



CENTER FOR INTERNATIONAL ENVIRONMENTAL LAW

Putting Health on the Fast Track

**Compliance with the Doha Declaration on
Public Health as a Principal Negotiating
Objective for Trade Promotion Authority**

August 2007



**The Center for International
Environmental Law**

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CIEL is a nonprofit organization that uses international law, institutions, and processes to protect the environment, promote human health, and create a just and sustainable world. Through our offices in Europe (Geneva) and North America (Washington D.C. and Berkeley, California), we provide advice and support to partners in civil society, government and intergovernmental organizations.

CIEL's Intellectual Property and Sustainable Development Project works with civil society and developing country governments to include sustainable development concerns in current multilateral and bilateral rules on intellectual property.

ABOUT THIS PAPER

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ACKNOWLEDGMENTS

Margaret Lee would like to acknowledge and thank Dalindyebo Shabalala and Nathalie Bernasconi for their wonderful supervision and guidance at CIEL. Also, special thanks to the Seattle University School of Law and especially to Externship Program Director Susan McClellan, for her ongoing support to all of the law school's students and externs in gaining practical experience in the U.S. domestic legal world and abroad.



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I. INTRODUCTION

[T]he Doha Declaration on the TRIPS Agreement and Public Health makes it clear that the public health problems addressed by the Declaration are those gravely afflicting many developing and least-developed countries . . .¹

-Permanent Mission for the United States to World Trade Organization, 2002.

Almost forty million people in the world are living with HIV; twenty-five million of those people live in Sub-Saharan Africa in developing or least-developed countries.² Because of the prohibitively high cost of pharmaceutical treatment, less than one percent of the people infected with HIV living in Africa receive any treatment at all.³ Part of the problem with the supply of pharmaceuticals is that the system relies on investments by private multinational companies to discover, develop, and deliver drugs. Unfortunately, in order to recover investments and to make profits, such companies rely on charging high prices. The international intellectual property system is designed to ensure that such companies receive effective monopolies over products and are able to charge the high prices thought necessary to recoup their investments and encourage further investment and innovation. However, serious problems arise where populations are unable to pay the prices charged and are left untreated. The global intellectual property regime attempts a difficult balancing act between encouraging innovation and research in developing new medicines to treat diseases such as HIV/AIDS, and allowing for those countries and populations in need to have access to affordable medicines to treat diseases.

The Doha Declaration on the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement and Public Health (the Doha Declaration) was negotiated and agreed upon by all Member countries of the World Trade Organization (WTO) because developing countries spoke out about concerns that the TRIPS Agreement does not allow adequate access to medicines needed to address their public health problems. This was a crisis that all acknowledged and for which they pledged to help developing countries find a solution. The Doha Declaration was incorporated into U.S. domestic law in the 2002 Bipartisan Trade Promotion Authority (TPA), 19 U.S.C. §3802(b)(4), legislation that has recently been the center of much debate with its expiration on 30 June 2007. Its expiration presents a much needed opportunity to assess whether or not the United States Trade Representative (USTR) has fully complied with TPA's public health mandate in its bilateral trade negotiations.

This article concludes that the USTR has not complied with one of the TPA's principal trade negotiating objectives for the United States regarding intellectual property which is "to respect the Declaration on the TRIPS Agreement and Public Health" in its negotiations of various free trade agreements. The Doha Declaration recognizes the right of developing countries to grant

¹ Second Communication from the Permanent Mission of the United States to the World Trade Organization on "Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health," Council for Trade-Related Aspects of Intellectual Property Rights, IP/C/W/358, 9 July 2002, *available at* http://www.ustr.gov/assets/Document_Library/Press_Releases/2002/June/asset_upload_file808_2021.pdf.

² 2006 AIDS Epidemic Update: Global Summary, *available at* http://data.unaids.org/pub/EpiReport/2006/02-Global_Summary_2006_EpiUpdate_eng.pdf.

³³ Jennifer Berman, *Using the Doctrine of Informed Consent to Improve HIV Vaccine Access in the Post-TRIPS Era*, 22 *Wis. Int'l L.J.* 273, 276 (2004).

compulsory licenses for pharmaceutical products and to use flexibilities inherent in TRIPS to address health crises.⁴ Recently negotiated U.S. Free Trade Agreements (FTAs) with developing countries such as Chile, Singapore, Morocco, Panama, Peru and CAFTA-DR countries, as well as with South Korea, include TRIPS-plus provisions that can restrict the use of flexibilities built into TRIPS and the ability of developing countries to acquire medicines at affordable prices.⁵ The USTR's trade negotiating policy to enhance and elevate IP protection has violated the TPA amendment establishing respect of the Doha Declaration as a principal objective of U.S. negotiations.

The article begins in Section II with an explanation of TRIPS and the Doha Declaration, its status in 2002 when the TPA was passed, and its current status in international law as a 2005 amendment to TRIPS. Section III covers how the U.S. Congress implemented the Declaration in TPA and what its intent was in doing so. Section IV discusses the legal effect of the TPA and the Declaration as an amendment to the Act. In Section V, the paper analyzes the non-compliance of the USTR with this mandate and possible reasons for non-compliance. Section VI looks at possible solutions for addressing non-compliance and suggests alternative language if negotiations for TPA are resumed.

II. THE TRIPS AGREEMENT AND THE DOHA DECLARATION

The TRIPS Agreement was adopted in 1994 as part of the Uruguay Round of negotiations, which led to the creation of the WTO, and establishes uniform minimum standards for all Member states in the area of intellectual property. Under TRIPS, WTO Members must grant most favored nation treatment (which forbids discrimination between nationals of other Members) and national treatment (which forbids discrimination between a Member's own nationals and nationals of other Members) for all intellectual property rights. TRIPS also requires Members to "ensure that enforcement procedures . . . are available under their law so as to permit effective action against any act of infringement."⁶ The Agreement prevents the unauthorized use, production, sale, import or distribution of patented products for the duration of the patent with limited exceptions.⁷ Article 7 sets out the objectives of the TRIPS Agreement, stating that these rights must be protected in a way that is mutually beneficial to both producers and consumers.⁸ These rights are to be enforced "in a manner conducive to social and economic welfare, and a balancing of rights and obligations."⁹

⁴ Rahul Rajkumar, *The Central American Free Trade Agreement: An End Run Around the Doha Declaration on TRIPS and Public Health*, 15 Alb. L.J. Sci & Tech. 433, 440 (2005).

⁵ Trade Agreements and Access to Medications under the Bush Administration, Prepared for Rep. Henry A. Waxman by the United States House of Representatives Committee on Government Reform – Minority Staff, Special Investigation Division, June 2005 [hereinafter Waxman Report].

⁶ Agreement on Trade-Related Aspects of Intellectual Property (TRIPS), Art. 41(1).

⁷ Jennifer Bjornberg, *Brazil's Recent Threat on Abbott's Patent: Resolution or Retaliation?*, 27 Nw. J. Int'l L. & Bus. 199, 201 (2006).

⁸ Bjornberg, *supra* note 7, at 201.

⁹ TRIPS, Article 7.

a. TRIPS Safeguards and Flexibilities

In order to accommodate the difficulties of developing countries, the Agreement establishes certain safeguards and measures that countries may adopt to protect public health, promote the public interest, and prevent abuse of IP rules.¹⁰ Article 8 of the TRIPS Agreement states that “Members may, in formulating, or amending their laws and regulations, 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 . . .” The importance of these safeguards was reaffirmed by the current WTO Director-General, Pascal Lamy, when he noted that these flexibilities “can make an important difference in saving life and ensuring more people can afford medical treatment.”¹¹ The TRIPS Agreement also contains certain flexibilities for these countries, including: longer transition periods for implementation of the provisions, exclusion of certain items from patentability, compulsory licensing, parallel importation, and technical and financial cooperation.¹²

One of these flexibilities is contained in Article 39(3) of the TRIPS Agreement, which establishes a minimum international standard for the protection of marketing approval data, but leaves considerable room for interpretation.¹³ For example, a WTO Member could limit the range of data that this provision applies to as well as limit the type of protection so that a third party could still apply for marketing approval using that data without committing unfair commercial use.¹⁴ This makes it easier to get approval for generic medicines since third parties do not need to create their own marketing approval data but can rely on the work done for the original patented drug.

Another available flexibility relates to the effective patent term of a drug. Article 33 of TRIPS states that, “the term of protection available shall not end before the expiration of 20 years.” This protection begins from the filing date of the patent, so depending on the length of a country’s administrative procedure for patenting, the patent term can be effectively less than 20 years.¹⁵ The procedural timeframe is only limited by language in Article 62(2) of TRIPS which states that the procedure must be within a “reasonable time,” a term which is undefined. Developing countries can work with this vague language to develop their own patenting systems and, if needed, ensure that patent terms are not extended so long as to withhold needed goods such as generic brand pharmaceuticals from their low- income citizens.

¹⁰ Patents versus Patients: Five Years After the Doha Declaration, Oxfam International, 14 November 2006.

¹¹ A. Jack, *WTO Head Flags Trade Rules as Way to Reduce Drug Costs*, Financial Times, 12 October 2006.

¹² Michelle M. Nerozzi, *The Battle Over Life-Saving Pharmaceuticals: Are Developing Countries Being “TRIPped” by Developed Countries?*, 47 Vill. L. Rev. 605, 611 (2002).

¹³ TRIPS Art. 39(3) states: “Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves considerable effort, shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use.”

¹⁴ Jean-Frederic Morin, *Tripping up TRIPS debates in IP and Health in Bilateral Agreements*, 1 Int’l J. Intellectual Property Mgmt. 37, 42 (2006).

¹⁵ *Id.*

The TRIPS Agreement, Article 30, also provides that Member countries, “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 . . .” This gives countries some flexibility in providing for exceptions to the patent monopoly and doesn’t exclude any specific exception, leaving much room for interpretation of the above language.

One of the most important safeguards in the TRIPS Agreement is the ability of a Member state to use compulsory licensing to manufacture generic pharmaceuticals in its country. The TRIPS Agreement incorporates specific limits on the ability of Member states to resort to compulsory licensing for manufacturing of patented medicines.¹⁶ Compulsory licensing is when a government allows a third party to produce the patented product or process without the consent of the patent owner.¹⁷ Although TRIPS has always contained an exception for compulsory licensing, one of the problems with this flexibility was that, until the Doha Declaration, it only allowed for licensing intended for domestic production. For many least developed countries, the infrastructure doesn’t exist for countries to produce their own generic drugs. This restriction is articulated in Article 31(f) which limits use of generic drugs to countries with a domestic market and manufacturing capabilities.¹⁸

The licensing problem is an acute one for the developing world because many new drugs, particularly those designed to deal with the HIV/AIDS epidemic, are subject to patent control.¹⁹ Pharmaceuticals subject to patent control are inevitably higher priced and thus effectively inaccessible to developing countries. Least developed countries without domestic manufacturing capacity thus wouldn’t be able to use the compulsory licensing exception and would be required to import patented drugs at substantially higher prices. The price difference can be staggering: a one-year supply of brand name “triple therapy” drugs for HIV costs up to \$15,000 in the United States whereas the generic competition can reduce this price to as low as \$140 in developing countries.²⁰ Prior to the Doha Declaration, developing countries were concerned that with the end of the transitional arrangements in the TRIPS Agreement in 2005, the extension of patent protection would lead to unacceptably high prices for important medicines in the developing world.²¹

b. The Doha Declaration on TRIPS and Public Health

The WTO Ministerial Conference was held in Doha in November 2001, partly in order to negotiate and restructure the differing interpretations of the TRIPS Agreements between developed and developing countries. The aim was to help developing countries with public

¹⁶ See Article 31(f) of the TRIPS Agreement.

¹⁷ Compulsory licensing of pharmaceuticals and TRIPS, WTO website, http://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm (last visited 25 April 2007).

¹⁸ See Article 31(f) of the TRIPS Agreement, which states: “(f) any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use.”

¹⁹ Duncan Matthews, *WTO Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: A Solution to the Access to Essential Medicines Problem?*, 7 J. Int’l Econ. L. 73, 74 (2004).

²⁰ See Rajkumar, *supra* note 4.

²¹ Matthews, *supra* note 19, at 74.

health issues. Fearful of trade reprisals,²² developing countries had been hesitant to implement the exceptions in the TRIPS Agreement that would allow for manufacture or importation of generic drugs to treat public health crises such as HIV/AIDS.²³

Developing countries advocated for an exemption from the international patent regime so that more patients might be able to afford access to medical care and so that developing countries as a whole could combat widespread epidemics. The other side of the argument, one promoted by some developed countries and pharmaceutical companies, was that intellectual property protections result in a net health benefit by encouraging research and development.²⁴

After difficult negotiations, Member states of the WTO adopted the Declaration on the TRIPS Agreement and Public Health in November 2001. This Declaration recognizes that developing countries faced serious public health threats and that TRIPS should be interpreted broadly and in a way that allows access to medicines that help prevent or cure treatable diseases. It affirms the right of all WTO Members to use the safeguards and flexibilities in TRIPS to promote access to medicines and recognizes that the listing of flexibilities is not exhaustive. The first three paragraphs of the Doha Declaration recognize the need to balance the patent holders' intellectual property interests with public welfare interests and provide an overview of the Declaration.²⁵ The Declaration reaffirms the right of developing countries to take full advantage of the flexibility available under TRIPS to: 1) grant compulsory licenses and determine the grounds upon which those licenses are granted; 2) determine what constitutes a national emergency, including emergencies created by a public health crisis; and 3) establish their own regimes for the exhaustion of IPRs.²⁶

Paragraph 6 of the Doha Declaration addresses the compulsory license and domestic production problem, stating 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." This paragraph instructed the Council for TRIPS to find a

²² Bjornberg, *supra* note 7, at 205.

²³ Margo A. Bagley, *Legal Movements in Intellectual Property: TRIPS, Unilateral Action, Bilateral Agreements, and HIV/AIDS*, 17 *Emory Int'l L. Rev.* 781, 784 (2003). Countries may have been afraid that Members would react similarly to their reaction to South Africa when the government tried to implement a law that allowed for compulsory licensing of AIDS drugs and was sued by forty-two pharmaceutical companies for violations of Article 17 of TRIPS. See also Ravi Nessman, *Drug Companies Sue South Africa Over Patent Law*, C-Health, 5 March 2001; Shubha Ghosh, *Pills, Patents, and Power: State Creation of Gray Markets as Limit on Patent Rights*, 14 *Fla. J. Int'l L.* 217, 244 (2002); Robert Block, *Big Drug Firms Defend Right to Patents on AIDS Drugs in South African Court*, *Wall St. J.*, 6 March 2001, at A3.

²⁴ Richard T. Rapp & Richard P. Rozek, *Benefits and Costs of Intellectual Property Protection in Developing Countries*, 24 *J. World Trade* 75, 86 (1990).

²⁵ "1. We recognize the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics. 2. We stress the need for the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) to be part of the wider national and international action to address these problems. 3. We recognize that intellectual property protection is important for the development of new medicines. We also recognize the concerns about its effects on prices." Declaration on the TRIPS Agreement and Public Health, available at

file:///C:/Documents%20and%20Settings/Meg%20Lee/My%20Documents/Fall%2006/IP/mindecl_trips_e.htm.

²⁶ http://www.ustr.gov/assets/Trade_Agreements/Bilateral/CAFTA/CAFTA_Reports/asset_upload_file63_5935.pdf

solution to this problem by 1 January 2003, in order to address the concerns of developing countries and their access to needed generic drugs.

c. U.S. position during Doha negotiations

The negotiations proceeded in two phases: the first phase resulted in the text of 16 December 2002, and the second phase resulted in the formulation of a statement that was to be read by the chairperson of the General Council prior to the formal adoption of the Decision.²⁷ Both texts were adopted in August 2003, and included a decision on the implementation of paragraph 6 of the Doha Declaration.²⁸

One of the most contentious issues in the negotiations prior to the adoption of the texts by the General Council was the controversy over what diseases were covered under the reference to “public health.” Developing countries advocated from the outset of the negotiations that the paragraph 6 solution should be as broad as possible to cover their citizens’ present and future health needs.²⁹ The United States was concerned that developing countries with large manufacturing capacity such as Brazil and India intended to use the negotiations to promote the export of other pharmaceuticals such as lifestyle drugs.³⁰ The U.S. proposed distinguishing between infectious and non-infectious diseases, thus limiting the number of patented technologies subject to the compulsory licensing for export exception.³¹

The final adopted text of paragraph 6 leaves open and flexible the patents subject to compulsory licensing (for export) by defining a “pharmaceutical product” as “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 Declaration.” This does not limit the scope of diseases or the situations in which a country can use compulsory licensing for export; it is thus up to each Member to decide whether it faces a public health problem that should be addressed by the use of compulsory licensing.³² As shown by the process of the negotiations, the intent of the language of the Doha Declaration and the August 2003 Decisions is meant to be broad to allow the most flexibility possible for developing countries to address their public health concerns. No Member state, including the U.S., can make any reservations on the text.³³ This means that the understanding the U.S. committed to allows for developing countries to have the flexibility to decide when there is a public health emergency, which drugs are needed in generic form to address any public health problems, and to also use the flexibilities built into the TRIPS Agreement to best structure their IP system so as to allow access to medicines for their citizens that otherwise would not be able to afford them.

²⁷ Frederick M. Abbott, *The WTO Medicines Decision: World Pharmaceutical Trade and the Protection of Public Health*, 99 *The American Journal of International Law* 317, 326-7 (2005).

²⁸ *Id.* at 327.

²⁹ *Id.* at 328.

³⁰ See USTR Press Release, U.S. Announces Interim Plan to Help Poor Countries Fight HIV/AIDS and Other Health Crises in Absence of WTO Consensus (20 Dec. 2002).

³¹ Abbott, *supra* note 27, at 329.

³² *Id.* at 332.

³³ See Protocol Amending the TRIPS Agreement, para. 2, WTO website, http://www.wto.org/english/tratop_e/trips_e/wtl641_e.htm.

On 6 December 2005, WTO Members made permanent the August 2003 decision and waiver allowing generic manufacture for export by amending the TRIPS Agreement.³⁴ Amendments can be made to the WTO Agreements (including the TRIPS Agreement) pursuant to Article X of the WTO Agreement and will be formally recognized once two-thirds of the Members accept the change. The deadline for acceptance is 1 December 2007, with extensions possible.³⁵

III. HOW DID THE U.S. CONGRESS IMPLEMENT THE DECLARATION?

a. Congressional Record of Kennedy-Feinstein-Feingold Amendment.³⁶

When first looking at TPA and the amendment concerning the Doha Declaration, it is imperative to ascertain what Congress actually intended when passing the legislation and the amendment specifically. When engaging in statutory construction, it is important to interpret “the words of th[e] statut[e] in light of the purposes Congress sought to serve.”³⁷

The amendment requiring the Executive branch to respect the Doha Declaration on Public Health was introduced by three senators: Senator Kennedy, Senator Feinstein, and Senator Feingold. “The amendment is very simple. It ensures that those countries hit hardest by the AIDS crisis and other public health emergencies will have access to the affordable medicines to address these crises. It does this by expressing support for the Doha Declaration on TRIPS and Public Health as adopted by the World Trade Organization.”³⁸

In February 2001, the Bush Administration stated its support for the U.S.’ maintaining a flexible approach that is sensitive to HIV/AIDS and other health crises in the developing world.³⁹ The Senators responsible for the amendment intended this support to be reflected in the U.S. trade negotiation agenda.

In order to ensure that U.S. trade negotiators fully support the implementation of the Doha Declaration in future negotiations, this amendment adds a single sentence to the section on negotiating objectives for intellectual property issues – ‘respect the Declaration on TRIPS and Public Health, as adopted by the World Trade Organization at the Fourth Ministerial Conference at Doha, Qatar on November 14, 2001.’ This

³⁴ Countries Accepting Amendment of the TRIPS Agreement, WTO website, http://www.wto.org/english/tratop_e/trips_e/amendment_e.htm (last visited 26 April 2007).

³⁵ *Id.* At the time of the writing of this article, seven Members had accepted the amendment: the United States; Switzerland; El Salvador; Rep. of Korea; Norway; India; and the Phillipines.

³⁶ Proposal by Senators Edward Kennedy (D-MA), Dianne Feinstein (D-CA), and Russell Feingold (D-WI), Amendment No. 3411 to Amendment No. 3401, Hearing on the Andean Trade Preference Expansion Act before the Senate, 107th Congress, S4319, S4345-47, 14 May 2002.

³⁷ *Norfolk Redevelopment & Housing Authority v. Chesapeake & Potomac Tel. Co.*, 464 U.S. 30, 36 (1983).

³⁸ Senator Kennedy, Amendment No. 3411 to Amendment No. 3401, Page S4319-20, Andean Trade Preference Expansion Act, Senate – May 14, 2002.

³⁹ See *US Announces Framework to Increase Access to Drugs to Fight HIV/AIDS and other Public Health Crises*, Office of the United States Trade Representative, 24 June 2002, available at http://www.ustr.gov/Document_Library/Press_Releases/2002/June/US_Announces_Framework_to_Increase_Access_to_Drugs_to_Fight_HIV-AIDS_other_Public_Health_Crises.html?ht=.

amendment directs our trade negotiations to support the Declaration without reservation.⁴⁰

The Senators that introduced the amendment intended this negotiating objective to preserve the flexibilities available to developing countries in the international IP trade regime. “We should not punish countries of the developing world for using different tools to provide affordable treatment for their citizens who are suffering. We should be a partner and a leader in this effort.”⁴¹ The tools available for these countries are the safeguards and flexibilities discussed above in the TRIPS Agreement. It was the intent of Congress to make sure that the U.S. in its trade agreements respected those rights available for the health of its and other countries’ citizens. It was important for the senators that put forward the amendment, as well as those voting for it, that the Doha Declaration be respected in U.S. trade negotiations; and that intellectual property negotiations would respect developing countries’ access to medicines and ability to use the flexibilities built into TRIPS in order to protect the public health of their citizens.

IV. WHAT IS THE LEGAL EFFECT OF THE TPA AMENDMENT REGARDING THE DOHA DECLARATION?

a. The structure and legal effect of TPA

Although Congress intended the USTR to follow the mandated negotiating objectives as stated in the TPA statute, there remains a question of whether or not Congress has the power to mandate the objectives of the Executive branch in their negotiations. This is dependant on the structure of the legislation. If the legislation is an agreement simply coordinating efforts between the two branches of government, then Congress does not have much power to direct the negotiations of the administration. On the other hand, if the legislation is a delegation of Congress’s authority under the foreign commerce clause, then Congress has the authority to put conditions on that delegation of power. In other words, Congress can mandate principal negotiating objectives and frameworks for trade agreements. This depends first of all on the question of the constitutional division of power in the area of international trade agreements.

The U.S. President holds the authority to negotiate treaties and international agreements pursuant to the Article II §2 “Treaty Clause” of the U.S. Constitution, which states that the President “shall have the Power, by and with the Advice and Consent of the Senate, to make Treaties, provided two-thirds of the Senators present concur.” The President also has the power, under Article II §1 of the U.S. Constitution, to interpret treaties as the Executor of the laws.

Conversely, Article I §8 of the U.S. Constitution gives Congress the power to regulate foreign commerce. Based on separation of powers principles under the Constitution, Article I §8’s express grant of foreign commerce power to Congress means that the Executive branch may not enter into trade agreements as treaties and rely on obtaining a two-thirds majority in the Senate alone. The Constitution requires both houses of Congress to participate in and consent to trade

⁴⁰ Senator Kennedy, Amendment No. 3411 to Amendment No. 3401, Page S4323, Andean Trade Preference Expansion Act, Senate – May 14, 2002.

⁴¹ Senator Feinstein, Page S4345, Trade Promotion Authority, Senate – May 15, 2002.

agreements with foreign nations, enabling each house to amend, in any way, the agreement before it. This usually requires the resolution of differences in House conferences and usually results in the production of texts that differ significantly from those negotiated by the Executive.

Based on separation of powers, the legislature cannot delegate its power to make a law; but, it can make a law to delegate its power to determine some fact or state of things upon which the law makes its own action depend.⁴² Accordingly, as “Congress has plenary authority over both interstate and foreign commerce,”⁴³ including authority over international trade, Congress may delegate a certain degree of its trade authority to the Executive branch as it so chooses. However, as treaty making authority is unavailable to the Executive in the case of foreign commerce, and the Constitution requires Congressional consent to international trade agreements, a procedural framework is required to provide guidelines for working within constitutionally prescribed powers.⁴⁴ In order to circumvent the lengthy legislative process and delegate international trade negotiation authority to the Executive branch under TPA, the President and Congress agreed to a fast-track procedure as a procedural framework that would co-ordinate their respective and overlapping responsibilities to a common, rather than a conflicting, end in international trade.⁴⁵ Under the fast track framework, TPA thus operates to facilitate the implementation of international trade agreements in the U.S.⁴⁶

Fast track results in a type of agreement known as a Congressional-Executive Agreement. Scholars have long debated the constitutionality of these types of agreements.⁴⁷ The prevailing view is that the Congressional-Executive Agreement, as trade agreements are commonly viewed, can be used as an alternative to the treaty method in every instance.⁴⁸ As such, fast-track procedures in international trade operate, in a sense, as a legislative grant of power to the Executive branch. However, much like the recently expired TPA legislation, any trade agreement reach under fast track must first be approved by Congress by a straight-forward “yes” or “no” vote, without any amendments, by both the House and the Senate before it can be signed into law. Accordingly, TPA does not impinge upon the exclusive power of Congress to regulate foreign commerce. The U.S. Constitution does not ban the adoption of a Senate or House rule which prohibits amendments from being offered to a bill during Floor consideration. The House considers bills almost every legislative week which cannot be amended on the Suspension Calendar.⁴⁹

⁴² *Field v. Clark*, 143 U.S. 649, 694 (1892).

⁴³ *California Bankers Ass’n v. Shultz*, 416 U.S. 21, 46 (1974).

⁴⁴ Michael A. Carrier, *All Aboard the Congressional Fast Track: From Trade to Beyond*, 29 Geo. Wash. J. Int’l L. & Econ. 687, 716 (1996).

⁴⁵ *Canadian Lumber Trade Alliance v. U.S.*, 425 F.Supp.2d 1321, 1359 (2006).

⁴⁶ Laura L. Wright, *Trade Promotion Authority: Fast Track for the Twenty-First Century?*, 12 Wm. & Mary Bill of Rts. J. 979, 979 (2004).

⁴⁷ See Connie de la Vega, *Human Rights and Trade: Inconsistent Application of Treaty Law in the United States*, 9 UCLA J. Int’l L. & Foreign Aff. 1, 7-11 (2004).

⁴⁸ Restatement (Third) of the Foreign Relations Law of the United States 303, cmt. E (1987).

⁴⁹ Rep. Bereuter, Conference Report on HR 3009, Trade Act of 2002, Page H5971-72, House of Representatives – July 26, 2002. The Suspension Calendar is restricted to non-controversial legislation. Bills brought up under this procedure, the suspension of rules, are spoken of as ‘suspensions’ in floor terminology, and the purpose of considering these bills under suspension is to dispose of non-controversial measures expeditiously. Debate on a bill brought up under suspension is limited to forty minutes and no amendments are allowed. A motion to suspend the

Fast-track procedure is essentially a rule of Congressional procedure, which is subject to modification or withdrawal by Congress at any time.⁵⁰ In employing the fast-track procedure, Congress sets up the framework for negotiations before any negotiations take place, so mandating the objectives beforehand rather than during negotiations. This has also been called an “advance negotiating mandate.”⁵¹ This means that it is in the best interest of both parties to follow the guidelines laid out in the fast-track procedures. For the legislative branch, these are its own expedited rules; it sets up the procedure for early and ongoing input from the Executive branch and allows for Congress’s input in trade negotiations. For the Executive branch, cooperation and adherence to guidelines means that this delegation of authority will continue, which gives the president more power in negotiations and more credibility as a negotiator with other heads of state:

The essence of the modern Congressional-Executive agreement is a forward-looking process in which Congress votes to authorize the president to negotiate under certain conditions and then votes on any agreement submitted. The two Congressional decisions on each end constitute the trusses of a more democratic architecture for U.S. treaty making. This architecture blends the benefits of presidential leadership with Congressional oversight of U.S. international commitments.⁵²

According to the procedures established under the recently expired TPA, the President must give advance report to the Senate Finance and House Ways and Means Committees at least ninety days before the U.S. enters into a trade agreement.⁵³ The report must include any amendments to U.S. laws that the President proposes to include in implementing the trade agreement. After the report is submitted, Chairs and ranking Members of committees provide their respective chambers with their own assessments of the integrity of the proposed agreement.

The history of fast-track procedures in international trade gives support to the understanding that TPA is a legislative grant of power to the Executive branch. TPA derived from the Reciprocal Trade Agreements Act of 1934 (P.L. 73-316) which established a policy under which Congress delegated advance authority to the President to negotiate reductions in tariff barriers and implement trade agreements.⁵⁴ The legislature continued this delegation of negotiating authority through 1967, at which time it was not renewed until 1974.⁵⁵ The Trade Act of 1974 (P.L. 93-618) was “the most comprehensive [act] yet submitted to the Congress on the subject of

rules requires a vote of two-thirds of the Members present and voting. *Floor Procedure in the U.S. House of Representatives*, U.S. House of Representatives: Committee on Rules Majority Office, available at http://rules.house.gov/archives/floor_man.htm.

⁵⁰ Michael A. Carrier, *All Aboard the Congressional Fast Track: From Trade to Beyond*, 29 Geo. Wash. J. Int’l L. & Econ. 687, 705 (1996) (quoting the Trade Act of 1974, “[The fast-track procedures] are enacted by the Congress with full recognition of the constitutional right of either House to change the rules . . . at any time . . .”)

⁵¹ Steve Charnovitz, *Editorial Comment: Using Framework Statutes to Facilitate U.S. Treaty Making*, 98 A.J.I.L 696, 709 (2004).

⁵² *Id.* at 707-08.

⁵³ Senator Hatch, Amendment No. 3408, Page S4320, Andean Trade Preference Expansion Act, Senate –

⁵⁴ Carolyn C. Smith: Information Research Specialist: Knowledge Services Group, *Trade Promotion Authority and Fast-Track Negotiating Authority for Trade Agreements: Major Votes*, CRS Report for Congress, Updated 29 September 2006, available at <http://fpc.state.gov/documents/organization/73937.pdf>.

⁵⁵ See John H. Jackson, *Two Centuries of Tariffs: The Background and Emergence of the U.S. International Trade Commission*, 143-44 (1976).

international trade,”⁵⁶ and this delegation of authority was renewed until President Clinton assumed office. This Act was the first introduction of the kind of fast-track procedures, most recently seen in the TPA legislation that expired June 30, 2007.⁵⁷

Fast-track procedures were extended through the Omnibus Trade and Competitiveness Act of 1988 until 1991, at which time a two-year extension was granted to President George H.W. Bush to cover implementing legislation for both NAFTA and then subsequently extended to April 16, 1994 for the Uruguay Round of GATT.⁵⁸ After 1993, there was a break in fast track authority until the most recent fast-track legislation, renamed the Trade Promotion Authority of 2002.

The Congressional Record demonstrates that many legislators understood the recently expired fast track to operate as a delegation of power to the Executive branch. For example, House Representative Kind stated that he believed that the TPA was, “based on trust and confidence in the delegation of this extraordinary power from the Congress to the Executive branch.”⁵⁹ This understanding was supported by Representative LaFalce, who stated, “[w]hat we are purporting to do is forfeit Congressional authority.”⁶⁰ Additionally, the Ways and Means Committee recently made a statement voicing their position on a new strategy for American trade. They concluded their proposals with the statement: “The Constitution provides the authority to regulate foreign commerce to Congress under Art. 1, Sec. 8. Congress delegates this authority to the President under certain conditions.”⁶¹

It is important to note, however, that Congress only possesses the Constitutional authority to mandate negotiating objectives of the Executive branch under fast track because the legislative grant of power to the Executive branch is conditional. The recently expired fast track was enacted with an understanding of this conditional grant of power: “[A] close examination suggests that fast track is a highly conditional grant of authority from a legal point of view; its considerable power in practice has derived from convention and the implicit political compact between the president and Congress.”⁶² Under TPA, one of those conditions is that the Executive branch must abide by the Doha Declaration on TRIPS and Public Health. As such, TPA represents statutory requirements for presidential negotiations of FTAs.⁶³ Congress draws on its constitutional authority and historical precedent when it defines the objectives that the Executive branch is to pursue in trade negotiations; these goals are a definitive statement of U.S. trade policy that the Administration is expected to honor if it expects the trade legislation to be

⁵⁶ John H. Jackson et. al., *Implementing the Tokyo Round: National Constitutions and International Economic Rules*, at 146 (1984).

⁵⁷ See Section 102 and Section 151 of the Trade Act of 1974, Pub. L. No. 93-618, §§102, 151, 88 Stat. 1978, 1982 (1975) (codified as amended at 19 U.S.C. §§2112, 2191 (1994)).

⁵⁸ Michael A. Carrier, *supra* note 50, at 712.

⁵⁹ Rep. Kind, Conference Report on HR 3009, Trade Act of 2002, Page H5971-72, House of Representatives – July 26, 2002.

⁶⁰ Rep. LaFalce, Conference Report on HR 3009, Trade Act of 2002, Page H5977, House of Representatives – July 26, 2002.

⁶¹ New Trade Policy for America, House Committee on Ways and Means, distributed 27 March 2007.

⁶² Hal Shapiro & Lael Brainard, *Trade Promotion Authority Formerly Known as Fast Track: Building Common Ground on Trade Demands More than a Name Change*, 35 Geo. Wash. Int’l L. Rev. 1,4 (2003).

⁶³ Mary Jane Bolle: Specialist in International Trade: Foreign Affairs, Defense, and Trade Division, *CRS Report for Congress: Trade Promotion Authority (TPA)/Fast-Track Renewal: Labor Issues*, 2 February 2007, available at <http://fpcc.state.gov/documents/organization/80673.pdf>.

considered under expedited rules.⁶⁴ The negotiating objectives serve effectively as a template for future trade agreements negotiated under these guidelines.⁶⁵

Effectively, this means that the amendment mandating that the USTR to respect the Doha Declaration in all trade negotiations must be followed as a condition of the delegation of power. If these conditions are not respected, the legislative branch may retract that power (as it recently did by allowing TPA to expire) or refuse, at any point, to abide by the Congressional-Executive Agreement embodied in any future TPA.

V. HAS THE USTR COMPLIED WITH THIS MANDATE?

a. The Doha Declaration as a principal negotiating objective.

A principal negotiating objective is a provision that is set forth as a “priority for negotiators to seek” in trade agreements.⁶⁶ TPA lays out three main negotiating objectives for IP provisions in trade agreements: 1) to further promote adequate and effective protection of IPRs; 2) to secure fair, equitable, and nondiscriminatory market access opportunities for U.S. citizens that rely on IP protection; and 3) to respect the Declaration on the TRIPS Agreement and Public Health.⁶⁷ There is no language in the statute to indicate that any one of these objectives takes priority over the others. Thus each principal trade negotiating objective must be complied with during all trade negotiations.

b. USTR interpretation of compliance.

When its compliance was questioned with regard to respecting the Doha Declaration in its trade negotiations, the USTR declared, “our FTAs not only do not conflict with the objectives expressed in the Doha Declaration but reinforce those objectives [to strengthen the value internationally of America’s innovation economy] and facilitate efforts to address public health problems.”⁶⁸ Yet the USTR has been advised by the Labor Advisory Committee for Trade Negotiations and Trade Policy (LAC) that the negotiated provisions of FTAs do not adhere to the TPA mandate of the Doha Declaration on Public Health:

[I]t appears that CAFTA undermines the protections for public health contained in TRIPS and the Doha Declaration. This not only violates Congressional negotiating objectives, it sets a terrible precedent for pending free trade agreements with developing countries in Southern Africa and elsewhere. In countries facing devastating public health crises,

⁶⁴ J.F. Hornbeck & William H. Cooper, *Trade Promotion Authority (TPA): Issues, Options, and Prospects for Renewal*, 5 December 2006, available at <http://fpc.state.gov/documents/organization/78415.pdf>.

⁶⁵ *Id.* at 64.

⁶⁶ Conference Report, H.Rept. 107-624, p.229.

⁶⁷ 19 U.S.C.A. §3802(b)(4)(A)-(C).

⁶⁸ Executive Office of the President, Office of the United States Trade Representative, Washington, D.C. July 19, 2004, House Report 108-627, United States-Morocco Free Trade Agreement Implementation Act.

governments must have adequate flexibility under international trade rules to provide their people with access to essential medicines.⁶⁹

USTR has knowledge that these principal negotiating objectives are more than mere suggestions; these are the legal parameters within which they must negotiate.

c. The Congressional Record

Because TPA is a delegation of Congressional power, it is important to look at whether or not the legislative branch views U.S. trade negotiations as complying with their conditional mandate. If Congress views USTR actions as not being in compliance with their mandates, Congress has the power to refuse to renew the authority delegated in TPA when it comes up for renewal this July. Senator Kennedy, as the initiator of the principal negotiating objective in question, has been the most outspoken on the subject of non-compliance. “The administration is defying the statutory requirement of the Doha Declaration, that our objective in these agreements must be to guarantee access to essential drugs for the sick and the poor in the developing nations of the world.”⁷⁰

When the policy of the Executive branch in trade negotiations was questioned, the response was that, “its tactics are consistent with another objective of the Trade Act, which is to seek standards for intellectual property protection and enforcement in other countries.”⁷¹ Yet this policy of seeking standards of IP protection similar of those in the U.S. “runs counter to the well accepted principle that the standard of intellectual property protection in each country should reflect the particular economic, social and cultural circumstances and level of development of the country.”⁷²

It is important to note that the objective promoting intellectual property protection is in the same provision as the objective requiring respect for the Doha Declaration. When interpreting a statute, every provision in the statute must be given effect, and language should be given its ordinary meaning in the context of the text. There is a “deep reluctance to interpret a statutory provision so as to render superfluous other provisions in the same enactment.”⁷³ The administration seems to be regarding one objective as more binding than the other, implying that these objectives are in conflict. The view that these two objectives are in conflict does not correlate with the basic rules of statutory interpretation; the objective to seek higher standards for IP must be read in harmony with all other provisions and negotiating objectives. It is a basic tenet of statutory interpretation that statutory provisions should be first construed together whenever possible to avoid conflict,⁷⁴ and a statute must be read to give effect to every provision

⁶⁹ The U.S.-Central America Free Trade Agreement, Report of the Labor Advisory Committee for Trade Negotiations and Trade Policy (LAC), 19 March 2004, *available at* http://www.ustr.gov/assets/Trade_Agreements/Bilateral/CAFTA/CAFTA_Reports/asset_upload_file63_5935.pdf.

⁷⁰ 151 Cong. Rec. S1498-99, Senator Kennedy.

⁷¹ *Id.*

⁷² Sisule F. Musungu (South Centre) & Cecilia Oh (World Health Organization), *The Use of Flexibilities in TRIPS by Developing Countries: Can They Promote Access to Medicines?*, Commission on Intellectual Property Rights, Innovation and Public Health Study 4C (August 2005).

⁷³ *Circuit City Stores, Inc. v. Adams*, 121 S. Ct. 1302, 1308 (2001).

⁷⁴ *In Re Bellamy*, 132 B.R. 810, 812 (D.Conn. 1991).

of that statute.⁷⁵ The United States Court of Appeals for the Ninth Circuit has stated, “we must avoid statutory interpretation that renders any section superfluous and does not give effect to all of the words used by Congress.”⁷⁶ Thus, the principal negotiating objectives for IP provisions in trade negotiations must be read together and coordinated during trade negotiations. The response by the USTR demonstrates that they have actively placed the achievement of one principal negotiating objective above another.

Trade agreements can promote adequate and effective protection of intellectual property rights (IPRs) while safeguarding the TRIPS flexibilities to allow for access to essential medicines. This was well stated by Alan Holmer, President of the Pharmaceutical Research and Manufacturers of America, when he said, “[t]he Declaration recognizes that TRIPS and patents are part of the solution to better public health, not a barrier to access. Without altering the existing rights and obligations under TRIPS, the Declaration provides assurances that countries take all measures consistent with the Agreement to protect the health of their citizens.”⁷⁷

Senator Kennedy called the legislature to action in saying, “here in Congress, we have to do a better job of insisting that our trade agreements comply with the letter and the spirit of the Doha Declaration. It's the law of the land, and it's a matter of life and death for hundreds of millions of people in other lands. The tactics we are so shamefully using against them can only breed greater resentment and greater hatred of the United States. And we can't afford to let that happen at this critical time in our role in the world.”⁷⁸

d. USTR Trade Negotiation Policy for IP provisions in U.S. FTAs

The trade negotiation policy of the USTR is demonstrated in its post-negotiation texts sent to Congress. The texts require countries to implement high standards of IPRs in their domestic laws. These types of provisions are known as TRIPS-plus measures because they go beyond what is required in TRIPS and can have the effect of further restricting developing countries' access to copyrighted materials, trademarks, and patented products such as pharmaceuticals due to higher prices and protection. The IP chapters negotiated by the U.S. in various FTAs since the passing of the Doha Declaration in 2001 restrict the use of flexibilities built into TRIPS specifically for use by developing countries.⁷⁹ “Contrary to the Doha Declaration, U.S. trade negotiators have repeatedly used the trade agreements to restrict the ability of developing nations to acquire medicines at affordable prices.”⁸⁰

It has been observed that, “the U.S. has consistently followed a policy of elevating IPRs standards abroad through the use of unilateral, bilateral, and multilateral action.”⁸¹ In order to lower transaction costs of bilateralism the U.S. has developed models or prototypes of the kind

⁷⁵ *Center for Auto Safety v. Peck*, 751 F.2d 1336, 1384 (D.C. Cir. 1985).

⁷⁶ *In Re Oxborrow*, 913 F.2d 751, 754 (9th Cir. 1990).

⁷⁷ Kennedy statement, Page S4323, May 14, 2002.

⁷⁸ 151 Cong. Rec. S1498-99, Senator Kennedy.

⁷⁹ Frederick Abbott, *The WTO Medicines Decision: World Pharmaceutical Trade and the Protection of Public Health*, 99 Am. J. INT'L L 317, 349-50 (2005).

⁸⁰ Waxman Report, *supra* note 5.

⁸¹ Peter Drahos, *BITs and BIPs – Bilateralism in Intellectual Property*, 4 J. WORLD INTELL. PROP. 791, 798 (2001).

of bilateral treaties it wishes to have with other countries.⁸² These boiler-plate IP provisions reflect the TRIPS-plus measures that give rise to strengthened IPRs; a policy that promotes the best interests of the pharmaceutical industry but could cause difficulties for countries seeking to use compulsory licensing to provide cheaper medicines to their citizens.

e. Intellectual Property Provisions in U.S. FTAs

Many provisions in the U.S. FTAs impose high standards of protection for IPRs, including patents, which take away the safeguards and flexibilities granted to developing countries in the TRIPS Agreement. The Doha Declaration was meant to clarify that these safeguards exist in order to protect public health in developing and least-developed Member states. The USTR's trade negotiating policy of adding in these TRIPS-plus provisions threatens specifically these countries access to medicines, which can affect their citizens' health care and treatment of diseases, especially HIV/AIDS.

i. Data exclusivity

The data exclusivity provisions essentially grant patent-like protection of the clinical data to the creator for a certain amount of time and for many of the same reasons that an actual patent is given to the pharmaceutical innovators.⁸³ TRIPS Art. 39.3 leaves this open and flexible; Members are required to protect such data from "unfair commercial use" provided that it required "considerable effort" to generate, was undisclosed and was a new chemical entity. The Singapore and Chile FTAs makes this much more specific and take away flexibility by mandating five years of data exclusivity for creators of clinical data.⁸⁴ CAFTA also establishes strong new protections for pharmaceutical test data which could be used by pharmaceutical companies to block the production of generic medicines.⁸⁵ These data exclusivity provisions have a large impact on countries ability to issue compulsory licenses for public health.

ii. Extension of Patent Terms and Subject Matter

The TRIPS Agreement provides that patent terms must be at least 20 years, provided that the administrative procedures of a country's patent office are concluded within a reasonable time. So long as there is not an "unreasonable delay" in patent filing and procedures, this time is included in the 20 year patent term. The Agreement does not define an "unreasonable delay" in any country's patent filing office, thus leaving open the possibility that the effective term of a patent could be considerably less than twenty years. Some U.S. FTAs foreclose this possibility by defining the term in FTAs as "a delay in the issuance of a patent of more than four years from the date of filing of the application of in the Party, or two years after a request for examination of

⁸² Courtney M. Arnold, *Protecting Intellectual Property in the Developing World: Next Stop – Thailand*, 2006 Duke L. & Tech. Rev. 10, P16 (2006).

⁸³ *Id.* at P24.

⁸⁴ United States – Singapore Free Trade Agreement, U.S. Sing., May 6, 2003, art. 16.8.1-3, available at http://www.ustr.gov/Trade_Agreements/Bilateral/Singapore_FTA/Final_Texts/Section_Index.html; United States – Chile Free Trade Agreement, Art 17.10(1).

⁸⁵ The U.S.-Central America Free Trade Agreement, Report of the Labor Advisory Committee for Trade Negotiations and Trade Policy (LAC), 19 March 2004, available at http://www.ustr.gov/assets/Trade_Agreements/Bilateral/CAFTA/CAFTA_Reports/asset_upload_file63_5935.pdf.

the application has been made, whichever is later.”⁸⁶ This means that once a developing country’s patent office has a delay it must extend the patent term to account for this delay, and continue extending the patent term without a cap. Prior to the new Congress’ demand for renegotiation, U.S. FTAs, such as the recently negotiated Peru, Colombia, and Panama FTAs, required patent extensions for such delays but did not require any limits, effectively enabling the patent term to stretch on indefinitely.⁸⁷ These have now been removed, but the danger of the inclusion of such a term in future agreement remains if USTR is not sufficiently constrained. FTAs with Singapore, Chile, and Australia all contain provisions granting patent term extension when a delay in the granting of a patent exceeds a certain amount of time (four to five years).⁸⁸ This is in direct contrast to U.S. domestic law which provides for a limit to the amount a delay can affect the patent term.⁸⁹

The Bush Administration’s proposal for the Andean Agreement requires countries to issue patents for diagnostic, therapeutic, or surgical methods.⁹⁰ This expands the scope of items that can be patented beyond what is covered in the TRIPS Agreement, further restricting developing countries access to needed medical supplies and methods. The UK Commission on Intellectual Property Rights, recommends that, “most developing countries, particularly those without research capabilities should strictly exclude diagnostic, therapeutic and surgical methods from patentability, including new uses of known products.”⁹¹

iii. Restrictions on compulsory licensing.

Compulsory licenses and parallel imports are important tools for promoting developing countries’ access to affordable medicines.⁹² Compulsory licensing is addressed in paragraphs 5.b of the Doha Declaration, stating: “Each Member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted,” and 5.c, declaring: “Each Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency . . .” This permits broad use of compulsory licensing and the 2003 Decision the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, allows for countries with insufficient local manufacturing capacity to issue compulsory licenses to foreign producers for later importation.

U.S. FTAs restrict the use of compulsory licensing by agreeing to a period of data protection⁹³ (generic companies typically rely on this data for safety and efficacy information) and by

⁸⁶ See Singapore-U.S., Art. 16.7(7); FTAA, Art. 9.2. Two other FTAs use the same language but extend delay to five years from the date of filing and three years after a request for examination of application is made. See Chile-U.S., Art. 17.9(6); CAFTA-DR, Art. 15.9(6).

⁸⁷ U.S.-Peru §16.9.6; U.S.-Colombia §16.10.3(a); U.S.-Panama §15.10.2(a).

⁸⁸ Arnold, *supra* note 82, at P17.

⁸⁹ See 35 U.S.C. §156(E)(i), stating that patent terms can be extended to account for delays in regulatory review period but extensions are “not to exceed 5 years from the date of expiration of the original patent term...”

⁹⁰ Waxman Report, *supra* note 5, citing Article 8.2(b) of the Andean FTA negotiating proposal.

⁹¹ UK Commission on Intellectual Property Rights - Study 4C (August 2002).

⁹² Carlos Correa, *Implications of Bilateral Free Trade Agreements on Access to Medicines*, Bull World Health Organ, 2006 vol. 84 no.5, pp 399-404, available at http://www.scielo.org/scielo.php?script=sci_arttext&pid=S0042-96862006000500021&lng=en&nrm=iso. ISSN 0042-9686.

⁹³ See NAFTA Section 1709, Article 10.

limiting the circumstances when compulsory licenses can be issued.⁹⁴ The TRIPS Agreement leaves it open for countries to decide when a compulsory license needs to be issued, but several U.S. FTAs limit this flexibility to emergencies, government non-commercial use, and competition cases only.⁹⁵

Other U.S. FTAs do not expressly limit compulsory licensing but they do not protect this right from potential conflicts with other negotiated provisions in these texts, such as data exclusivity.⁹⁶ Data exclusivity protection, discussed *supra*, may make illusory the granting of compulsory licenses and the availability of government non-commercial use.⁹⁷ The non-commercial use provisions may be deemed as only permitting the use of the patented invention and not the protected data. Without access to this data, companies that would formally be able to produce generic drugs under compulsory licenses at affordable prices would need much more time and resources to expend on their own studies to generate the pharmaceutical data required for safe production.

iv. Prohibitions on parallel importation of low-cost drugs

Parallel importation of cheaper drugs arises when a country imports a patented medicine that is being sold more cheaply in another country. This access depends on exhaustion of patent-holders' rights. TRIPS allows each WTO Member to decide for itself whether patent rights have been exhausted under its laws once the drug is introduced anywhere in the world.⁹⁸ The Doha Declaration clarified this flexibility in paragraphs 5c, "[t]he effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each Member free to establish its own regime for such exhaustion without challenge . . ."⁹⁹ The Singapore and proposed FTAA language restrict countries' ability to use parallel importation by giving patent holders the means to block importation of the patented drugs, and, in the proposed FTAA region, by obliging countries to set up regional exhaustion under their laws within five years.¹⁰⁰

The USTR defended a similar provision in the U.S.-Morocco Agreement stating that Morocco had already adopted a policy not to permit parallel imports well before the signing of the FTA with the U.S., thus the restriction on parallel imports did not lessen USTR's commitment to the Doha Declaration.¹⁰¹ Yet, domestic laws and regulations can be changed to reflect changes in administration and public needs. Now that Morocco has signed the FTA, prohibitions against

⁹⁴ See Singapore Article 16.7(6); FTAA Section B.2.e, Article 6.

⁹⁵ Waxman Report, *supra* note 5, at 10.

⁹⁶ *Id* at 11.

⁹⁷ Carlos Correa, *Implications of Bilateral Free Trade Agreements on Access to Medicines*, Bulletin of the World Health Organization, May 2006, Vol. 84, 399-404, at 402., available at <http://www.who.int/bulletin/volumes/84/5/399.pdf>.

⁹⁸ Comparison of Five FTAs, Oxfam Briefing Note, June 2004.

⁹⁹ See also Paragraph 4 of the Declaration: "... we reaffirm the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose."

¹⁰⁰ See Singapore Article 16.7(2); FTAA Section B.2.e, Article 4.

¹⁰¹ House Report 108-627, United States-Morocco Free Trade Agreement Implementation Act, USTR Robert B. Zoellick, Letter to Rep. Sander M. Levin, July 19, 2004.

this mode of access to generic drugs are not easily changed and must be negotiated with an important trading partner rather than simply going through their domestic legislative process.

f. What effect do the Public Health side letters have on compliance with the Declaration?

Some of the recent bilateral trade agreements have subsequently or concurrently involved so-called side letters that attempt to provide assurance that public health and access to medicines have been taken in to account.¹⁰² The extent to which these side letters influence interpretation of the IP provisions in FTAs is uncertain.¹⁰³ The language in the side letters remains fairly consistent throughout recently negotiated U.S. FTAs. For example, the United States and Morocco agreed to a side letter on public health in which both Parties stated their understanding that, “[t]he obligations of Chapter Fifteen of the Agreement do not affect the ability of either Party to take necessary measures to protect human health by promoting access to medicines for all, in particular concerning cases such as HIV/AIDS, tuberculosis, malaria, and other epidemics as well as circumstances of extreme urgency or national emergency.”¹⁰⁴

Side letters could provide some basis for issuing a compulsory license in these countries, but this is a matter of interpretation, and any provision not directly incorporated into the text will be problematic. Further, the legal effect of these letters is not entirely clear. They can be viewed as separate agreements and thus binding on the parties. Or they could operate simply as letters of clarification that do not actually contain any legal mandates for the parties.

The USTR views the side letters as constituting “a formal agreement between the Parties” and “thus, a significant part of the interpretive context for [the] agreement and not merely rhetorical.”¹⁰⁵ However, this clarification by USTR only addressed the issue of data exclusivity, leaving open the status of other issues in the FTA. The Vienna Convention states that “any subsequent agreement between the parties regarding the interpretation of the treaty or application of its provisions” shall be considered together with its context in the interpretation of the treaty.¹⁰⁶ Subsequent agreements that fit this definition can be used to interpret the actual terms of the treaty.¹⁰⁷ An established principle of international law is that the right of giving authoritative interpretation to a treaty belongs to the parties who have the power to modify or

¹⁰² See, e.g., U.S.-Morocco, U.S.-CAFTA-DR

¹⁰³ Correa *supra* note 97.

¹⁰⁴ House Report 108-627, United States-Morocco Free Trade Agreement Implementation Act, USTR Robert B. Zoellick, Letter to Rep. Sander M. Levin, July 19, 2004.

¹⁰⁵ Executive Office of the President, Office of the United States Trade Representative, Washington, D.C. July 19, 2004, House Report 108-627, United States-Morocco Free Trade Agreement Implementation Act. The side letter further states, “Chapter Fifteen does not prevent the effective utilization of the TRIPS/health solution reached in the WTO last year to ensure that developing countries that lack pharmaceutical manufacturing capacity may import drugs. Therefore, if circumstances ever arise in which a drug is produced under a compulsory license, and it is necessary to approve that drug to protect public health or effectively utilize the TRIPS/health solution, the data protection provisions in the FTA would not stand in the way.”

¹⁰⁶ Vienna Convention on the Law of Treaties, art. 31, §3(a) at 692.

¹⁰⁷ James Thuo Gathi, *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, 300 (2002).

suppress it, in other words, the signatories to a treaty.¹⁰⁸ In a letter from the General Counsel of the USTR to a Member of Congress, the USTR stated that: “if circumstances ever arise in which a drug is produced under a compulsory license, and it is necessary to approve that drug to protect public health or effectively utilize the TRIPS/health solution, the data protection provision in the [U.S.-Morocco] FTA would not stand in the way.”¹⁰⁹

The other view is that the side letters have some clarification value but don’t change the binding IP provisions in the text of the agreement.¹¹⁰ Civil society and industry groups have interpreted these side letters as not imposing any additional obligations on the parties.¹¹¹ According to this view, these side letters can serve as clarifying devices, but they may have only been formed to assuage Congressional concerns and do not change the text of the agreement.¹¹² Because side letters must be considered “together with its context” which includes the TRIPS-plus provisions of the treaty, it is difficult to see how these understandings alter the effect of, or create exceptions to, the FTAs’ IP provisions.¹¹³

The legally binding status of a side letter depends on the circumstances in which it was formulated and signed, the specific wording, and its subject matter.¹¹⁴ First of all, the side letters were negotiated at the same time yet kept separate from the main text. But the letters may still be considered subsequent if they were signed after the main text itself. These commitments on the part of both parties to provide access to medicines would have stronger legal significance if they had been incorporated into the IP provision of the main agreement. Yet, in all FTAs thus far negotiated by the USTR, the provisions stating that the IP obligations “do not affect a Party’s ability to take necessary measures to protect public health” were kept apart from the rest of the agreement. Thus, the circumstances of formulation give weight to the argument that the side letters are not intended to be legally binding, or at least not carry as much legal significance as the main text IP provisions which contain TRIPS-plus obligations.

The language and subject matter of the side letters show the intent of the parties for the agreement to have some interpretative force. The side letters state that the parties “have reached the following *understandings* regarding Chapter Fifteen (Intellectual Property Rights).”¹¹⁵ This is in contrast to the language in Chapter Fifteen, which states “[e]ach party *shall*” throughout its

¹⁰⁸ Sir Ian Sinclair, *THE VIENNA CONVENTION ON THE LAW OF TREATIES* 2ND ED., Manchester University Press, at 136, 1984.

¹⁰⁹ Executive Office of the President, Office of the United States Trade Representative, Washington, D.C. July 19, 2004, House Report 108-627, United States-Morocco Free Trade Agreement Implementation Act

¹¹⁰ Comparison of Five U.S. FTAs, Oxfam Briefing Note, June 2004, *available at* http://www.oxfam.org.uk/what_we_do/issues/health/downloads/undermining_access_ftas.pdf.

¹¹¹ See The U.S.-Colombia Trade Promotion Authority (TPA): Intellectual Property Provisions, Report of the Industry Trade Advisory Committee on Intellectual Property Rights (ITAC-15), 20 September 2006, at 16; *see also* Statement of Joseph E. Brenner and Ellen R. Shaffer, Center for Policy Analysis on Trade and Health, San Francisco, California, House Committee on Ways and Means, *available at* <http://waysandmeans.house.gov/hearings.asp?formmode=view&id=2825>.

¹¹² J.F. Hornbeck & William H. Cooper, *CRS Report for Congress: Trade Promotion Authority (TPA): Issues, Options, and Prospects for Renewal*, 5 December 2006.

¹¹³ Correa, *supra* note 97, at 7.

¹¹⁴ See James Thuo Gathi, *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, 314 (2002).

¹¹⁵ CAFTA-DR Side Letter (emphasis added by author).

provisions.¹¹⁶ The word “shall” indicates mandatory provisions, provisions that each country must follow or else be in breach of the treaty, in violation of international law. When parties have an understanding, this indicates a mutual interpretation of the agreed treaty or a clarification of the referenced text. Other side agreements have been found to have some interpretative force when taken with the context and language of the treaty, but not to have substantive or even interpretive force standing alone. For example, a Canadian Tribunal found that NAFTA side agreements to labor provisions were one of several sources of interpretive guidance in reading the investment chapter of the treaty.¹¹⁷

Furthermore, other language in the side letters restricts parties’ application of the Doha Declaration. The side letter to the CAFTA, Morocco, and Bahrain FTAs provides that the IP obligations of the agreement do not affect the parties’ ability to take “necessary” measures to protect public health. This is more limited than the Doha Declaration because the Declaration leaves open the situations when a country may issue compulsory licenses and does not limit it to only to situations of necessity.¹¹⁸ Also in the CAFTA-DR FTA, the side letter states that the parties’ obligations in the treaty do not affect their ability to take measures for public health, “in particular concerning cases such as HIV/AIDS, tuberculosis, malaria, and other epidemics as well as circumstances of extreme urgency or national emergency.” This is the language of limitation; “in particular” introduces a limited scope of diseases for when a compulsory license could be issued.¹¹⁹ This is the negotiating position that the U.S. took during the 2002 Doha negotiations and a position that was not accepted in the final Declaration which created the permanent waiver for developing countries. It is thus understood by all WTO Members that the Doha Declaration is not restricted to any named diseases or defined public health emergencies, and any attempt to restrict access to medicines in this way does not follow the Declaration.

The letters “appear intended to clarify the relationship between the intellectual property provisions of the FTA and the ability of [the parties] to take measures to protect the public health.”¹²⁰ But based on the context of the formation of the side letters and the language within the letters themselves, the letters do not seem to be legally binding and thus do not serve as a legal basis upon which a developing country could implement compulsory licenses or allow for parallel importation, both of which are important means to access pharmaceuticals. If the side letters are erroneously treated as creating substantive legal obligations, then in the situation where a party attempted to follow this understanding and issue a compulsory license, that party would be in violation of one or more of the IP provisions in the main text. A side letter cannot have substantive legal force as an interpretative device and run contrary to the parties’ obligations under the treaty itself.

¹¹⁶ CAFTA-DR, Chapter Fifteen: Intellectual Property Rights (emphasis added by author).

¹¹⁷ S.D. Myers and Government of Canada, Decision of the Tribunal, liability phase, 13 November 2000, paras. 217 et seq; separate concurring opinion of Bryan Schwartz, 12 November 2000, (2001) 1 *Asper Rev. of Int’l Bus. And Trade Law* 337-408, available at http://www.dfait-maeci.gc.ca/tna-nac/documents/myerscanadapartialaward_final_13-11-00.pdf. The Tribunal found that the side agreement, along with the preamble to NAFTA and international agreements affirmed in NAFTA, suggested that the provisions in NAFTA in question should be interpreted in light of certain general principles.

¹¹⁸ Waxman Report, *supra* note 5.

¹¹⁹ Abbott, *supra* note 27, at 352.

¹²⁰ House Report 108-627, United States-Morocco Free Trade Agreement Implementation Act.

Within U.S. law, determining the status of the side letters has also proven elusive. USTR has determinedly characterized them as part of the FTA, while remaining ambiguous about their exact legal effect in the United States. There is little analysis on this issue, and neither Congress nor the Executive have acted to clarify the status of the letters. Nevertheless, what is most important is the actions of USTR with respect to the way in which countries have implemented their obligations. The example of implementation under CAFTA-DR shows that the U.S. has pushed for the broadest possible interpretation of the TRIPS-plus provisions while ignoring the provisions in the side-letters.¹²¹ The implementation process can be protracted and subject to continuous checks to ensure that the countries are implementing the agreement according to the requirement of the USTR. As other observers have noted, it is clear that “the U.S. Government does not view the side letters as creating any kind of exemption that would allow parties to the FTAs to ignore obligations in the agreements’ intellectual property chapters.”¹²²

Although the letters may serve some clarification if there is any ambiguity in the IP provisions of the relevant FTAs, they do not give back the safeguards that are stripped away by TRIPS-plus provisions. Side letters are not a strong enough tools for countries in need of medicines for their citizens and thus do not demonstrate USTR compliance with the principal negotiating objective to follow the Doha Declaration.

VI. WHAT ARE POSSIBLE SOLUTIONS FOR NON-COMPLIANCE?

The principal means of addressing a violation of Congress’ negotiating objectives is through political recourse.¹²³ Congress can act by: voting down pending FTAs under TPA; warning the administration that it will not pass agreements with similar provisions; altering the language of a renewed TPA by mandating more specific objectives in negotiations; or by refusing to renew TPA at all. In addition, Congress may, at any time, refuse to apply the provisions of TPA to any pending agreement, if it determines that the Executive has breached it by failing to comply with the negotiating mandate.

a. Pending FTAs

A good example of Congressional action is the successful demand for renegotiation by the new Congress for the pending U.S. FTAs with Peru, and Panama. The administration determined that these would not pass the Congress without modification and so negotiated specific provisions on labor, environment and public health with the Congress which would be submitted to the partner countries. This shows that renegotiation is not a serious obstacle to concerted Congressional post-negotiation action if its mandates are not properly met.

b. Suggestions for different language in possible renewal/extension TPA.

¹²¹ Pedro Roffe, *Intellectual Property, Bilateral Agreements and Sustainable Development: The Challenges of Implementation*, (CIEL Intellectual Property and Sustainable Development Series 1, January 2007) available at http://www.ciel.org/Publications/FTA_ImplementationPub_Jan07.pdf

¹²² Carsten Fink & Patrick Reichenmiller, Tightening TRIPS: The Intellectual Property Provisions of Recent US Free Trade Agreements (World Bank Trade Note No. 20, 2005), World Bank, Global Economic Prospects 2005, ch. 5, at 98-110.

¹²³ 25 CLLPJ 201, 217.

With regard to the possible renewal of TPA, Congress can choose to either: take no action and to not renew TPA; allow for a temporary extension; renew TPA with revisions; grant permanent authority to Executive branch; or some hybrid of the previous options.¹²⁴ Congress could refuse to renew TPA unless language is inserted regarding health and IP provisions in future FTAs; this could be in the form of an IP/health template that must be used in all future negotiations. If Congress were to revisit TPA in the near future, it could mandate a template for IP negotiations that went beyond the provisions contained in the renegotiated Peru and Panama texts. Given USTR's failure to comply with the previous clear mandate, any new approach would need to be specific regarding the provisions that could affect developing countries access to medicines. For example, it could include:

- language mandating respect for the Doha Declaration within the main body of the text of all negotiated FTAs;
- removal of data exclusivity provisions beyond those regarding basic unfair competition rules (this would enable the use of such data by legitimate generic producers);
- a provision within the text of the agreement mandating that a country is free to use compulsory licensing for any of the stated reasons in the Doha Declaration or any other public health concern;
- a provision allowing for parallel importation of drugs and not allowing patent holders to block this route of access to medicines;
- not allowing for expansion of patentable subject matter to untested and controversial areas such as new therapeutic uses of existing medicines;
- leaving it open for countries to determine what constitutes an unreasonable delay in their administrative offices and thus allowing for flexibility in patent terms.

At the very least, any new iteration of TPA should include the language formerly contained in side letters; the understandings that both parties would respect the Doha Declaration, and making it mandatory so that “the parties *shall* respect the Doha Declaration.”

c. Suggestions for different procedures

Some commentators have argued that what is needed is changes in the Congressional procedure and coordination between Congress and the USTR offices. This concern was stated to the House Committee on Ways and Means as follows:

[T]here are no representatives for the public's health or for access to medicines on any of the USTR's Advisory Committees, including those that address intellectual property negotiations....Because there is no public health representation on the committees, and trade negotiations are secret until the agreements are completed, this opposition has been

¹²⁴ J.F. Hornbeck & William H. Cooper, *CRS Report for Congress: Trade Promotion Authority (TPA): Issues, Options, and Prospects for Renewal*, 5 December 2006, available at <http://fpcc.state.gov/documents/organization/78415.pdf>.

expressed only after it has been too late to influence the agreement. Better representation during the process would contribute to more effective outcomes.¹²⁵

If the negotiation process and USTR's consultation with Congress included more diverse representation from civil society, and if that consultation were truly open and inclusive, problems with FTA texts could be brought to the attention of Congress much earlier in the process. In this way, negotiations and USTR trade policy positions would be more transparent and open to public comment, promoting more democratic representation in our trade negotiations. Regardless of the future of TPA, Congress must act to ensure full and equitable representation of public health interests in U.S. Trade Advisory Committees affecting Health. These must be bona fide public health advocates representing a broad range of stakeholders, not simply individuals or organizations funded by the pharmaceutical industry.

VII. CONCLUSION

The WTO Doha Declaration on Public Health is founded on the recognition that a fundamental right of every human being is the right to the highest attainable standard of health; this includes access to affordable medicines.¹²⁶ The U.S. pledged to support developing countries' access to medicines by abiding by the Doha Declaration as a principal negotiating objective in its TPA, but this pledge has not been followed in the texts of recently negotiated FTAs. Regardless of whether TPA will be renewed, Congress must refuse to approve any FTAs that do not fulfill this pledge and must mandate stronger and more specific language in IP chapters allowing for increased flexibility in developing countries' patent regimes for pharmaceuticals. Congress must ensure that during the negotiations and ratification process of future FTAs, IP provisions include respect for the Doha Declaration and allow for access to generic medicines for public health. Perhaps most importantly, Congress must insist on greater transparency and civil society participation in trade and intellectual property policy-setting so that the values of all sectors of society are reflected rather than those of a narrow group of pharmaceutical companies.

¹²⁵ *Statement of Joseph E. Brenner and Ellen R. Shaffer, Center for Policy Analysis on Trade and Health, San Francisco, California, House Committee on Ways and Means, 21 April 2005, available at <http://waysandmeans.house.gov/hearings.asp?formmode=view&id=2825>.*

¹²⁶ See *The Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health*, Report of the Special Rapporteur of the Commission on Human Rights, E/CN.4/2003/58, 13 February 2003, para. 10-36; see also The Committee on Economic, Social and Cultural Rights General Comment 14 (E/C.12/2004/4), para. 43.



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