notified its needs to the Council for TRIPS;

(ii) products produced under the licence shall be clearly identified as being produced under the system set out in this Decision through specific labeling or marking. 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; and

(iii) before shipment begins, the licensee shall post on a website the following information:

- the quantities being supplied to each destination as referred to in indent (i) above; and

- the distinguishing features of the product(s) referred to in indent (ii) above;

Id.

⁶⁵ See Implementation Agreement, *supra* note 9, at 3.

Where a compulsory licence is granted by an exporting Member under the system set out in this Decision, adequate remuneration pursuant to Article 31(h) of the TRIPS Agreement shall be paid in that Member taking into account the economic value to the importing Member. Where a compulsory licence is granted for the same products in the eligible importing Member, the obligation of that Member under Article 31(h) *shall be waived* in respect of those products for which remuneration in accordance with the first sentence of this paragraph is paid in the exporting Member.

Id. (emphasis added)

⁶⁶ See Implementation Agreement, *supra* note 9, at 3. The Decision states that to ensure that products which are granted under a compulsory license are used for the public health purposes underlying the license, "eligible importing Members shall take reasonable measures within their means, proportionate to their administrative capacities and to the risk of trade diversion to prevent re-exportation of the products that have actually been imported into their territories under the system." *Id.*

⁶⁷ See Implementation Agreement, *supra* note 9, at 3. This provision states that if an eligible importing Member is having difficulty implementing adequate measures to prevent re-exportation, "developed country Members shall provide, on request and on mutually agreed terms and conditions, technical and financial cooperation in order to facilitate its implementation." *Id.*

⁶⁸ See *General Council Chairperson's Statement*, *supra* note 52.

Furthermore, it suggests that any disputes arising between Members be resolved “expeditiously and amicably.”⁶⁹

2. *What are Some Potential Problems with the Implementation Agreement?*

As recently observed by one commentator, there are problems with the new Decision.⁷⁰ Among these problems are the possibilities for delay, the fact that two Member countries will have to obtain compulsory licenses, and an increase in transaction costs.⁷¹ That commentator also notes that a few things remain uncertain, such as the self-determination of inadequate manufacturing capacity by a developing country, and also how compensation to the patent holder is to be calculated.⁷² The remainder of this Comment will discuss the latter of these two uncertainties and look at relevant policy concerns of both developing and developed countries. It will also look at United States case law for a possible interpretation of “adequate remuneration” to be included in a proposed amendment to TRIPS.

B. Cases Decided in the United States Under 28 U.S.C. § 1498

One method of finding and analyzing the meaning of adequate remuneration is by examining cases brought against the United States government due to its compulsory licensing of U.S. patents. Title 28, section 1498 of the United States Code⁷³ allows the United States government to use a patentee’s invention without his permission, in other words, to issue a compulsory license.⁷⁴ As a remedy for this action, the statute provides that the patentee shall be entitled to “reasonable and entire compensation.”⁷⁵ The courts have set forth numerous guidelines and factors to be considered in determining what reasonable and entire compensation entails.

One notable case involving this statute is *Leesona v. U.S.* Leesona filed an infringement suit against the United States government for taking its patent rights

⁶⁹ See General Council Chairperson’s Statement, *supra* note 52.

⁷⁰ See Rudolf V. Van Puymbroeck, *Exportation of Drugs Under Compulsory Licenses: The WTO Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health* (Oct. 3, 2003), available at http://www1.worldbank.org/hiv_aids/docs.GHAPnote10.03.03.pdf.pdf (last visited Nov. 8, 2003). This report analyzes the Decision as a whole, as well as the individual provisions themselves. *Id.*

⁷¹ *Id.* at 8–9.

⁷² *Id.* at 10.

⁷³ 28 U.S.C. § 1498 (2000).

Whenever an invention described in and covered by a patent of the United States is used or manufactured by or for the United States without license of the owner thereof or lawful right to use or manufacture the same, the owner’s remedy shall be action against the United States in the United States Court of Federal Claims for the recovery of his *reasonable and entire compensation* for such use and manufacture.

Id. (emphasis added).

⁷⁴ *Id.*

⁷⁵ *Id.*

to mechanically rechargeable metal-air batteries without Leeson's permission.⁷⁶ The trial court found that the patents were valid and infringed and awarded Leeson royalties, attorneys' fees, and lost profits.⁷⁷ On appeal, regarding the issue of reasonable compensation, the court found that the award was excessive because the trial judge assumed the claim was to be decided under Title 35, section 284 of the Code.⁷⁸

The court found that the taking of patent rights by the government was analogous to an eminent domain taking under the Fifth Amendment, which requires just compensation to the victim.⁷⁹ The court went on to discuss that, traditionally, courts view such an action as a "compulsory compensable license" in the patent⁸⁰ and that just compensation is defined as a "reasonable royalty" for that license—another method of estimating the value lost.⁸¹ Additionally, the court noted that eminent domain takings are necessary for the protection of the public health, and that a court should base compensation on what the owner has lost, not what the taker has gained.⁸²

The case of *Standard Manufacturing, Co. v. United States* is a recent case that further elaborated on *Leeson* and displayed a practical application of reasonable royalty.⁸³ The court determined that the plaintiff's patent was infringed and the plaintiff moved for damages.⁸⁴ The court stated that a reasonable royalty is "the amount a person who desires to manufacture, use, or sell a patented article would be willing to pay as a royalty and yet still be able to make a reasonable profit."⁸⁵ In determining an amount, the court reiterated precedent, which states that a court should first look to an established royalty, and second, the court should perform a hypothetical negotiation between the parties.⁸⁶ The court also found that there are

⁷⁶ *Leeson Corp. v. United States*, 599 F.2d 958, 963 (Ct. Cl. 1979).

⁷⁷ *Id.* at 962.

⁷⁸ *Id.* The court commented that infringement by the government is not the same as a tort claim for infringement between private parties and therefore damages should not be decided under 35 U.S.C. § 284. *Id.* at 964. The court held that 28 U.S.C. § 1498, which authorizes governmental infringement, does not have a similar purpose or foundation as Title 35 and should not be read in addition to § 1498 in calculating damages because that would give the patent holder compensation in excess of just compensation. *Id.* at 968–69.

⁷⁹ *Id.* at 964. The court noted that whenever the government has infringed a patent, it is considered to be a taking under the Fifth Amendment; therefore, just compensation to the patent holder is required. *Id.*

⁸⁰ *Id.* at 968.

⁸¹ *Id.*

⁸² *Id.* at 969.

⁸³ *Standard Mfg. Co. v. United States*, 42 Fed. Cl. 748, 767–775 (Ct. Cl. 1999). The court applied every factor from *Georgia-Pacific* to the facts before it. *Id.* The court also noted that it has discretion to consider additional factors, such as "non-infringing alternatives" and "reducing the royalty rate when the government procurement is voluminous." *Id.* at 764.

⁸⁴ *Id.* at 751.

⁸⁵ *Id.* at 759.

⁸⁶ *Id.* at 762.

many factors that are relevant to the determination of a reasonable royalty,⁸⁷ including those set forth in *Georgia-Pacific Corp. v. United States Plywood Corp.*⁸⁸

A recent example of governments issuing (or threatening to issue) compulsory licenses can be found in the wake of the September 11, 2001 tragedy in the United

⁸⁷ *Id.* at 763.

⁸⁸ *Georgia-Pacific Corp. v. United States Plywood Corp.*, 318 F.Supp. 1116, 1120 (S.D.N.Y. 1970). In finding that the defendant had infringed the plaintiff's patent, the court set forth the following fifteen factors for the court to consider in the determination of a reasonable royalty in a patent infringement case:

1. The royalties received by the patentee for the licensing of the patent in suit, proving or tending to prove an established royalty.
2. The rates paid by the licensee for the use of other patents comparable to the patent in suit.
3. The nature and scope of the license, as exclusive or non-exclusive; or as restricted to non-restricted in terms of territory or with respect to whom the manufactured product may be sold.
4. The licensor's established policy and marketing program to maintain his patent monopoly by not licensing others to use the invention or by granting licenses under special conditions designed to preserve that monopoly.
5. The commercial relationship between the licensor and licensee, such as whether they are competitors in the same territory in the same line of business; or whether they are inventor and promoter.
6. The effect of selling the patented specialty in promoting sales of other products of the licensee; the existing value of the invention to the licensor as a generator of sales of his non-patented items; and the extent of such a derivative or convoyed sales.
7. The duration of the patent and the term of the license.
8. The established profitability of the product made under the patent; its commercial success; and its current popularity.
9. The utility and advantages of the patent property over the old modes or devices, if any, that had been used for working out similar results.
10. The nature of the patented invention; the character of the commercial embodiment of it as owned and produced by the licensor; and the benefits to those who have used the invention.
11. The extent to which the infringer has made use of the invention; and any evidence probative of the value of that use.
12. The portion of the profit or of the selling price that may be customary in the particular business or in comparable businesses to allow for the use of the invention or analogous inventions.
13. The portion of the realizable profit that should be credited to the invention as distinguished from non-patented elements, the manufacturing process, business risks, or significant features of improvements added by the infringer.
14. The opinion testimony of qualified experts.
15. The amount that a licensor (such as the patentee) and a licensee (such as the infringer) would have agreed upon (at the time infringement began) if both had been reasonably and voluntarily trying to reach an agreement; that is, the amount which a prudent licensee – who desired, as a business proposition, to obtain a license to manufacture and sell a particular article embodying the patented invention – would have been willing to pay as a royalty and yet be able to make a reasonable profit and which amount would have been acceptable by a prudent patentee who was willing to grant a license.

Id.

States. The governments of the United States and Canada threatened to exercise their powers to override Bayer's rights to the patent on Cipro⁸⁹ and issue compulsory licenses.⁹⁰ This was in response to the anthrax attacks unleashed on America in 2001⁹¹ and done to ensure that the public was well protected.⁹² However, Bayer significantly reduced its prices on Cipro under the threat of an eminent domain taking before any compulsory licenses were issued.⁹³

In light of the foregoing discussion, one can see that there is a logical and strong relationship between § 1498 and the TRIPS Agreement. The WTO should view compulsory licensing and the determination of adequate remuneration under TRIPS in a way similar to governmental compulsory licensing. As stated in *Leesona*, takings of patent rights under § 1498 are viewed as an eminent domain taking under the Fifth Amendment.⁹⁴ Eminent domain is defined as "the inherent power of a governmental entity to take privately owned property and convert it to public use, subject to reasonable compensations for the taking."⁹⁵ Within the Fifth Amendment, the governmental entity is the United States, however, under TRIPS, the WTO is the "governmental entity" that converts the patent to public use. Due to this similarity, the principles set forth in United States case law regarding governmental compulsory licenses and just compensation in eminent domain takings of patent rights are important considerations when deciding what adequate remuneration should be under TRIPS.

C. Decisions of U.S. Courts Under 35 U.S.C. § 284

Private infringement actions⁹⁶ are another area of intellectual property to evaluate when determining what constitutes adequate remuneration. Under § 284,

⁸⁹ See Cipro News Archives, *FDA Approves Ciprofloxacin for Victims of Anthrax Inhalation*, at http://www.ciprousa.com/news/press_anthrax_release.asp (last visited Nov. 12, 2003). Ciprofloxacin, also known as Cipro, is a standard treatment for individuals exposed to anthrax. *Id.*

⁹⁰ See Resnik, *supra* note 5. Canada and the United States considered overriding Bayer's patent rights to Cipro, and Canada actually did override it for a few days until an agreement was reached with Bayer. *Id.*

⁹¹ See Editorial, *The Spreading Anthrax Toll*, WASH. POST, Oct. 24, 2001, at A24 (referring to the anthrax laced letters sent to NBC anchor Tom Brokaw, Senate Majority Leader Tom Daschle, and the New York Post, which "shut down Congress," White House officials still suspected a link between these attacks and the September 11 attacks).

⁹² See Consumer Project on Technology, *Talking Points on Cipro Patent Dispute*, at <http://www.cptech.org/ip/health/cl/cipro/talkingpoints.html> (Oct. 24, 2001). The Secretary of Health and Human Services, Tommy Thompson, requested 1.2 billion pills to treat ten million Americans. *Id.*

⁹³ See Resnik, *supra* note 5. By October 2001, Bayer had reduced its price of Cipro more than seventy percent as a result of its agreements with the United States and Canada. *Id.*

⁹⁴ See U.S. CONST. amend. V. "[N]or shall private property be taken for public use without just compensation." *Id.*

⁹⁵ See BLACK'S LAW DICTIONARY 541 (7th ed. 1999).

⁹⁶ 35 U.S.C. § 271 (2000). Section (a) provides that "whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefore, infringes the patent." *Id.*

when a court determines that infringement has occurred, it must award the patentee “damages adequate to compensate for the infringement.”⁹⁷ The courts consistently recognize two ways to calculate damages—actual damages or reasonable royalty.⁹⁸ While the courts utilize the same “hypothetical negotiation” approach under § 284 as they do under § 1498, there are some principles that are noteworthy when interpreting what constitutes adequate remuneration under TRIPS.

First, courts have cautioned that a hypothetical willing-buyer/willing-seller negotiation “necessarily involves an element of approximation and uncertainty.”⁹⁹ What is reasonable under all circumstances¹⁰⁰ and the relevant factors expressed in *Georgia-Pacific* are additional considerations in determining a reasonable royalty.¹⁰¹ The court in *Golight* found that because a court imposes a hypothetical negotiation on the plaintiff it amounts to a form of compulsory licensing.¹⁰² This finding makes these considerations all the more relevant in the present context.

Based on these decisions, it is necessary to point out some relevant factors in deciding what adequate remuneration is under the TRIPS Agreement. Most importantly, it must be stressed that the circumstances under which such a license will be granted are ominous, to say the least. The licensee is presumably using a compulsory license to protect the public health for a legitimate reason, as is required by the WTO. Also, the reason for which the license is being granted is likely that one country (or its citizens) cannot afford to buy drugs from Western pharmaceutical companies. It is in light of these circumstances and the following policy concerns that the WTO must amend the TRIPS Agreement to clearly define adequate remuneration.

The statute also provides for contributory infringement, and safe harbors, including an experimental use exception. *Id.*

⁹⁷ 35 U.S.C. § 284 (2000). “Upon finding for the claimant the court shall award the claimant damages adequate to compensate for the infringement, but in no event less than a reasonable royalty for the use made of the invention by the infringer, together with interest and costs as fixed by the court.” *Id.*

⁹⁸ *Trell v. Marlee Elecs. Corp.*, 912 F.2d 1443, 1445 (Fed. Cir. 1990). In this case, the Federal Circuit affirmed the lower court’s finding of infringement, but held that the plaintiff was not entitled to lost profits; rather, it was entitled to a reasonable royalty to be determined on remand to the district court. *Id.* at 1448. The court also noted that the plaintiff was required to present evidence of a reasonable royalty based upon a hypothetical negotiation. *Id.* at 1447.

⁹⁹ *Unisplay S.A. v. Am. Elec. Sign Co.*, 69 F.3d 512, 517 (Fed. Cir. 1995) (noting that although there is uncertainty involved, the trier of fact must determine a reasonable royalty on a factual basis).

¹⁰⁰ *See Trell*, 912 F.2d at 1446 (discussing considerations in performing a hypothetical negotiation, the court stated that a district court can hear evidence on anticipated profits, expert testimony, and what rate the patentee would have charged for a license, but eventually the determination comes down to what is reasonable under all the circumstances).

¹⁰¹ *Unisplay S.A.*, 69 F.3d at 517 n.7 (recognizing that a determination of reasonable royalty by a trier of fact must be supported by the relevant evidence and that relevant factors are those set out in *Georgia-Pacific*).

¹⁰² *Golight, Inc. v. Wal-Mart Stores, Inc.*, 216 F. Supp. 2d 1175, 1183 (D. Colo. 2002). In a private infringement action, the court analyzed the hypothetical negotiation between a willing licensor and a willing licensee. *Id.* at 1182. The court found that this approach is used as a tool in assessing damages in accordance with § 284. *Id.* at 1183.

*D. Policy Concerns of Developed and Least Developed Countries**1. Developed Countries Demand Full Compensation*

Developed countries, where most major pharmaceutical companies reside, posit that if developing and least developed countries are to grant compulsory licenses, full compensation to the patent holder is required.¹⁰³ They advance numerous reasons for this position, including that their patent rights are diminished, thereby discouraging innovation, and that sales to the patent holder are lost through parallel importing.¹⁰⁴

One of the most persuasive arguments for full compensation is that it increases the incentive for pharmaceutical companies to develop new and useful products. Pharmaceutical companies spend hundreds of millions of dollars on research and development of multiple drugs every year.¹⁰⁵ Of these drugs, only one out of ten that is approved by the FDA recovers the cost of research and development from inception to marketing, which is typically around \$500 million.¹⁰⁶ The essence of the argument is that patentees receive a monopoly for their new ideas and when this monopoly is eviscerated through compulsory licensing, they lose the most meaningful right accorded by their patent—the right to exclude.¹⁰⁷ One statute supporting this view is 28 U.S.C. § 1498, which permits compulsory licensing with adequate compensation.¹⁰⁸ This being said, pharmaceutical companies also maintain that they will lose profits if compulsory licensing is allowed, further justifying full compensation.

The pharmaceutical companies, through developed countries' governments, also maintain that not awarding them full compensation amounts to a taking of their

¹⁰³ See Nabila Ansari, *International Patent Rights in a Post-Doha World*, 11 CURRENTS: INT'L TRADE L.J. 57, 59 (2002). This article notes that developed countries are concerned with the pirating of their innovations. This is because use of one's patent without authorization or compensation to the patent holder results in a loss of profits, thereby stifling innovation of new products. *Id.*

¹⁰⁴ *Id.*

¹⁰⁵ See Jerry Stanton, *Lessons for the United States from Foreign Price Controls on Pharmaceuticals*, 16 CONN. J. INT'L L. 149, 155 (2000). This article reports on the current state of pharmaceutical production. It also looks at various ways that the government can control prices on pharmaceuticals and the affects of such controls, concluding that government price controls may violate the exclusive rights provision of the Constitution's patent clause. *Id.* at 170.

¹⁰⁶ *Id.* at 155.

¹⁰⁷ See 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, 282 (2001). The U.S. Constitution states the purpose of intellectual property protection is "to Promote the Progress of Science and useful Arts." See U.S. CONST. art. I, § 8, cl. 8. The South African law that permits compulsory licensing is contrary to this purpose and thereby creates a disincentive to innovate. See Bombach, at 282.

¹⁰⁸ See 28 U.S.C. § 1498 (2000). This statute involves compulsory licensing by the U.S. government. It states in section (a) that recovery by the patent holder shall be his "reasonable and entire compensation for such use and manufacture," including reasonable costs in pursuing the action. *Id.* See also 35 U.S.C. § 284 (2000). This statute awards no less than a reasonable royalty, plus interest and costs, to a prevailing patent holder in a private infringement action. *Id.*

profits.¹⁰⁹ They claim this situation exists because if compulsory licensees make patented drugs, those drugs may be diverted into other countries where a market for them already exists and they may be sold at lower prices.¹¹⁰ This practice is known as parallel importing¹¹¹ and can significantly undercut the profits of the patent holder.¹¹² By not giving full compensation, parallel importation is thus further injuring the patent holder.

However, the General Council Chairperson's statement stresses that Members are to utilize the Decision in good faith to protect the public health and not to promote economic growth.¹¹³ The Implementation Agreement also provides that "eligible importing Members shall take reasonable measures within their means . . . to prevent re-exportation of the products that have actually been imported into their territories" and also "developed country Members shall provide . . . technical and financial cooperation in order to facilitate its implementation."¹¹⁴ Idealistically, there is no reason to believe that Member countries will not act in good faith to fully comply with these provisions. Therefore, developed countries should not expect this to occur or use it as a basis for demanding more compensation for a compulsory license than is just.

2. Developing & Least Developed Countries Request No/Low Compensation

At the other end of the spectrum, developing and least developed countries propose that the patent holder receive no, or at most minimal, remuneration for use of the patent.

Granting adequate remuneration in the form of full market value, as developing countries urge, would not only be contradictory to the TRIPS Agreement and the Doha Declaration, but would also give the patent holders a windfall by enabling them to reap profits in a market where there were none previously.¹¹⁵ The fact that least

¹⁰⁹ See Ansari, *supra* note 103.

¹¹⁰ See *id.*

¹¹¹ See BLACK'S LAW DICTIONARY 1136 (7th ed. 1999). Defining parallel imports as "[g]oods bearing valid trademarks that are manufactured abroad and imported into the United States to compete with domestically manufactured goods bearing the same valid trademark." *Id.* Here, we are dealing with patents that are imported from the compulsory licensee to markets in which the patent holder has enforceable rights.

¹¹² See George K. Foster, *Opposing Forces in a Revolution in International Patent Protection: The U.S. and India in the Uruguay Round and Its Aftermath*, 3 UCLA J. INT'L L. & FOREIGN AFF. 283, 297-98 (1998) (noting that foreign copiers reduce annual revenues from foreign sales by nearly \$5 billion).

¹¹³ See General Council Chairperson's Statement, *supra* note 52. "Members recognize that the system that will be established by the Decision should be *used in good faith to protect public health* and, without prejudice to paragraph 6 of the Decision, *not to be an instrument to pursue industrial or commercial policy objectives.*" *Id.* (emphasis added).

¹¹⁴ See Implementation Agreement, *supra* note 9, at 3.

¹¹⁵ See Judy Rein, *International Governance Through Trade Agreements: Patent Protection for Essential Medicines*, 21 NW. J. INT'L L. & BUS. 379, 404 (2001). The author noted that commercial pharmaceutical producers do not address diseases suffered by countries with no purchasing power because there is a lack of demand and there is no chance to recover the expenses of research and

developed countries are not presently a major percentage of the pharmaceutical marketplace supports the argument for little or no remuneration to the patent holder.¹¹⁶

The emotional thrust of the least developed countries' argument for low or no remuneration comes from words put forth by the WTO in the Implementation Agreement, TRIPS, and the Doha Declaration. In these documents, the WTO consistently stressed the importance of interpreting its documents in a manner consistent with protection of public health.¹¹⁷ The General Council Chairperson's Statement recites that "the system [established] by the Decision should be used in good faith to protect the public health" and in conjunction with the objectives of TRIPS.¹¹⁸

The objectives of TRIPS—to promote protection of intellectual property rights *and* public health—can be conflicting when trying to interpret "adequate remuneration."¹¹⁹ On the one hand, the developed countries want to protect their intellectual property rights and investments, which means full compensation and prices too high for impoverished individuals to afford. On the other hand, developing countries want to increase access to essential medicines at minimal costs. It is in light of these views that the WTO must determine a clear and definite meaning of adequate remuneration.

From the above-mentioned sources and through the WTO, Members must reach an agreement as to what constitutes adequate remuneration under the TRIPS Agreement. The next section will propose that the WTO amend TRIPS to clearly and unambiguously define adequate remuneration in light of the above discussion.

III. PROPOSAL: THE WTO SHOULD AMEND THE TRIPS AGREEMENT & INCLUDE A DEFINITE DETERMINATION FOR ADEQUATE REMUNERATION TO THE PATENT HOLDER

development. *Id.* AIDS is an anomaly because although most of the sufferers are in developing countries, AIDS drugs are developed for those afflicted in developed countries. *Id.* at 405.

¹¹⁶ See Lanjouw, *supra* note 4, at 90. Citing empirical evidence that the profit derived from having full patent protection and sales in a poor country are marginal when compared to the total profits of the same drug worldwide. *Id.* The result of this is that the incentive to create new drugs does not come from sales in poor countries; rather, the meaningful profits come from the developed countries. *Id.*

¹¹⁷ See TRIPS Agreement, *supra* note 7, art. 8 (1); *Doha Declaration*, *supra* note 26, ¶ 4; *General Chairperson's Statement*, *supra* note 52.

¹¹⁸ See *General Council Chairperson's Statement*, *supra* note 52.

¹¹⁹ See Arvind Subramanian, *The AIDS Crisis, Differential Pricing of Drugs, and the TRIPS Agreement*, 4 J. WORLD INTELL. PROP. 323, 331 (2001) (discussing numerous examples and hypothetical situations in which compulsory licensing will or will not work). Subramanian also notes that "there is an inherent contradiction between compulsory licensing, which aims to increase competition and reduce prices, and a profit-based standard for compensation that would preserve the monopoly right[s] of the patent." *Id.* The article proceeds to find that a "simple" mathematical formula can solve the debate, and that pharmaceutical companies should charge different prices within a given country, depending on whether the customer is rich or poor. *Id.* at 336.

This section will propose that the WTO should amend¹²⁰ the TRIPS Agreement to include a definite determination of adequate remuneration that in large part reflects the objectives of TRIPS and the Doha Declaration to protect the public health, as well as the concerns of those countries who will exercise this privilege for their own benefit. WTO Members will have to face this issue in the future when they amend TRIPS in accordance with the Implementation Agreement.¹²¹ Failure to unambiguously define adequate remuneration for the purposes of compulsory licensing will inevitably result in actions before the Dispute Settlement Board¹²² of the WTO, which will give rise to further delays in providing medicines to those who need them. It will also result in increased transaction costs for those Members utilizing compulsory licenses, thereby defeating the purpose of increasing access to medicine for those Members' citizens.¹²³

In defining adequate remuneration, the WTO should limit the amount of compensation to the patent holder to a small royalty rate to allow the compulsory licensee to retain significant profits, rather than the ordinary calculation of a

¹²⁰ See Agreement Establishing the Multilateral Trade Organization [World Trade Organization], Dec. 15, 1993, LEGAL INSTRUMENTS – RESULTS OF THE URUGUAY ROUND vol. 31, 33 I.L.M. 13 (1994)[hereinafter “WTO Agreement”].

Amendments to provisions of this Agreement, or the Multilateral Trade Agreements in Annexes 1A and 1C, other than those listed in paragraphs 2 and 6, of a nature that would alter the rights and obligations of the Members, shall take effect for the Members that have accepted them upon acceptance by two-thirds of the Members and thereafter for each other Member upon acceptance by it. The Ministerial Conference may decide by a three-fourths majority of the Members that any amendment made effective under this paragraph is of such a nature that any Member which has not accepted it within a period specified by the Ministerial Conference in each case, shall be free to withdraw from the MTO or to remain a Member with the consent of the Ministerial Conference.

Id. at art. X, ¶ 3. See also, TRIPS Agreement, *supra* note 7, art. 71 (2).

Amendments merely serving the purpose of adjusting to higher levels of protection of intellectual property rights achieved, and in force, in other multilateral agreements and accepted under those agreements by all Members of the WTO may be referred to the Ministerial Conference for action in accordance with paragraph 6 of Article X of the WTO Agreement on the basis of a consensus proposal from the council for TRIPS.

Id.

¹²¹ See Implementation Agreement, *supra* note 9, at 4. The Agreement states that “[t]his Decision, including the waivers granted in it, shall terminate for each Member on the date on which an amendment to the TRIPS Agreement replacing its provisions takes effect for that Member.” *Id.* It also further directs the TRIPS Council to initiate by the end of 2003 preparation of such an amendment based on the Implementation Agreement with its adoption within six months. *Id.*

¹²² See World Trade Organization, *Understanding the WTO: Settling Disputes*, at http://www.wto.org/English/thewto_e/whatis_e/tif_e/disp1_e.htm (last visited Sept. 21, 2003). The Dispute Settlement Body consists of WTO Members who resolve disputes between Members when one country takes some action that the other believes violate WTO policy or regulations. *Id.*

¹²³ See Van Puymbroeck, *supra* note 70, at 9. In discussing the potential problems of the Implementation Agreement, the author notes that increased transaction costs will result under the new system. *Id.* This is because action is required by two governments now, the importing and exporting Member, as well as by the generic manufacturer. *Id.*

reasonable royalty.¹²⁴ In looking at all the circumstances surrounding a compulsory license granted under TRIPS, it is apparent that the patent holder should receive minimal compensation. Because the WTO is a “governmental entity,”¹²⁵ and a compulsory license is analogous to an eminent domain taking for the protection of the public health, compensation for this allocation should not be the same as that for private infringement. Rather, it should be calculated in accordance with what it is, a taking by the government, and therefore compensation should only be “just.” This contention is also supported when the objectives of the TRIPS Agreement and the result of the license are observed.¹²⁶

Therefore, in considering what to award the patent holder, several factors suggest that the patent holder receive low compensation. First, the nature and scope of the license require that the compensation is reduced.¹²⁷ The license here would be restricted as to where and to whom the product may be sold (it would only be sold to the citizens of the country to whom the compulsory license was issued). Second, the fact that the patent holder is making little, if any, profit is of the utmost importance and further suggests reduced compensation. Also, the parties might have negotiated if they were both willing to reach an agreement—in good faith and with the objectives of TRIPS in mind. In this situation, the compensation would be lower than it would be in a normal commercial setting.¹²⁸ Additionally, these factors should not constrain the WTO, and it should consider any other relevant factors that members enumerate in amending TRIPS.¹²⁹

For these reasons, the WTO should base adequate remuneration on a very small royalty rate in order to establish a definite and certain result that Members can rely upon. It is important that the manufacturer producing the drugs is able to retain

¹²⁴ See *Standard Mfg. Co. v. United States*, 42 Fed. Cl. 748, 759 (Ct. Cl. 1999). The court found that a reasonable royalty is the “amount that a person who desires to manufacture, use, or sell a patented article would be willing to pay as a royalty and yet still be able to make a reasonable profit.” *Id.* The court also noted that all the facts of a particular case are important to the calculation, which involves a two step process: “(1) determination of a reasonable compensation, i.e., the total value of the infringing items on which the plaintiffs are entitled to royalty payments, and (2) determination of a reasonable royalty rate to apply to that compensation base.” *Id.*

¹²⁵ See WTO Agreement art. VIII, *supra* note 120. “The MTO (also known as the WTO) shall have legal personality, and shall be accorded by each of its Members such legal capacity as may be necessary for the exercise of its functions.” *Id.* This provision provides adequate notice that members must recognize the MTO as a legal authority and comply with its rules and decisions.

¹²⁶ See Ministerial Declaration, *supra* note 24, at 4 (stressing the importance of interpreting TRIPS in a manner that promotes access to medicines and protects the public health). When a compulsory license is issued to a generic manufacturer it will result in lower prices to the public of the country in which the compulsory license is granted, either because the generic is cheaper or the brand name manufacturer lowered its prices in the face of the compulsory license.

¹²⁷ See *Georgia-Pacific Corp. v. United States Plywood Corp.*, 318 F. Supp. 1116, 1120 (S.D.N.Y. 1970). This is factor number three in the list of factors relevant to a determination of a reasonable royalty.

¹²⁸ See *id.* This is factor number fifteen. It states that the amount is that which a prudent licensee would be willing to pay as a royalty. *Id.* In the present circumstances of compulsory licensing under TRIPS, a reasonable licensee would negotiate for a lower than normal royalty because the expected profits will be lower than if sold to a developed country.

¹²⁹ *Standard Manufacturing*, 42 Fed. Cl. at 764. The court stated that it has the discretion to consider additional factors and should not feel constrained by the *Georgia-Pacific* factors. *Id.*

profits, which will increase the incentive to create and provide better access to those drugs. It will also allow manufacturers to sell those drugs at affordable prices to citizens of developing countries.¹³⁰ The benefits of increasing access to drugs far outweighs any harm that may be done to the patent holder by its not being able to exploit a particular area of the world where it previously had no significant market. In fact, not allowing a patent holder to receive full compensation will increase the likelihood that pharmaceutical companies will reduce prices¹³¹ in order to salvage any profit they can in the markets of developing countries.

While the rate that the WTO should establish should not equal that which willing parties would reach in the ordinary commercial setting, it should not be so minimal as to extinguish all rights the patent holder has. A brief review of the rates of other countries and a suggested rate from a U.S.-based pharmaceutical trade company shows that a reasonable royalty rate would be in the range of 3-5%.¹³² This figure does not depart greatly from the decisions of the U.S. courts in cases decided under § 1498.¹³³ This would provide the generic drug companies with the ability to retain a sufficient amount of their profits, so as to permit them to sell the drugs at low prices. This would also encourage large pharmaceutical companies to participate in the markets of developing countries by lowering their prices.

It is very important that the WTO establish a set royalty rate that is followed for all drugs. In establishing a set rate, the WTO should consider factors that courts in the United States consider relevant in establishing a reasonable royalty for governmental compulsory licensing. This provides Members with certainty and avoids costly litigation and delays that could hinder the objectives of protecting the public health and promoting access to life saving medicines.

¹³⁰ If an exporting Member were not allowed to keep a significant amount of its profit, this would greatly reduce any incentive to implement a compulsory license. This would be in direct conflict with the spirit of the TRIPS Agreement because it would reduce the probability that least developed countries would have access to affordable medicines.

¹³¹ See *South Africa: Drug Firms Drop Patent Suit*, *supra* note 33; Donnelly, *supra* note 41. Both discuss the fact that in the face of compulsory licenses issued by local governments, pharmaceutical prices were significantly lowered. See generally Press Release, Joint United Nations Programme on HIV/AIDS (UNAIDS), *UNAIDS Applauds Clinton Foundation's Agreement with Pharmaceutical Companies to Cut Prices of AIDS Drugs* (Oct. 23, 2003) (noting that an agreement between the Clinton Foundation and four pharmaceutical companies significantly reduced the price of HIV/AIDS treatment in the developing world, including several countries in Africa) available at http://www.unaids.org/html/pub/Media/Press-Statements01/Clinton_PS_23Oct03_en.pdf.htm.

¹³² See James Love, *Compulsory Licensing: Models for State Practice In Developing Countries, Access to Medicine and Compliance with the WTO TRIPS Accord*, Consumer Project on Technology, at: <http://www.cptech.org/ip/health/cl/recommendedstatepractice.html> (last visited Nov. 1, 2003). This Comment addresses government authorization to use a patent without permission of the owner in light of the TRIPS Agreement. *Id.* Specifically, the report cited Japan using rates from two to four percent; Germany from two to ten percent; Canada used a set rate of four percent; and the U.S.-based trade group, Pharma, suggested a five percent royalty rate. *Id.*

¹³³ See *Hughes Aircraft Co. v. United States*, 86 F.3d 1566, 1568 (Fed. Cir. 1996). In this case, the plaintiff appealed a judgment of the Federal Court of Claims that held their patent infringed and awarded a one percent royalty rate. *Id.* The Federal Circuit affirmed this rate, holding that the lower court properly considered the entirety of the circumstances. *Id.* at 1570.

IV. CONCLUSION

Any ambiguities regarding compulsory licensing under the new Implementation Agreement must be resolved quickly and effectively due to what is at stake.¹³⁴ There are millions of people dying worldwide because they do not have access to drugs that could save their lives. Amending TRIPS to incorporate a definition of adequate remuneration will help prevent further delays in providing access to much needed medicines.

To this point, no country has yet declared itself an eligible importing or exporting Member.¹³⁵ However, it is inevitable that such a declaration will occur, and when it does, the WTO needs to be prepared to deal with the repercussions of the Implementation Agreement. Expediently amending TRIPS and unambiguously setting forth all the requirements necessary to implement and utilize a compulsory license will best deal with this potential problem. By doing so, it will speed up the process to increase access to life-saving medicines. While passing such an amendment with WTO Member countries will be difficult¹³⁶, any uncertainties that remain after the amendment may make it even more difficult for individual Members' legislatures to ratify it in their respective countries.

Even though an amendment to TRIPS will assist in increasing access to essential medicines, other problems still exist in least developed countries that impede access to necessary drugs and treatment. Many countries lack the necessary infrastructure to route the drugs and to assure that they are administered properly.¹³⁷

However, the Implementation Agreement, as well as the active involvement of WTO Members, shows a willingness and desire to increase access to essential life-saving medicines in least developed countries. These factors provide some hope for the future resolution to the appalling health crises in least developed countries.

¹³⁴ See UNICEF, Press Release, *Orphan's Crisis: Worst is Yet to Come*, Nov. 26, 2003, available at http://www.unaids.org/html/pub/cosponsors/UNICEF/UNICEF_PR_OrphanReport_26Nov03_en_htm.htm. The release states that AIDS has already orphaned over 11 million children in Africa, half of whom are between the ages of ten and fourteen. *Id.* It also notes that this is an enormous problem with significant economic, as well as moral, implications. *Id.*

¹³⁵ See World Trade Organization, *Dedicated Webpage for Notifications Under 30 August 2003 Decision* (November 25, 2003) at http://www.wto.org/English/tratop_e/trips_e/public_health_e.htm. Following the provisions of the Implementation Agreement, the WTO has created a website dedicated to Members who wish to take advantage of the system set out in that agreement. Members must post their intentions to issue a compulsory license a particular product, whether to import or export such a product. *Id.* To this date, no Member has posted such a notice.

¹³⁶ See WTO Agreement art. X, *supra* note 120.

¹³⁷ See Daniel Pruzin, *Developing Countries Prepared to Use New WTO Accord to Import Cheap Medicines*, PAT., TRADEMARK & COPYRIGHT DAILY (Sept. 3, 2003). Quoting assistant U.S. trade representative for services, investment, and intellectual property, James Mendenhall, the article states that the new agreement will not solve the problem of disease. *Id.* Mendenhall says that the new agreement "does not, in and of itself, ensure the production needs of medicines in these developing countries", and that the "more fundamental problem is the lack of effective pharmaceutical delivery systems in many developing nations." *Id.*