UNITED STATES HOUSE OF REPRESENTATIVES
COMMITTEE ON GOVERNMENT REFORM – MINORITY STAFF
SPECIAL INVESTIGATIONS DIVISION
JUNE 2005

# TRADE AGREEMENTS AND ACCESS TO MEDICATIONS UNDER THE BUSH ADMINISTRATION

**PREPARED FOR**

**REP. HENRY A. WAXMAN**

## TABLE OF CONTENTS

## EXECUTIVE SUMMARY

In 2001, 142 countries, including the United States, adopted "the Doha Declaration," an international agreement that trade obligations should be interpreted and implemented in ways that protect public health and access to essential medications. In August 2002, the U.S. Congress passed the Trade Promotion Authority Act, which directs adherence to the Doha Declaration in U.S. trade negotiations.

Since the adoption of the Doha Declaration and the passage of the Trade Promotion Authority Act, the Bush Administration has signed and Congress has ratified bilateral free trade agreements with three developing countries: Chile, Singapore, and Morocco. The Administration has signed one regional free trade agreement, commonly referred to as CAFTA, with five Central American nations and the Dominican Republic, and a bilateral agreement with Bahrain. Six more free trade agreements with 13 developing countries have been initiated, including a proposed agreement with four Andean nations. Negotiations have also continued on the Free Trade Agreement of the Americas (FTAA).

At the request of Rep. Henry A. Waxman, this report examines whether the Administration is complying with the Doha Declaration in its pursuit of these trade agreements. The report finds that 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. In effect, the President's trade representatives have elevated the protection of pharmaceutical patents above the pressing health needs of developing countries.

Specifically, the report finds that the agreements:

- **Delay approval of generic drugs.** CAFTA and the other four signed trade agreements, as well as the Andean proposal and FTAA draft, contain provisions that block the approval of inexpensive generic drugs until the more expensive brand-name drug has received at least five years of market exclusivity in the developing nation. Under the agreements, the developing nations will often have to wait longer than the United States to gain access to low-cost versions of essential medications.

- **Require patent extensions.** CAFTA and the other four signed trade agreements, as well as the Andean proposal, require the developing nations to grant patent extensions to the manufacturers of brand-name drugs to account for delays in the regulatory approval process in the developing nation. These provisions can extend the term of patents in the developing nations beyond their duration in the United States.

- **Link drug approval to patent status.** CAFTA and the other four signed trade agreements, as well as the Andean proposal and the FTAA draft, require drug regulatory authorities in the developing nations to adjudicate patents despite their lack of expertise in the area of patent enforcement, placing an additional constraint on the approval and availability of low-cost generics.

- **Restrict compulsory licensing.** The Singapore agreement, the Andean proposal, and the FTAA draft limit the circumstances under which developing nations can issue compulsory licenses authorizing generic manufacturers to produce low-cost versions of patented drugs.

- **Prohibit parallel importation.** The trade agreements with Morocco and Singapore, as well as the Andean proposal and the FTAA draft, prevent the developing nations from importing patented drugs from abroad at the lowest available price.

- **Expand patent protections.** The Andean proposal has a provision that would require the Andean nations to issue patents for diagnostic, therapeutic, and surgical methods that are currently exempted from patentability.

Taken together, these trade provisions will significantly impede the ability of developing countries to obtain access to inexpensive, lifesaving medications. Contrary to the principles of the Doha Declaration, these provisions in the trade agreements advance the financial interests of large multinational drug companies at the expense of the developing world's ability to address public health problems.

## I. INTRODUCTION

### A. Access to Medications in the Developing World

According to the World Health Organization, 40 million people are infected with HIV, and three million people died of AIDS in 2004.[1] More than eight million people become sick with infectious tuberculosis each year, and nearly two million die.[2] Malaria kills an estimated two million people each year.[3] All told, infectious diseases kill over 14 million people per year, nine out of ten of whom live in the developing world.[4]

Treatable but noninfectious chronic illnesses are also leading causes of death in the developing world. Cancer kills seven million people per year, and cardiovascular disease kills 17 million.[5]

Despite the high incidence of disease in developing countries, one-third of the world's population has no access to any medicines to treat infectious disease.[6] According to international medical experts, "millions of people worldwide are dying of treatable diseases like malaria while effective drugs exist."[7]

A principal strategy used by developing nations to improve access to lifesaving drugs has been to authorize the production or importation of low-cost "generic" versions of the medicines. This approach has had notable success in key areas, such as treatment for HIV. A decade ago, a year of antiretroviral treatment for HIV infections cost approximately $10,000, which was impossible for developing

---

1 UNAIDS, *Table of country-specific HIV and AIDS estimates and data, end 2003* (UNAIDS, July 2004) (online at http://www.unaids.org/html/pub/Global-Reports/Bangkok/Table_countryestimates_2004_en_xls.xls).

2 World Health Organization, *Fact Sheet No. 104: Tuberculosis: Infection and Transmission* (Apr. 2005) (online at http://www.who.int/mediacentre/factsheets/fs104/en/).

3 Doctors Without Borders, *Campaign for Access to Essential Medicines* (2004) (online at http://www.accessmed-msf.org/documents/campaignbrochure2004.pdf).

4 *Id.*

5 World Health Organization, *WHO Cancer Control* Program (online at http://www.who.int/cancer/en); World Health Organization, *The Atlas of Heart Disease and Stroke* (online at http://www.who.int/cardiovascular_diseases/resources/atlas/en/index.html).

6 Doctors Without Borders, *Campaign for Access to Essential Medicines, supra* note.

7 *Id.*

nations to afford.[8] In the late 1990s, generic manufacturers in Thailand, India, Brazil, and other countries began to produce generic versions of antiretrovirals.[9] Once these alternatives became available, the annual cost of treatment dropped dramatically. Today the cost can be as low as $200 per patient in developing nations with access to these low-cost generic drugs.[10]

## B. The Doha Declaration

The 1994 agreement on Trade Related Aspects of Intellectual Property (TRIPS) established an international framework under the World Trade Organization (WTO) for protecting trademarks, copyrights, and patents.[11] Since its adoption, multinational drug companies, often with the support of the United States, have challenged measures by developing nations to increase access to generic medicines. For example, a pharmaceutical industry association and its affiliate companies filed a lawsuit in 1999 challenging provisions of the South African Medicines Act related to access to generics.[12] The U.S. Congress passed legislation that withheld funds from South Africa until the Secretary of State reported on efforts to negotiate the "repeal, suspension, or termination" of portions of the South African law.[13]

Although the legal action against South Africa was ultimately withdrawn, developing nations objected that such a challenge had been facilitated by the

---

8 Doctors Without Borders, *Untangling the Web of Price Reductions* (Feb. 2005) (online at http://www.accessmed-msf.org/documents/untanglingtheweb%207.pdf).

9 Doctors Without Borders, *HIV/AIDS Medicine Pricing Report: Setting Objectives: Is there a political will?* (Dec. 2000 update) (online at http://www.accessmed-msf.org/upload/ReportsandPublications/49200113585/Durban%20report%20update%20dec%202000.pdf).

10 Doctors Without Borders, *The Campaign: Frequently Asked Questions* (Sept. 16, 2004) (online at http://www.accessmed-msf.org/campaign/faq.shtm).

11 World Trade Organization, *Agreement on Trade-Related Aspects of Intellectual Property Rights* (1994) (TRIPS).

12 The South African law provided for multiple measures to lower drug costs and included the provision that the health minister "may prescribe conditions for the supply of more affordable medicines in certain circumstances so as to protect the health of the public." South African Medicines and Related Substances Control Act No. 90 §10, introducing § 15(c)(1997 Amendment). In the lawsuit, the South African Pharmaceutical Manufacturers' Association joined with 39 affiliate companies to challenge the law as in conflict with TRIPS. *Notice of Motion in the High Court of South Africa, In the matter between: The Pharmaceutical Manufacturers' Association of South Africa, First Applicant, and The President of the Republic of South Africa, The Honorable Mr. N.R. Mandela N.O., First Respondent* (Case number: 4183/98) (Feb. 18, 1998).

13 Pub. L. No. 105-277 (105th Congress, 1998).

TRIPS agreement. A coalition organized by African countries petitioned the WTO to consider the relationship between TRIPS and public health. This request was granted, and the issue was placed on the agenda of the Fourth Ministerial Meeting of the WTO in Doha, Qatar, in November 2001.

The document that emerged, "The Doha Declaration on the TRIPS Agreement and Public Health," was endorsed by 142 countries, including the United States. The Doha Declaration states that "the TRIPS agreement does not and should not prevent Members from taking measures to protect public health."[14] According to the Declaration, "the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' rights to protect public health, and in particular, to promote access to medicines for all."[15]

The Doha Declaration recognizes the need for nations to take actions to lower the cost of medicines. The Declaration expressly affirms the right of developing nations to authorize the production of generic versions of patented drugs (compulsory licensing) and the importation of patented drugs at the lowest price available (parallel importation).[16]

## C. The U.S. Response

The Bush Administration immediately pledged its support of the Doha Declaration. U.S. Trade Representative Robert Zoellick praised the agreement as a "landmark political declaration" and "a good example of developed and developing nations advancing common goals."[17]

Congress also endorsed this international consensus on trade and health. A provision of the 2002 Trade Promotion Authority Act, which authorizes the President to send signed trade agreements to Congress for consideration under expedited procedures, established respect for the Doha Declaration as a "principal negotiating objective" in the area of intellectual property.[18]

---

[14] Paragraph 4, 'Declaration on the TRIPS Agreement and Public Health', WTO Ministerial Conference — Fourth Session, WT/MIN(01)/DEC/2, adopted 14 November 2001. (Doha Declaration).

[15] *Id.*

[16] Doha Declaration, Paragraph 5.

[17] USTR, *Press Release: Zoellick Says World Has Chosen Path of Hope, Openness, Development and Growth*, (Nov. 14, 2001).

[18] Pub. L. No. 107-210; 19 U.S.C. §3802(b)(4)(C).

Since the adoption of the Doha Agreement, the Bush Administration has initiated 11 bilateral and regional free trade agreements with 23 developing countries.[19] Of these agreements, three bilateral agreements, with Chile, Singapore, and Morocco, have been both signed by the Administration and ratified by Congress.[20]

Two agreements have been negotiated and signed by the partner countries, but are still pending congressional consideration. These are the Central America Free Trade Agreement (CAFTA) with Costa Rica, El Salvador, Guatemala, Honduras, Nicaragua, and the Dominican Republic, and a bilateral agreement with Bahrain.[21] CAFTA is expected to be considered by Congress in the summer of 2005.

Six free trade agreements with 13 additional countries have been initiated and are still in negotiations. These are the Andean agreement with Bolivia, Colombia, Ecuador and Peru; a Southern Africa agreement with Botswana, Lesotho, Namibia, South Africa, and Swaziland; and bilateral agreements with Thailand, Panama, Oman, and the United Arab Emirates.[22]

In addition, the Free Trade Agreement of the Americas, which was initiated in 1994, is still under negotiation. The FTAA would coordinate trade policy among 34 countries in the Western Hemisphere, including Latin American and Caribbean countries.[23]

---

[19] The countries are identified as developing countries on the Organization of Economic Cooperation and Development (OECD), *List of Developing Countries and Territories* (online at www.oecd.org/dataoecd/35/9/2488552.pdf).

[20] United States-Chile free trade agreement. Signed at Miami June 6, 2003; entered into force January 1, 2004. (Chile FTA). United States-Singapore free trade agreement. Signed at Washington May 6, 2003; entered into force Jan. 1, 2004. (Singapore FTA). United States-Morocco free trade agreement. Signed at Washington June 15, 2004. (Morocco FTA). The Morocco FTA is expected to enter into force on July 1, 2005. U.S. International Trade Commission, *Effect of Modifications to the U.S.-Morocco Free Trade Agreement* (Apr. 2005) (online at http://prototype.usitc.gov/Wais/pub3774.PDF).

[21] United States-Dominican Republic-Central America free trade agreement. Signed at Washington May 28, 2004 and Aug. 5, 2004. Parties: Costa Rica, Dominican Republic, El Salvador, Guatemala, Honduras, Nicaragua and the United States. (CAFTA). United States-Bahrain free trade agreement. Signed at Washington Sept. 14, 2004. (Bahrain FTA).

[22] At this time Bolivia is only an observer to the Andean negotiations. United States Trade Representative, *2005 National Trade Estimate Report on Foreign Trade Barriers*, (Mar. 2005) (online at http://www.ustr.gov/Document_Library/Reports_Publications/2005/2005_NTE_Report/Section_Index.html).

[23] A complete list of the 34 FTAA countries is available online at http://www.ftaa-alca.org/alca_e.asp.

## II. PURPOSE AND METHODOLOGY

At the request of Rep. Henry A. Waxman, this report examines the terms of the five trade agreements negotiated and signed by the Bush Administration since the adoption of the Doha Declaration. The report also examines the text of two trade agreements that are under negotiation by the Bush Administration and have been released or disclosed to the public. These are the U.S. negotiating proposal for the Andean trade agreement, which was published in the Colombian press,[24] and the latest public draft text of the FTAA.[25] The report assesses whether these trade agreements are consistent with the Doha Declaration and the principle that trade obligations should not block developing nations from meeting their public health needs.

The report does not examine the terms of the other trade agreements currently being negotiated by the Administration. The terms of these proposed trade agreements have not been released or disclosed to the public.

## III. FINDINGS

The developing countries that have completed or are negotiating trade agreements with the United States have an enormous need for better access to medication. In these countries, over 10 million people are infected with HIV.[26] The five Sub-Saharan countries alone account for 300,000 new cases of tuberculosis annually.[27] In Latin America and the Caribbean, over 15 million people suffer from diabetes.[28]

---

[24] The negotiating proposal from the United States for the intellectual property chapter of the Andean FTA was published in Spanish by Colombia's La República newspaper. *Serias peticiones de Estados Unidos en patentes,* La República (Sept. 1, 2004) (online at http://www.la-republica.com.co/noticia.php?id_notiweb=16964&id_subseccion=88&template=noticia&fecha=2004-09-01_11:59pm).

[25] Third Draft FTAA Agreement Derestricted FTAA.TNC/w/133/Rev.3 (Nov. 21, 2003) (online at http://www.ftaa-alca.org/FTAADraft03/Index_e.asp).

[26] UNAIDS, *Table of country-specific HIV and AIDS estimates and data, end 2003* (UNAIDS, July 2004) (online at http://www.unaids.org/html/pub/Global-Reports/Bangkok/Table_countryestimates_2004_en_xls.xls).

[27] World Health Organization Global Tuberculosis Database (online at http://globalatlas.who.int/globalatlas/Dataquery).

[28] Alberto Barcelo et al., *The Cost of Diabetes in Latin America and the Caribbean*, Bulletin of the World Health Organization. (Jan. 23, 2003).

Despite the compelling health needs of these developing nations, the trade agreements analyzed in this report undermine the basic protections of the Doha Declaration. The Bush Administration's trade negotiators have repeatedly pressured the developing countries to forgo their rights under the Doha Declaration and to adopt intellectual property standards that impede access to essential medications. In particular, the Administration has used the trade agreements to delay generic drug approvals, require patent extensions, link drug approval to patent enforcement, restrict compulsory licensing, prohibit parallel importation, and expand patent protections.

## A. Delays in the Approval of Generic Drugs

An essential prerequisite to the marketing of any drug, patented or generic, is approval by a country's regulatory authorities. Contrary to the principles of the Doha Declaration, the trade agreements negotiated by the Bush Administration interfere with the authority of developing nations to grant approval to generics by requiring at least five years of market exclusivity for brand-name drugs.

In developed nations like the United States, a manufacturer seeking approval of a new drug must provide extensive clinical data on its safety and efficacy. A generic company can apply for permission to market a generic version of the drug after the expiration of the patent by demonstrating that the generic copy is biologically equivalent to the brand-name version.[29] In this situation, the generic manufacturer and the regulatory agency rely on the safety and efficacy data that formed the basis of the earlier approval.[30] Some developing countries follow a similar model. Others also permit approval of drugs based on prior approval in another country.

The trade agreements negotiated by the Bush Administration impose significant restrictions on this process in the developing nations. The CAFTA agreement, for example, prohibits the developing nations from approving a generic drug unless the developing nations have given the brand-name drug five years of market exclusivity. This five-year period of market exclusivity starts at the time the brand-name drug is approved in the developing country.[31] Similar provisions

---

[29] 21 U.S.C. §355(j). The current U.S. framework for the approval of generics was established by the *Drug Price Competition and Patent Term Restoration Act,* Pub. L. No. 98-417 (98th Congress, 1984). This legislation is also known as the "Hatch-Waxman Act."

[30] *Id.* Generic companies typically do not conduct their own trials of the effectiveness of their drugs. They generally only conduct bio-equivalence studies to demonstrate that the generic version is metabolized the same way as the branded version.

[31] CAFTA, Article 15.10.1(a) and 15.10.1(b).

providing for five years of competition-free marketing are contained in the completed trade agreements negotiated with Chile, Singapore, Morocco, and Bahrain, as well as in the Andean proposal and the FTAA draft.[32]

Under CAFTA and the other agreements, this period of market exclusivity operates independently of patent protection. As a result, the developing nation must give the brand-name product market exclusivity even if its patent has expired and the generic could otherwise be approved.

The consequences of these provisions in CAFTA and the other trade agreements negotiated by the Bush Administration are the exact opposite of those intended by the Doha Declaration. The Doha Declaration recognized that developing nations should have improved access to inexpensive generic drugs because of their pressing health needs. But under CAFTA and the other agreements, the developing nations will often have to wait longer than the United States to gain access to inexpensive generic medicines. Because brand-name manufacturers typically seek approval of their products in the United States and other developed nations before they seek approval in developing nations, the period of market exclusivity will usually expire in the United States before it expires in the developing nations. The perverse result is that the developing nations, which have the greatest need for lower cost drugs, have to wait the longest to obtain them.[33]

Periods of marketing exclusivity for new drugs can make sense for a wealthy nation like the United States. In 1984, Congress passed drug legislation, commonly known as the Hatch-Waxman Act, that provided brand-name companies five years of exclusive marketing in exchange for measures that streamlined approval of generic drugs after the period of exclusivity expired.[34] But wealthy nations can afford to pay for the additional costs and generally have

---

[32] Singapore FTA, Article 16.8.1 and 16.8.2; Chile FTA, Article 17.10.1; Morocco FTA, Article 15.10.1; Bahrain FTA, Article 14.9.1; Andean FTA negotiating proposal, Article 9.1; FTAA, Chapter 20, Subsection B.2.j, Articles 1.2 and 1.3.

[33] Some of the countries have taken steps to shorten the wait by requiring branded drug manufacturers to seek approval for new drugs soon after U.S. approval. For example, after ratification of its trade agreement with the Bush Administration, the government of Chile passed a law requiring that branded drugs be registered within one year of U.S. approval in order to benefit from market exclusivity. Ley No. 19.996, VIII, Article 91(e) (March 11, 2005) (in Spanish online at http://sdi.bcn.cl/boletin/publicadores/normas_publicadas/archivos/19996.pdf). However, CAFTA explicitly requires developing nations that enact such laws to give the manufacturers of the brand-name drug up to five years to register their products and still allow them to claim five years of market exclusivity upon entry to each country. CAFTA, Article 15.10.1.b.

[34] P.L. 98-417; 35 U.S.C. §156.

widely accessed systems of government or private health insurance. Developing nations obviously lack these resources.

## B. Mandatory Patent Extensions

Under TRIPS, all WTO members make patents available for pharmaceutical inventions for 20 years from the time the patent is filed.[35] The existence of this patent bestows important benefits. While the patent remains in effect, it is generally illegal for a competing manufacturer to produce a generic version of the drug that violates the terms of the patent.[36]

CAFTA and the other trade agreements negotiated by the Bush Administration prolong the wait for generics by requiring the developing nations to grant patent extensions to compensate for delays in the approval processes. According to CAFTA, the developing countries must extend the patent term to compensate the patent owner for "unreasonable" delays in the marketing approval process.[37] Similar provisions appear in the trade agreements with Singapore, Chile, Morocco, and Bahrain, and the proposed Andean agreement.[38] The Bahrain and proposed Andean agreements also provide for other extensions. In these countries, if a drug is approved based on prior approval in another country, the agreements require that they also grant any patent extensions provided because of delays in the other country's approval process.[39]

Like the provisions providing market exclusivity for brand-name drugs, the patent extension provisions can work to delay access to low-cost generic drugs in developing nations beyond the date they are available in the United States. If the approval process takes longer in a developing country than it does in the United States, the term of the patent will actually be longer in the developing country than in the United States. Moreover, U.S. law contains complex provisions to limit the length of any patent extension.[40] These limitations are left out of the

---

35 TRIPS, Article 27.1 and Article 33.

36 *See*, e.g., TRIPS, Article 28.

37 CAFTA, Article 15.9.6(b).

38 Singapore FTA, Article 16.8.4(a); Chile FTA, Article 17.10.2(a); Morocco FTA, Article 15.10.3; Bahrain FTA, Article 14.8.6(b)(i); Andean FTA negotiating proposal (Article 8.8(b)(i).

39 Bahrain FTA, Article 15.6.(b)(ii); Andean FTA negotiation proposal, Article 8.8(b)(ii).

40 In the United States, patent extensions in cases of approval delay are limited in the following ways: (1) only one five-year extension is permitted; (2) the extension applies to only one patent per product; and (3) the total life of a patent from the time of marketing approval cannot exceed 14 years. 35 U.S.C. § 156.

trade agreement, and there is no guarantee that developing nations will be able to adopt or implement a similar system.

## C. Linking Drug Approval to Patent Status

In both developed and developing nations, the primary responsibility of drug regulatory agencies is to ensure the safety and quality of medicines sold. Patent adjudication is left to specialized patent offices or the court system.

The trade agreements negotiated by the Bush Administration disrupt these relationships and force the drug regulators in the developing countries to become patent enforcers even though they have no expertise in this area. For example, CAFTA specifies that regulatory agencies must implement measures to prevent the marketing of a generic version of a patented drug during the term of the patent.[41] Similar provisions appear in the trade agreements with Singapore, Chile, Morocco, Bahrain, and the proposed Andean agreement.[42]

U.S. law does require the Food and Drug Administration, which has many more resources at its disposal than its counterparts in developing countries, to consider patent status when reviewing generic applications.[43] But even the FDA does not have adequate expertise or resources to review the applicability of patents, and it has been unable to prevent abuses of the system by patentholders that have led to delays in the availability of generic drugs.[44] To address the misuse of patents to delay generic competition, both the Congress and the FDA have imposed reforms on the U.S. system. For example, U.S. law explicitly allows generic manufacturers to go to market under certain circumstances while a patent challenge is pending in court.[45] No analogous measures, however, are included in the recent trade agreements.

---

41 CAFTA, Article 15.10.2(a).

42 Singapore FTA, Article 16.8.4(c); Chile FTA, Article 17.10.2(c); Morocco FTA, Article 15.10.4(a); Andean FTA negotiating proposal, Article 9.4(a).

43 21 U.S.C. §355.

44 59 Fed. Reg. § 50338, 50343 (Oct. 3, 1994) ("FDA does not have the expertise to review patent information. The agency believes that its resources would be better utilized in reviewing applications rather than reviewing patent claims."); 54 Fed. Reg. § 28872, 28910 (1989) ("In deciding whether a claim of patent infringement could reasonably be asserted . . . the agency will defer to the information submitted by the []applicant." The Federal Trade Commission issued a report in 2002 revealing that brand name companies had filed multiple patents with FDA that were later found by patent courts to be inapplicable. Federal Trade Commission, *Generic Drug Entry Prior to Patent Expiration: An FTC Study* (2002).

45 21 U.S.C. § 355(j)(5)(b)(iii) (2005).

## D. Restrictions on Compulsory Licensing

"Compulsory licensing" is the governmental granting of a license to a manufacturer other than the patentholder to produce and sell a patented drug. This measure can be an important mechanism for countries to ensure the production of a critical medication when it is not available at an affordable price. Typically in such a circumstance, the country first attempts to obtain from the patentholder a voluntary license for generic production on "reasonable commercial terms."[46] If the patentholder does not agree to issue a voluntary license, the country may grant a compulsory license to a generic manufacturer.

The Doha Declaration permits broad use of compulsory licensing, stating that each country "has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted."[47] A subsequent WTO decision allows countries with insufficient local manufacturing capacity to issue such licenses to foreign producers.[48]

Rather than preserve the rights endorsed in the Doha Declaration, several of the trade agreements negotiated by the Bush Administration expressly restrict the use of compulsory licenses. The Singapore agreement, for example, sets three narrow conditions under which compulsory licenses will be permissible. Under this agreement, a compulsory license will only be allowed: (1) if a court determines that the patentholder engaged in "anti-competitive" behavior; (2) when a government agency or contractor needs to use the patent; or (3) in a "national emergency or other circumstances of extreme urgency."[49] Additionally, the Singapore agreement provides that a patent owner subject to a compulsory license under condition (2) or (3) cannot be required to transfer "technical know how" to the licensed generic manufacturer.[50] The Bush Administration is negotiating similar restrictions in its negotiations with the Andean nations and in the FTAA.[51]

---

46 Prior negotiations are not required when the license is issued in the event of a national emergency or public non-commercial use. TRIPS, Article 31(b).

47 Doha Declaration, Paragraph 5(b).

48 *Id. Paragraph 6;* WTO, *Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health* (Sept. 1, 2003) WT/L/540.

49 Singapore FTA, Article 16.7.6.

50 Singapore FTA, Article 16.7(b)(iii).

51 Andean FTA negotiating proposal, Article 8.7; FTAA, Chapter 20, Subsection B.2.e, Article 5, Article 6.1.

The other trade agreements negotiated by the Bush Administration do not specifically limit compulsory licensing. But they also do not protect this right from potential conflicts with other intellectual property obligations such as market exclusivity.[52] A "side letter" provided in CAFTA and the Morocco and Bahrain agreements provides that the obligations of the intellectual property chapter of the agreement do not affect the parties' ability "to take necessary measures to protect public health."[53] This language, however, is more limited than the Doha Declaration, which does not use the restrictive qualifier "necessary."[54] Furthermore, the letters have only interpretive value. In the event that a brand-name drug company challenges a decision to approve a generic drug produced under a compulsory license, the Bush Administration has acknowledged that the conflict will only be "informed" by the letter and will have to be "resolved on the merits of a particular case."[55]

## E. Prohibitions on Parallel Importation of Low-Cost Drugs

Another measure nations can use to reduce drug costs is to authorize "parallel importation," the importation of a patented product from another nation. By enabling the purchase of patented medicines at the lowest market price available, parallel importation can introduce competition and reduce prices. The right to parallel importation is expressly recognized in the Doha Declaration.[56]

However, both the Singapore and Morocco agreements effectively block parallel importation. Under the terms of these agreements, patentholders must be allowed to control all importation of their products from outside the country through their contracts with foreign distributors.[57] A similar provision has been proposed by

---

52 See *infra* section III(A).

53 *U.S.-Morocco FTA: "Side Letter on Public Health"*, signed June 15 2004; U.S.-Central America-Dominican Republic FTA: *Understanding Regarding Certain Public Health Measures*, signed August 5, 2004; *U.S.-Bahrain FTA: "Side Letter on Public Health,"* signed September 14, 2004.

54 Doha Declaration, Paragraph 5.

55 Letter from USTR General Counsel John K. Veroneau to Representative Sander M. Levin concerning the U.S.-Morocco Free Trade Agreement (July 19, 2004). (Response to question 11).

56 The right to parallel importation is affirmed in Paragraph 5(d) of the Doha Declaration. It is also recognized in Article 6 of TRIPS. The right is based on the principle of international exhaustion, which deems that patentholder control of the sale of a patented product expires once the product has been sold by the patentholder in any part of the world.

57 Singapore FTA, Article 16.7.2; Morocco FTA, Article 15.9.4.

the Bush Administration in the Andean agreement.[58] And the FTAA contains language that would direct countries without parallel import restrictions to enact laws permitting patentholders to control all importation from outside the region.[59]

In response to criticism of the ban on parallel importation in the U.S.-Morocco agreement, the Bush Administration asserted that the restriction merely codified existing policy in the two countries.[60] But this argument does not justify the Andean and FTAA provisions, where multiple nations allow parallel importation.[61] Moreover, making this policy permanent in a trade agreement prevents countries that do currently restrict parallel importation from reconsidering their national policies. Even in the United States, there is broad support for a form of parallel importation: both the House and the Senate have passed measures that would allow the importation of lower-priced patented drugs from Canada.[62] The trade agreement language would make it difficult for the United States or other nations with current restrictions on importation to revisit their national policies.

## F. Expansion of Patent Protection

The TRIPS agreement explicitly permits countries to exclude diagnostic, therapeutic, and surgical methods from being patentable.[63] This exception helps ensure that new medical procedures involving diagnosis and treatment remain widely available. The United States itself has taken advantage of this exception to legislate that patents for medical methods cannot be enforced against physicians who use them in practice.[64]

---

58 Andean FTA negotiating proposal, Article 8.4.

59 FTAA Chapter 20, Subsection B.2.e, Article 7.1.

60 USTR letter to Rep. Sander M. Levin (July 19, 2004) (Response to question 1).

61 In 2000, for example, the Andean Community adopted a decision allowing parallel imports by the standard of international patent exhaustion. Decisión 486: Régimen Común sobre Propiedad Industrial', Comisión de la Comunidad Andina, Lima, 14 de setiembre 2000 (Artículo 54). (online in Spanish at http://www.comunidadandina.org/normativa/dec/D486.htm).

62 During the 108th Congress, H.R. 2427, the Pharmaceutical Market Access Act of 2003, passed the House of Representatives by a vote of 243 to 186 on July 25, 2003. During the 107th Congress, S.Amdt. 4299, an amendment to the Greater Access to Affordable Pharmaceuticals Act of 2002 passed the Senate by a vote of 69 to 30 on July 17, 2002.

63 TRIPS, Article 27.3.

64 35 U.S.C. § 287(c).

Under the Bush Administration's proposal for the Andean agreement, however, Andean nations would be required to issue patents for diagnostic, therapeutic, or surgical methods.[65] As a result, the trade agreement could impede Andean doctors in their training and practice, raise the cost of medical care, and reduce access to innovative medical procedures.

## IV. CONCLUSION

In 2001, the United States joined the international community in adopting the Doha Declaration, which recognized that trade agreements should not impede the efforts of developing nations to obtain essential drugs at affordable prices. Since then, the Bush Administration has negotiated multiple trade agreements with developing nations, including the CAFTA agreement now pending before Congress. Contrary to the principles of the Doha Declaration, the Administration has used these trade agreements to restrict the access of developing nations to low-cost generic drugs. By delaying generic drug approvals, extending patent terms, limiting compulsory licensing, prohibiting parallel importation, and otherwise restricting countries' efforts to improve access to affordable drugs, the trade agreements undermine the safeguards outlined in the Doha Declaration. These agreements may offer advantages to multinational pharmaceutical companies, but they do so at a serious cost to public health in the developing nations.

---

[65] Andean FTA negotiating proposal, Article 8.2(b).