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INTELLECTUAL PROPERTY

U.S. Trade Policy Guidance on WTO Declaration on Access to Medicines May Need Clarification



GAO-07-1198

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Highlights

Highlights of GAO-07-1198, a report to congressional requestors

INTELLECTUAL PROPERTY

U.S. Trade Policy Guidance on WTO Declaration on Access to Medicines May Need Clarification

Why GAO Did This Study

The WTO Agreement on Trade-Related Intellectual Property (TRIPS) requires all 151 World Trade Organization (WTO) members to provide baseline protections, including 20-year patents for innovative pharmaceuticals. The Trade Act of 2002 granting Trade Promotion Authority (TPA) to the President outlined three negotiating objectives related to intellectual property (IP). The first two aim to strengthen IP rights and enforcement abroad. The third calls for respect of the WTO Doha Declaration on TRIPS and Public Health, which addresses access by developing countries to patented medicines, particularly in epidemic and emergency situations.

This report (1) describes the Declaration and its interpretation by the United States and other nations; (2) analyzes how USTR has balanced respect for the Doha Declaration with the other two IP objectives in negotiating free trade agreements; and (3) evaluates the extent of public health input by agencies and the private sector. We reviewed official WTO and U.S. government documents, interviewed U.S. and foreign government officials, and obtained private sector views.

What GAO Recommends

If Congress disagrees with USTR's interpretation and implementation of TPA guidance with regard to IP and public health, it should specify more clearly its intentions for U.S. trade policy and public health policy input.

To view the full product, including the scope and methodology, click on GAO-07-1198. For more information, contact Kireb Tager at (202) 512-4128 or YagerL@gao.gov.

What GAO Found

The 2001 Doha Declaration on TRIPS and Public Health was adopted by WTO members to stress the importance of implementing the TRIPS Agreement in a manner supportive of public health. The U.S. interprets the Declaration as a political statement that recognizes the severity of public health crises while affirming the importance of IP protection. It maintains that the Declaration neither changes existing TRIPS obligations, nor creates new rights and does not assigns public health greater priority than IP protection. USTR says the Declaration clarifies flexibilities already in TRIPS, including the flexibility to compulsorily license patents under certain circumstances. USTR recognizes these as being allowed for WTO members, including those facing public health crises, but only in a fashion that will not unduly harm patent holders. Some developing countries assert they provide broad discretion to ensure access to medicines when IP regulations present barriers to affordable care.

USTR balances respect for the Doha Declaration with TPA's other two IP negotiating objectives by actively promoting high levels of IP protection for pharmaceuticals while making targeted allowances for developing country partners. USTR believes that this longstanding U.S. pursuit of high IP protections for pharmaceuticals creates incentives for investment in research and development of new treatments, ultimately enhancing public health. With regard to the TPA objective of respecting the Doha Declaration, USTR's key policy change was to not insist upon two provisions it sees as relevant to the Declaration in FTAs with developing country trading partners. Otherwise, USTR has continued to pursue other pharmaceutical related IP protections that it does not consider related to the Doha Declaration. Reactions to USTR's record are mixed. The pharmaceutical industry considers these types of FTA provisions critical for preserving incentives for research and innovation. However, some academics, experts, nongovernmental organizations (NGOs), and generic producers have expressed concerns that these provisions may delay entry by cheaper generic products. In response to similar concerns in Congress, a bipartisan agreement was reached with the Administration to revise four recent FTA's prior to their submission for Congressional approval.

U.S. interagency and private sector input into trade negotiations related to public health have remained limited since Congress enacted TPA. The Department of Health and Human Services (HHS) and other agencies generally endorse USTR's view that strong IP protection promotes public health and access to medicines, and interagency input has been primarily technical in nature. Within the formal private sector trade advisory system, a public health representative was recently added to 2 of the 16 private sector advisory committees, but not until USTR had concluded nine trade agreements. USTR did obtain some public health views through other formal and informal means during this period.

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Abbreviations

ADI	Access to Drugs Initiative
ARV	antiretroviral
CAFTA-DR	Central America-Dominican Republic United States Free Trade Agreement
CIEL	Center for International Environmental Law
CPPATH	Center for Policy Analysis on Trade and Health
DNDI	Drugs for Neglected Diseases Initiative
EU	European Union
FDA	Food and Drug Administration
FSI	Foreign Service Institute
FTA	free trade agreement
GAP	Health Global Access Project
GDP	Gross Domestic Product
GPhA	Generic Pharmaceutical Association
HHS	Department of Health and Human Services
ICTSD	International Center for Trade and Sustainable Development
IFPMA	International Federation of Pharmaceutical Manufacturers & Associations
IP	intellectual property
ITAC	Industry Trade Advisory Committee
MSF	Doctors without Borders
NAFTA	North American Free Trade Agreement
NGO	nongovernmental organization
NIH	National Institutes of Health
OECD	Organization for Economic Cooperation and Development
OGAC	Office of the Global AIDS Coordinator
OGHA	Office of Global Health Affairs
OTT	Office of Technology Transfer
PPP	purchasing power parity
PEPFAR	President's Emergency Plan for AIDS Relief
PhRMA	Pharmaceutical Research and Manufacturers of America

PTO	U.S. Patent and Trademark Office
TEPAC	Trade and Environment Policy Advisory Committee
TPRG	Trade Policy Review Group
TPSC	Trade Policy Staff Committee
TRIPS	Trade-Related Aspects of Intellectual Property Rights
TPA	Trade Promotion Authority
UNAIDS	The Joint United Nations Program on HIV/AIDS
UNCTAD	United Nations Conference on Trade and Development
USAID	United States Agency for International Development
USTR	U.S. Trade Representative
WHO	World Health Organization
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

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United States Government Accountability Office
Washington, DC 20548

September 28, 2007

The Honorable Edward M. Kennedy
Chairman
Committee on Health, Education, Labor and Pensions
United States Senate

The Honorable Henry A. Waxman
Chairman
Committee on Oversight and Government Reform
House of Representatives

An international effort led by the United States in the 1980s to incorporate intellectual property (IP) protection into the trading system culminated with the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) in 1995. Under TRIPS, all WTO member countries are obligated to establish a minimum standard of laws and regulations protecting copyrights, trademarks, patents and other forms of IP rights. Patents are particularly important to the U.S. pharmaceutical industry and provide patent owners the legal means to prevent others from making, using, or selling new inventions for a limited period of time, subject to certain conditions and exceptions. As the 2000 deadline for developing countries to implement TRIPS obligations approached, however, some developing countries expressed concern about subjecting health-related inventions such as new drugs to IP rules, especially given the increasingly serious AIDS epidemic. These concerns were part of a larger and still ongoing debate over how to balance long-term incentives for drug innovation with the short-term affordability of existing medicines, particularly when dealing with emergency public health situations.

The 2001 WTO Doha Declaration on TRIPS and Public Health is recognized as a watershed event in this debate. The declaration states, in part, that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health and, while reiterating a commitment to the TRIPS agreement, that the TRIPS Agreement should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and promote access to medicines for all. Subsequently, in the United States, the Trade Act of 2002 granting Trade Promotion Authority (TPA) to the President outlined three principal trade negotiating objectives related to IP, one of which referred to the Doha

Declaration.[1] The objectives were (1) to promote adequate and effective protection of IP rights similar to U.S. law, (2) to secure fair and equitable market access opportunities as related to IP rights, and (3) to respect the Doha Declaration. Since then, negotiations at the WTO continued through late 2005 in an effort to resolve outstanding issues related to the Doha Declaration, and the United States has negotiated 11 free trade agreements (FTA); several are now being implemented. Some in Congress are concerned about how the U.S. Trade Representative (USTR) has interpreted, pursued, and implemented TPA principal IP objectives pertaining to the pharmaceutical industry, particularly in light of the third objective calling for respect for the Doha Declaration.

In response to your request, this report (1) describes the Doha Declaration on TRIPS and Public Health and evaluates how the United States and other key nations have interpreted its intent and meaning, (2) analyzes how the United States has balanced respect for the Doha Declaration with the other two IP negotiating objectives in negotiating FTAs, (3) assesses the U.S. approach to overseeing the implementation of pharmaceutical-related IP provisions in FTAs and other agreements, and (4) evaluates the nature and extent of public health related agency and private sector input into trade negotiations. You also expressed interest in technical assistance on IP rights and public health that U.S. agencies provide to foreign countries. Appendix II provides an overview of U.S. technical assistance and technology transfer activities.

To meet these reporting objectives, we performed reviews of agency documentation and correspondence, WTO documents and meeting minutes, academic studies, pharmaceutical industry and public health advocacy group reports and position papers, and media reports. We examined the text of the FTAs negotiated since the Trade Act of 2002 and compared the language of the IP pharmaceutical provisions found in each FTA. In addition, we examined trends and patterns found in USTR's annual reports identifying foreign countries that deny adequate and effective protection of IP rights. We traveled to Geneva, Switzerland, to meet with officials from the U.S. Mission in Geneva, WTO, World Health Organization (WHO), World Intellectual Property Organization (WIPO), The Joint United Nations Program on HIV/AIDS, the Global Fund to Fight AIDS, Tuberculosis and Malaria, as well as nongovernmental organizations

[1]Trade Act of 2002, Pub. L. No. 107-210, § 2102, 116 Stat. 933, 995-996 (codified at 19 U.S.C. § 3802).

(NGO) from the pharmaceutical sector and public health community. To evaluate the nature and extent of interagency input to USTR from other executive branch agencies such as the Department of State, Department of Health and Human Services (HHS), and Department of Commerce, including the Patent and Trademark Office (PTO), we reviewed documentation and interviewed officials. Regarding private sector input, we interviewed agency officials and reviewed documents such as formal advisory committee reports, responses to *Federal Register* notices, and correspondence related to the trade advisory system. Currently, there is ongoing litigation regarding the balance of representation on certain trade advisory committees. In accordance with GAO policy, we did not take any position on matters under litigation, which in this case meant on the appropriateness of the current composition of the trade advisory committees. Regarding technical assistance, we interviewed agency officials and reviewed agency documents. We also interviewed stakeholders to gather perspectives on the range of issues involved, including pharmaceutical industry representatives, public health groups, academics, and selected IP experts; each had recently published or spoken on this issue. Access to medicines is recognized as a complex issue driven by many factors, including funding levels, infrastructure, and effective institutions, which are addressed by various U.S. government programs and international efforts. As agreed with your staff, we did not seek to independently assess the actual or potential effect of these larger U.S. trade efforts on public health and access to medicines.

See appendix I for a detailed discussion of our scope and methodology. See appendix II for information about technical assistance on IP rights and public health. We conducted our review from November 2006 through September 2007 in accordance with generally accepted government auditing standards.

Results in Brief

The Doha Declaration on TRIPS and Public Health was adopted by WTO members as a carefully crafted compromise among competing perspectives that stresses the importance of implementing the TRIPS agreement in a manner supportive of public health. Balancing the goals of promoting both access to existing medicines and development of new medicines, it was a separate declaration adopted at their Fourth Ministerial Conference on November 14, 2001, in Doha, Qatar. The United States interprets the declaration as a political statement that recognizes the severity of public health crises while affirming the importance of IP protection. It maintains that the declaration neither changes existing TRIPS obligations nor creates new obligations, and does not assign public

health greater priority than IP protection. Instead, USTR says, the declaration simply clarifies certain flexibilities already in TRIPS for WTO members facing public health crises, including overriding patents through the issuance of compulsory licenses under certain circumstances. Supported to some extent by other developed countries such as the European Union (EU) members, Japan, and Switzerland, USTR recognizes these flexibilities as being allowed for WTO members, including those facing public health crises, but only in a fashion that will not unduly harm patent holders. Some developing countries believe they provide broad discretion to ensure access to medicines when IP regulations present barriers to addressing not only health issues, but also social welfare. Differences between the United States and key developing WTO countries such as Thailand, Brazil, and India over a narrower versus a broader interpretation continued well after the 2001 declaration. Notably, in debate over how to help countries with little or no manufacturing capacity in the pharmaceuticals sector take full advantage of the flexibilities, controversy emerged over which members should be eligible and for what diseases.

USTR maintains that it balances respect for the Doha Declaration with TPA's other two IP negotiating objectives by actively promoting high levels of IP protection related to pharmaceuticals while making targeted allowances for Doha Declaration flexibilities for developing country partners. USTR believes that this continuation of long-standing U.S. pursuit of high IP protections for pharmaceuticals creates incentives for investment in research and development of new treatments, which in turn enhances public health. With regard to the TPA objective to respect the Doha Declaration, USTR officials told us that the key policy implication was to not insist upon two pharmaceutical-related IP provisions it sees as relevant to the Declaration with developing country trading partners. Otherwise, USTR has continued to pursue a number of other pharmaceutical-related IP protections that USTR does not consider related to the Doha Declaration. Reactions to USTR's approach to its trade negotiations have been mixed. The pharmaceutical industry considers these types of FTA provisions to be crucial in preserving incentives for future research and innovation. However, some academics, public health experts, NGOs, and generic pharmaceutical producers have said such provisions could delay entry of cheaper generic products onto the market, thereby decreasing access to affordable medication and violating the spirit and principles of the Doha Declaration. Several Members of Congress have also expressed similar concern over the pharmaceutical-related IP provisions in FTAs with developing countries, and this concern was recently addressed through a bipartisan compromise, between Congress

and the administration, to revise, prior to their submission to Congress, the last four FTAs concluded under TPA.

USTR's approach to overseeing the implementation of pharmaceutical-related IP provisions is consistent with its overall negotiating approach in FTAs, which is to secure high levels of IP protection. Following FTA negotiations, USTR rigorously oversees trading partner implementation of pharmaceutical-related IP provisions, in order to advise the President whether he can determine that the FTA partner has taken the measures necessary to comply with the provisions of the FTA that are to take effect on the date the FTA enters into force. In addition, in its annual report detailing global IP challenges, USTR has focused largely on the same pharmaceutical IP provisions concentrated on during FTA negotiations, in keeping with its strategy of gaining high levels of IP protection for pharmaceutical products, similar to U.S. law. However, USTR has had a measured response to Thailand and Brazil's recent usage of a TRIPS flexibility, compulsory licensing. For example, when Thailand recently issued a compulsory license, USTR acknowledged its right to do so, restricting its criticism to commenting on a lack of transparency.

Input related to public health into U.S. trade negotiations has remained limited since Congress enacted TPA. In negotiating trade agreements under TPA, the President must seek advice and information from executive departments and public and private sectors.[2] HHS and other agencies involved in the interagency trade policy process generally endorse USTR's view that strong IP protection promotes public health and access to medicines, but interagency input has been primarily technical in nature. For instance, HHS, the lead U.S. health agency, ensures that IP provisions related to pharmaceuticals in FTAs do not violate U.S. law, but has not addressed policy-related questions, such as whether FTA provisions might affect public health in trading partner countries. Within the formal private sector trade advisory system that plays a role under TPA in reviewing trade agreements, a public health representative was recently added to 2 of the 16 private sector industry trade advisory committees, after USTR had concluded nine trade agreements. The two advisory committees that the public health representatives were appointed to are respectively composed of 20 and 33 private sector representatives from the pharmaceutical and other industries. Although USTR has received limited input on public health through the formal advisory

[2]19 U.S.C. §§ 2152, 2155.

system, the agency has obtained some public health views through other formal and informal means throughout the period, such as public hearings, *Federal Register* comments, and written correspondence.

In this report, we suggest that Congress should consider this record as it contemplates renewal of Trade Promotion Authority (TPA) and, if it has concerns over USTR's approach to date, may wish to specify more clearly its intentions for U.S. trade policy and input related to balancing public health concerns and the negotiation of IP protections in trade agreements.

Background

By way of providing context for our examination of U.S. trade policy as it relates to TPA guidance and the Doha Declaration on TRIPS and Public Health, the following is an overview of ongoing U.S. government efforts to address the wider issue of access to medicine and public health both related and unrelated to IP, as well as how the WTO first became involved in public health issues, and the origin of IP and public health in TPA.

U.S. Government Has Addressed IP and Access to Medicine

The U.S. government has supported innovation, competition, and access to medicine. The Federal government, primarily through the National Institutes of Health (NIH), conducts and supports medical research, investing annually over $28 billion. About 55 percent of NIH's budget supports basic research. While basic research may not have an immediate impact on drug innovation, such "untargeted" research often ultimately leads to developing new medicines and technologies.

In principle, U.S. intellectual protection laws are designed to support innovation. Patents are considered to be especially valuable for innovations in pharmaceuticals.[3] According to the pharmaceutical industry, IP protection is crucial to its ability to offer new, innovative medicines. Research and development of new drugs is very risky and time-consuming. The industry faces high fixed or "sunk" costs associated with lengthy discovery and clinical trials. Moreover, a large proportion of new

[3]Nevertheless, critics have questioned IP rights' contributions to innovation. A November 2006 GAO study found that new drug applications submitted by pharmaceutical companies to the FDA had increased at a much slower pace than R&D expenditures, and that many of these were for new uses of existing compounds, rather than for completely new drugs. IP rights were among the factors some experts cited as slowing drug development. See GAO, *New Drug Development: Science, Business, Regulatory, and Intellectual Property Issues Cited as Hampering Drug Development Efforts*, GAO-07-49 (Washington, D.C.: Nov. 17, 2006).

drugs never make it to market due to their lack of efficacy or inadequate safety. Thus, drug companies seek a relatively high return on the medicines they do bring to market. U.S. patents give companies a 20-year period during which they have an exclusive right to make, sell, and use their invention.[4] They use this period when they cannot be undercut by competitors to charge relatively higher prices, thus allowing them to recoup their investments and earn profits. However, the effective life of a patent is typically much shorter than this 20-year period, since the preclinical and clinical testing phases necessary for securing FDA marketing approvals can take more than a decade.

Public policy has also played a role in fostering generic competition to hold down prices. Generic drugs--copies of brand-name drugs--can enter the market after the brand-name's patent or other market exclusivities expire and FDA approval is granted. Under the Hatch-Waxman Act of 1984,[5] generic manufacturers do not have to repeat expensive research and clinical trials to obtain approval.[6] Instead, they only need to show the FDA that their drugs are bioequivalent to the branded medicines.[7] Because they do not incur the same research and clinical trial expenditures, generic firms can enter the market more quickly once patents have expired and sell drugs at lower prices. Generic entry may also put pressure on innovator companies to develop more new drugs.

Governments have also taken collective and individual steps to provide medicines—particularly since 2001. At the global level, funds for combating HIV/AIDS through the Global Fund to Combat AIDS, Tuberculosis and Malaria, established in 2003, and UNAIDS, established in 1994, have grown considerably since 2001. Among other things, the United States established the President's Emergency Plan for AIDS Relief, or PEPFAR, a 5-year, $15 billion initiative run by the Office of the Global AIDS Coordinator at State, which has supported HIV prevention activities, antiretroviral treatment and training, and HIV-related care and training at more than 15,000 project sites primarily in 15 focus countries, mainly in

[4]35 U.S.C. § 154.

[5]Pub. L. No. 98-417, 98 Stat. 1585.

[6]21 U.S.C. § 355.

[7]For the purposes of this report, bioequivalent means the generic drug has the same rate and extent of absorption and delivers the same amount of active ingredients into a patient's bloodstream in the same amount of time as the name-brand patented drug.

sub-Saharan Africa.[8] More affluent developing countries, such as Brazil and Thailand, have themselves been taking more aggressive steps to combat AIDS and improve access, including universal access schemes paid for with public funds.

Some of these government efforts have been undertaken with private sector support. The research-based pharmaceutical industry has engaged in private-public partnerships to address neglected diseases found in poor countries, such as tuberculosis and malaria. Research-based pharmaceutical companies have also instituted pricing schemes whereby the same drug is sold at different prices, depending on the consumer's or country's ability to pay. Ensuring that the supply remains in the intended market, not resold elsewhere, is critical to this strategy's success, but can be problematic. Governments have also supported industry efforts to donate medicines outright—about $4.4 billion worth of medicines and other medical help over the 2000-2005 period, according to estimates by the London School of Economics.[9]

Access to Medicines Remains a Global Challenge

Despite government and industry initiatives, available data suggest that many people currently lack access to existing medicines. According to the World Health Organization (WHO), one third of the global population does not have regular access to essential medicines. This matters: WHO estimates that over 10.5 million lives a year could be saved by 2015 by scaling up access to existing interventions for infectious diseases, maternal and child health, and noncommunicable diseases. Indeed, WHO says unaffordable prices of medicine and the need for new medicines for diseases that disproportionately affect lower income populations are among the primary challenges in expanding access to medicines globally. According to WHO, in developing countries today, medicines account for up to 70 percent of health care expenditure. This compares to less than 15 percent in most high income countries, and about 10 cents of every health care dollar spent in the United States in 2005. Because of this imbalance in health care expenditure worldwide, WHO's various projects on access to

[8]United States Leadership Against HIV/AIDS, Tuberculosis, and Malaria Act of 2003, Pub. L. No. 108-25, 117 Stat. 711.

[9]This compares with Giving USA's estimates that donations by U.S. corporations and corporate foundations totaled $12.72 billion in 2006. For further information, see "U.S. charitable giving reaches $295.02 billion in 2006: third straight year of growth," June 27, 2007, press release, Giving USA Foundation. www.aafrc.org.

medicines and IP rights continue.[10] The Group of 8 Industrialized Nations, the Organization for Economic Cooperation and Development (OECD), and the United Nations Conference on Trade and Development (UNCTAD) are among the other organizations that have also undertaken efforts to address aspects of the issue.

IP and Pharmaceuticals Became Part of WTO at Its Inception in 1995

The April 1994 Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations led to the establishment of WTO on January 1, 1995. The Uruguay round was the product of long and complex negotiations that not only liberalized manufactured goods trade in such sectors as apparel, but also added IP and services rules and obligations to the trading system. The WTO TRIPS Agreement was part of the Uruguay Round's results and established minimum levels of protection that each government has to give to IP of fellow WTO members. The United States had fought hard to secure worldwide adoption of minimum IP protection and enforcement standards through TRIPS as home to the world's largest and most innovative pharmaceutical industry. TRIPS extended patent protection for inventions of both products and processes, while allowing certain exceptions, for at least 20 years. It also required WTO members, when requiring as a condition of marketing approval the submission of undisclosed test data or other data (such as data submitted to health authorities for regulatory approval of pharmaceutical safety), the origination of which involves considerable effort, to protect such data, against unfair commercial use.[11] When all of the WTO agreements took effect, developed countries were given 1 year to ensure their laws and practices conformed with TRIPS, but developing countries were given

[10]According to the WHO, its work on trade, IP rights, and access to medicines can be summed up under two headings: (1) monitoring and analyzing the pharmaceutical and health implications of international trade agreements, and (2) assisting member states in assessing and developing pharmaceutical and health policies and regulatory measures that maximize the positive and mitigate the negative impact of those agreements. In May 2006, WHO established an Intergovernmental Working Group on Public Health, Innovation and Intellectual Property with a mandate to prepare a global strategy and plan of action on essential health research to address conditions affecting developing countries disproportionately. A May 2007 resolution, adopted without U.S. support, requests WHO "to provide as appropriate, upon request, in collaboration with other competent international organizations, technical and policy support to countries that intend to make use of the flexibilities contained in the agreement on Trade-Related Aspects of Intellectual Property Rights and other international agreements in order to promote access to pharmaceutical products, and to implement the Doha Ministerial Declaration on the TRIPS Agreement and Public Health and other WTO instruments."

[11]TRIPS Agreement, Art. 39.3.

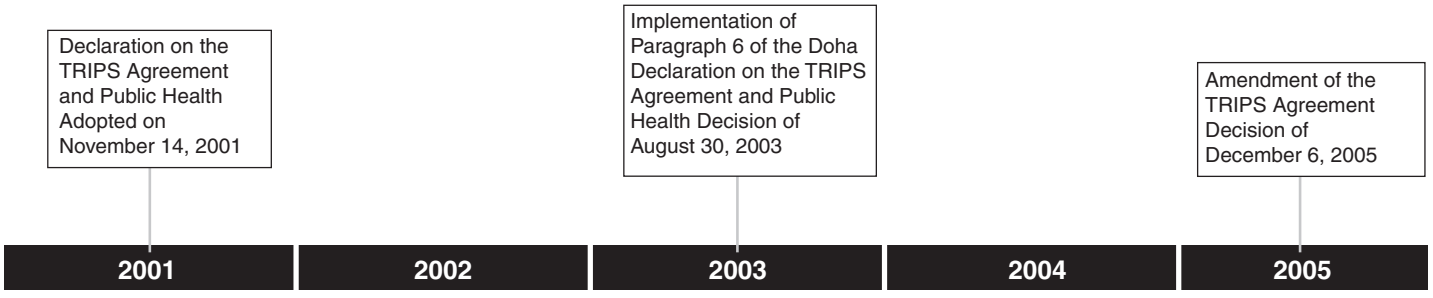
transition periods of 5 or more years. Even so, many developing countries complained about having to comply with the new requirements.

The HIV/AIDS Pandemic Put Access to Medicine in the Forefront for WTO

The issue of IP and access to medicine came to a head at WTO in 2001 when the HIV/AIDS pandemic in sub-Saharan Africa was reaching catastrophic levels. Separately, South Africa attempted to use its laws to lower prices for imported medicines, but faced opposition from U.S. and other drug companies that felt its actions compromised their rights. Brazil and the United States, meanwhile, were in dispute over a Brazilian law that could make exceptions to patents if products were not manufactured in Brazil. Nongovernmental organizations (NGO) became involved in discussing the implications of TRIPS to public health.

In April of 2001, WTO and the World Health Organization (WHO) jointly sponsored a workshop on pricing and access to medicine. Initially, many WTO members were skeptical about whether WTO was the proper forum for the debate. However, this quickly changed when the African members successfully pleaded their case for help in resolving the AIDS pandemic, and WTO members subsequently devoted one day to the issue in June 2001, then continued discussions throughout the summer of the same year. Subsequently, the Declaration on the TRIPS Agreement and Public Health was adopted at the fourth WTO Ministerial Conference in Doha, Qatar, on November 14, 2001. As shown in figure 1, the Declaration on TRIPS and Public Health was the first of three important decisions over the next several years, all of which are discussed in detail later in this report.

Figure 1: Timeline of Major WTO Events on IP and Public Health



Source: World Trade Organization.

Congress Addressed IP and Public Health in Trade Promotion Authority Legislation

Shortly after WTO adopted the Declaration on TRIPS and Public Health, Congress passed the Trade Act of 2002, which granted the President Trade Promotion Authority (TPA) for reciprocal trade agreements to liberalize U.S. trade with foreign nations. TPA contains guidance from Congress concerning U.S. goals in negotiated trade agreements. One of the three goals for IP specified in TPA, "to respect the Doha Declaration on TRIPS and Public Health," was added in response to an amendment by Senator Edward Kennedy. In his remarks about the amendment, Senator Kennedy explained that the Declaration on TRIPS and Public Health struck a balance between the legitimate interests of intellectual property protection and the preservation of public health. Senator Kennedy went on to assert that "[t]his amendment directs our trade negotiators to support the declaration without reservation."[12] Senators Grassley and Baucus also asserted their support for the amendment and emphasized the importance of IP issues with respect to public health and innovation of new medicines. Congress otherwise provided no guidance at the time on how to interpret and apply this TPA objective. Recently, in response to the expiration of the President's Trade Promotion Authority (TPA) on June 30, 2007, before the Doha round of global trade talks had been successfully concluded, there have been some calls to renew it.

The United States Has a Narrower Interpretation of the Doha Declaration Than Some Other WTO Members

To help address public health problems affecting many developing countries, WTO members adopted the Doha Declaration (reprinted in full below) to stress the importance of implementing the TRIPS agreement in a manner supportive of public health.[13] As part of a carefully worded compromise among competing perspectives, this statement was placed in the context of shared challenges and goals, such as promoting both access to existing medicines and research into and development of new medicines. The United States interprets the declaration as a political statement recognizing public health crises and affirming the importance of IP protection that neither changes existing TRIPS obligations nor creates new obligations, and does not assign public health greater priority than IP protection. Significantly, the declaration clarifies certain flexibilities explicit in TRIPS that allow WTO members to address public health crises. USTR argues that these flexibilities should be applied judiciously and

[12]For the text of these remarks, see *Congressional Record*, Senate, S4322-4324, May 14, 2002.

[13]Based on paragraph 17, Ministerial Declaration, Fourth Ministerial Conference, Doha, Qatar, November 14, 2001.

subject to certain conditions specified in the TRIPS agreement. Some developing countries, however, believe these flexibilities provide broad discretion to ensure access to medicines when IP regulations present barriers to addressing not only health issues, but also social welfare. Differences over a narrower versus broader interpretations continued long after the declaration. Notably, debate over how to help countries with little or no pharmaceuticals manufacturing capacity take full advantage of the flexibilities, including which members should be eligible and for what diseases, became controversial.

Declaration on the TRIPS Agreement and Public Health

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.

4. We agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all.

In this connection, we reaffirm the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.

5. Accordingly and in the light of paragraph 4 above, while maintaining our commitments in the TRIPS Agreement, we recognize that these flexibilities include:

a. In applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles.

b. Each Member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted.

c. Each Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.

d. The 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, subject to the MFN and national treatment provisions of Articles 3 and 4.

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

7. We reaffirm the commitment of developed-country Members to provide incentives to their enterprises and institutions to promote and encourage technology transfer to least-developed country Members pursuant to Article 66.2. We also agree that the least-developed country Members will not be obliged, with respect to pharmaceutical products, to implement or apply Sections 5 and 7 of Part II of the TRIPS Agreement or to enforce rights provided for under these Sections until 1 January 2016, without prejudice to the right of least-developed country members to seek other extensions of the transition periods as provided for in Article 66.1 of the TRIPS Agreement. We instruct the Council for TRIPS to take the necessary action to give effect to this pursuant to Article 66.1 of the TRIPS Agreement.

The Doha Declaration Addresses Flexibilities in TRIPS That Can Be Used to Deal with Public Health Crises

In the wake of the HIV/AIDS crisis at the time, some WTO members were concerned about the extent to which the TRIPS agreement allowed them to address public health needs. The African members known as the African Group were among the members pushing for clarification. WTO members formally addressed this issue in the main Doha Ministerial Declaration and their intention to adopt a separate declaration, as shown below.

Ministerial Declaration - Fourth Session November 2001

Paragraph 17

We stress the importance we attach to implementation and interpretation of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) in a manner supportive of public health, by promoting both access to medicines and research and development into new medicines and, in this connection, are adopting a separate Declaration.

The Doha Declaration is divided into seven paragraphs. Paragraphs one through four are general principles that WTO members agreed to that describe the relationship between IP rights and public health.

Paragraph five lays out specific flexibilities provided in TRIPS that can be used by WTO members to address public health related problems. Below is a summary of these flexibilities:

5(a) that each provision in TRIPS should be read in light of the agreement's objectives and principles;

5(b) the right to grant compulsory licenses. The WTO fact sheet on TRIPS and pharmaceuticals describes the term compulsory licensing as when a government allows someone else to produce the patented product or process without the consent of the patent owner—in this case in reference to pharmaceuticals, but it could also apply to patents in any field.[14]

5 (c) the right to determine what is a national emergency; and

5 (d) the right to establish an exhaustion regime without challenge. The WTO fact sheet on TRIPS and pharmaceuticals describes the term exhaustion as a legal principle consisting of the idea that once a company (patent holder) has sold a batch of its product, its patent distribution rights are exhausted with respect to that batch, and it no longer has any rights to control distribution of that batch. Exhaustion is the legal principal behind parallel imports. [15]

WTO members appear to agree that the TRIPS and Public Health declaration makes no change to TRIPS itself. However, two changes are foreshadowed. Specifically, paragraphs six and seven calls upon WTO members to take future action in specific areas. Paragraph six mandates WTO members to resolve a potential problem with regard to compulsory licensing by WTO members with insufficient or no pharmaceutical manufacturing capacities. Because TRIPS specifies that a country may only compulsory license primarily for supplying the domestic market, countries with little or no manufacturing capacity (and therefore no domestic company to which the government could grant a compulsory license) could face difficulties in effectively using compulsory licensing. They must import their medicines, but the supplier (the exporter) would be prevented under TRIPS from exporting them the patented medicines under a compulsory license if the product was patented in its territory. Paragraph seven instructs WTO members to take the steps necessary to

[14]See http://www.wto.org/english/tratop_e/trips_e/factsheet_pharm00_e.htm

[15]See http://www.wto.org/english/tratop_e/trips_e/factsheet_pharm00_e.htm

extend the deadline from for least developed countries to implement their TRIPS obligations with respect to pharmaceutical products to 2016.[16]

The United States Has a Narrower Interpretation of the Declaration Than Some Other WTO Members

The United States believes that the declaration does not change existing TRIPS obligations or create new rights, nor does it give public health greater priority than IP protection. Overall, leading up to Doha and since, the United States has consistently opposed creating broader exemptions to TRIPS to protect public health, but instead has called for permitting targeted exceptions to TRIPS to avoid eroding patent protections that it deems necessary for research and development of medicines to treat life-threatening diseases. Some developing countries had wanted to modify TRIPS provisions if they were considered insufficient to protect public health.

According to a USTR official, paragraph four of the declaration–"The TRIPS agreement does not and should not prevent members from taking measures to protect public health."—does not provide a broad exception in TRIPS for public health purposes and in addition, the provision should be considered in context with the rest of the declaration. Some developing countries had originally called for the declaration to have stronger language–"Nothing in the TRIPS agreement should prevent Members from taking measures to protect public health."–in an attempt to make the declaration legally binding.

With regard to paragraph five, which enumerates flexibilities in TRIPS that may be used to address public health, the United States supports the view that these flexibilities preserve the ability of members to formulate public health policies while also maintaining effective patent systems. But some developing countries see paragraph five as providing broader discretion to address public health. For example, a group of developing countries, including the African Group, Brazil, India, and Thailand, has maintained that there should be a common understanding that confirms the right of governments to ensure access to medicines at affordable prices and to

[16]According to USTR, developed country members were required to implement the TRIPS Agreement fully as of January 1, 1996. Developing countries were given a transition period for many obligations until January 1, 2000. Recognizing the particular challenges faced by least-developed countries, in 2005, the United States worked closely with them and other WTO members to extend the implementation date for these countries from January 2006 to July 2013. The least developed country members in turn pledged to preserve the progress that some had made toward TRIPs compliance.

make use of TRIPS provisions whenever the scope or exercise of IP regulations results in barriers to access to medicine. These members believe that TRIPS objectives and principles (referred to in the last phrase in paragraph five (a) of the declaration) support the view that TRIPS protections are and should be contingent on IP rights contributing to social goals, such as nutrition and social and economic welfare. (TRIPS objectives and principles are found in articles 7 and 8 respectively, shown below).

TRIPS Article 7 – Objectives

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

TRIPS Article 8 – Principles

1. 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, provided that such measures are consistent with the provisions of this Agreement.

2. Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.

The United States has maintained that, rather than impeding access to medicines, patent regimes meet the objectives of article 7 by contributing to the promotion of technological innovation and dissemination of technology. Furthermore, the United States has argued that the final clause in article 8–"provided that such measures are consistent with the provisions of [the TRIPS]Agreement"–precluded article 8 from providing such a broad exception to the obligations of TRIPS. The European Union (EU), Switzerland, and Japan were concerned that the countries were suggesting the ability to make significant exceptions to patent protection under TRIPS.

The interpretation of paragraph five (b) on compulsory licensing has sparked the most controversy among WTO members. The WTO fact sheet

on TRIPS and pharmaceuticals describes the declaration as affirming compulsory licensing [as a TRIPS flexibility] as part of its overall attempt to strike a balance between promoting access to existing drugs and promoting research and development into new drugs.[17] Significantly, the declaration clarifies that WTO members can determine the grounds for issuing a compulsory license. This is because TRIPS does not specifically list the reasons that might be used to justify compulsory licensing, but rather enumerates a number of conditions for doing so.[18]

During the debate over the declaration, the United States stressed that, while it considered compulsory licensing to sometimes be appropriate, it believed its widespread use for any purpose could have negative implications for the patent system and, more importantly, for the availability and development of new drugs. Moreover, the United States argued using compulsory licensing as a mechanism for directing industrial policy or protecting domestic industries against foreign competition would be contrary to the letter and purpose of TRIPS.

In addition, USTR emphasizes that while the declaration is clear that members can determine the grounds for compulsory licensing, they still must meet certain conditions articulated in TRIPS article 31. These are aimed at protecting the legitimate interests of the patent holder when circumstances allow compulsory licensing and government use of a patent without the authorization of the patent holder. Summarized below are some relevant excerpts from selected article 31—"Other use without authorization of the patent holder"—provisions, including important exceptions in recognition of the fact that time can be of the essence in some situations, such as national emergencies. Basically, with some exceptions, whoever issues a compulsory license must first inform the patent holder and seek to obtain authorization (voluntary license) from the patent holder. In all cases, they must remunerate the patent holder.

Summaries of article 31(b) (h) (k) provisions:

[17]See http://www.wto.org/english/tratop_e/trips_e/factsheet_pharm00_e.htm

[18]The term "compulsory licensing" does not appear in the TRIPS agreement. However, it does appear in the Paris Convention, and WTO members are required to comply with relevant portions of that Convention (see TRIPS article 2.1). The phrase "other use without authorization of the right holder" appears in the title of TRIPS article 31.

- Prior to use, user makes effort to obtain authorization from the patent holder on reasonable commercial terms and conditions within a reasonable period of time.
- Above authorization requirement may be waived in cases of
  - national emergency or other circumstances of extreme urgency
  - public noncommercial use
  - to correct anticompetitive practices as determined by judicial or administrative processes.
- Patent holder shall be
  - notified as soon as reasonably practicable in case of national emergency
  - informed promptly in case of noncommercial use
- Patent holder shall receive adequate remuneration.

Some developing countries, including the African Group, Brazil, India, and Thailand, expressed the view that the TRIPS agreement in no way stands in the way of public health protection, and therefore that it should provide the broadest flexibility for the use of compulsory licensing to obtain lower cost medicines. Differences over compulsory licensing have continued to reemerge, including later during the later debate over how to resolve the paragraph six problem.

Finally, the United States and some WTO members have different interpretations of paragraph five (d), which says that TRIPS leaves each member free from challenge to establish its own exhaustion regime, based on TRIPS article 6 (shown below).

TRIPS Article 6 – Exhaustion

For the purposes of dispute settlement under this Agreement, subject to the provisions of Articles 3 and 4, nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights.

The United States stated during the debate leading up to the declaration that it did not interpret this to mean that TRIPS permits parallel imports,[19] and expressed misgivings about their use. To be specific, USTR pointed out that permitting parallel imports inhibits the patent holder's willingness to offer prices differentiated according to countries' ability to pay. This is because, when prices are higher in one country than in others, there is a tendency for diversion to higher income countries. These are precisely the markets where patent owners want to maintain high prices in order to recoup costs and earn the profits that fund future research. This differential pricing has been a key feature of pharmaceutical industry efforts to promote improved access to medicine since the Doha Declaration.

In contrast to the U.S. position, some developing countries, including the African Group, Brazil, India, and Thailand, called parallel importation a significant way of increasing access to medicines, particularly for developing countries, and a relevant tool when compulsory licenses may be ineffective.

Differences over a Narrower Versus a Broader Approach Continued in Debating the 2003 and 2005 Council Decisions

Differences over whether the use of compulsory licensing should be restricted or widespread continued during the subsequent debate leading up to the 2003 Council Decision on the Implementation of Paragraph Six. The United States believed that situations requiring a compulsory license for export (sometimes referred to as the "paragraph six solution") would likely be somewhat limited but emphasized that the grave health problems faced by certain developing and least developed countries made a solution imperative. The United States called for restricting compulsory licensing for export to a narrower set of scenarios to ensure that only countries facing genuine crises and with no effective manufacturing capacity could use it. WTO members disagreed about the legal means to address paragraph six and its scope and coverage, including which members should participate in the solution and for what diseases.

[19]For the purposes of this report, parallel or grey-market imports are products marketed by the patent owner or by someone else with the patent owner's permission in one country and subsequently imported into another country without the approval of the patent owner. For example, suppose company A had a drug patented in two countries, Belladonna and Calamine, which it sold at a lower price in Calamine. A parallel import would occur if a second company B bought the drug in Calamine and imported it into Belladonna at a price that was lower than company A's price.

USTR Maintained Paragraph Six Would Be Less Applicable in the Near Term

During deliberations in 2001 leading up to the Declaration, the United States maintained that situations requiring a paragraph six solution would likely remain somewhat limited in the near term, but recognized that the grave health problems faced by certain developing and least developed countries foreshadowed serious consequences should they occur. First, difficulties falling under paragraph six would only be expected to arise when pharmaceuticals were not provided by the patent holder through normal commercial arrangements or through discount, donation, or other aid programs. In addition, a paragraph six solution would only apply if a patent existed in the WTO member country or territory that was exporting the pharmaceutical. However, some developing countries at the time were not obligated to provide patents until January 2005, most notably India.[20]

WTO Members Differed on the Legal Means to Address Paragraph Six

The legal mechanism by which to address paragraph six could also affect the widespread use of compulsory licensing and the effective force of TRIPS obligations. WTO members had to decide whether to craft the paragraph six solution on the basis of TRIPS article 30 or on a waiver of article 31. The United States and the EU supported article 31. The United States argued that a targeted moratorium or waiver of obligations of TRIPS article 31(f) (see below) was the most expeditious, workable, transparent, sustainable, and legal solution. Essentially, the TRIPS requirement that compulsory licensing should be primarily for domestic use would be waived.

[20]While this deadline has now passed, as a practical matter questions still remain about how soon pharmaceuticals produced in India will be under patent. For example, generic drugs produced in India or anywhere in the world before 2005 would be grandfathered under the old system and thus not effectively subject to patents.

TRIPS Article 31

"Other use without authorization of the patent holder"

Where the law of a Member allows for other use of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected:

Article 31 (f): Any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use;

The African Group also supported the article 31 approach and had laid out several options for doing so. Above all, however, they said that they wanted an expeditious solution. According to WTO officials, there was a tacit agreement among the WTO members that the African Group "had the moral high ground" on this issue because the HIV/AIDS pandemic was so acute in Africa.

Alternatively, countries such as Brazil, India, and Thailand argued that the best solution was to interpret TRIPS article 30 (see below) so as to recognize the right of WTO members to authorize third parties to make, sell, and export patented public-health-related products, without the consent of the patent holder to address the public health needs in another country. These acts would be considered "limited exceptions to the exclusive rights" conferred by patents. The countries argued that an authoritative interpretation of article 30 would also have the advantage of avoiding the potentially cumbersome requirement under a waiver of article 31(f) that the exporting country must also grant a compulsory license as well as change its own laws to allow compulsory licensing for exporting.

TRIPS Article 30

Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.

USTR contended that such a broad reinterpretation of article 30 allowing members to amend their patent laws to permit compulsory licenses would

unreasonably conflict with patent owners' normal exploitation of patents and with their legitimate interests. Furthermore, unlike article 31, article 30 contains no procedural safeguards, such as requirements for notifying a patent owner of use, establishing terms and conditions, or remuneration to the patent holder. USTR stated that creating an exception through article 30 was hard to defend legally as being consistent with TRIPS. Moreover, it contended that there was too much danger that such an exception would be misused and thus subject to dispute settlement challenge.

WTO Members Disagreed on Countries Covered under Paragraph Six

The question of which countries should be able to take advantage of a paragraph six solution also provoked controversy. Basically, the United States and other WTO members with large name-brand pharmaceutical industries, including the EU and Switzerland, wanted the paragraph six solution to focus on developing and least developed countries lacking pharmaceutical manufacturing capacity as importing beneficiaries. The United States wanted to establish specific procedures to clarify which developing country members could be considered to have insufficient or no manufacturing ability, and thought it inappropriate to extend the solution to developed countries or to countries that had manufacturing capacity but chose not to manufacture certain drugs based on policy, economic, or other reasons. WTO officials told us they tried to collect data on manufacturing capability, but could find none. Ultimately, the 2003 Council Decision required importing countries to explain how they had no or insufficient manufacturing capacity for the product in question.

After facing strong resistance from other WTO members, the United States did not insist on a specific list of eligible countries. However, the United States maintained that not every member country should be able to use a paragraph six solution, and suggested that some members, such as OECD countries and certain developing countries opt out. WTO officials told us that the United States put pressure on many countries to opt out. In the end, 23 developed countries agreed to opt out, and the 10 countries soon to join the EU partially opted out, with agreement to opt out completely after they joined the EU. Finally, some other WTO members agreed that

they would only use the system as importers in situations of national emergency or other circumstances of extreme urgency.[21]

United States Had Difficulty Joining Consensus on Paragraph Six concerning Diseases

The other controversial issue was the scope of diseases to be covered under paragraph six of the declaration. In November and December 2002, the United States said that it was willing to join the consensus on all of a paragraph six solution draft except for language on the scope of diseases. The United States, the EU, and Japan wanted coverage limited to the diseases mentioned in paragraph one of the declaration, namely "HIV/AIDS, TB, malaria and other epidemics" of potentially pandemic proportions. Others, including Brazil and Argentina, disagreed and wanted no restrictions on diseases. According to WTO officials, some WTO members discussed using either paragraph one or paragraph four–"access to medicine for all"–of the declaration to address the scope of diseases, and settled on the former after being reassured that the declaration did not restrict itself to specific diseases. According to WTO officials, in April 2003, the new TRIPS Council Chair, Singapore, conferred with the United States and the U.S. pharmaceutical industry, drafted a new paragraph six text, and led negotiations among a few members—namely, South Africa, Kenya, Brazil, India, and the United States. USTR officials noted that this group of countries represented the spectrum of views on this debate. The final text contained no specifics on diseases, but relied on paragraph one of the declaration.

[21]To quote the chairman's statement on the General Council decision on the implementation of paragraph 6: "The following Members have agreed to opt out of using the system as importers: Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Japan, Luxembourg, Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland, United Kingdom and United States of America. Until their accession to the European Union, Czech Republic, Cyprus, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, Slovak Republic and Slovenia agree that they would only use the system as importers in situations of national emergency or other circumstances of extreme urgency. These countries further agree that upon their accession to the European Union, they will opt out of using the system as importers. Some other Members have agreed that they would only use the system as importers in situations of national emergency or other circumstances of extreme urgency: Hong Kong (China), Israel, Korea, Kuwait, Macao (China), Mexico, Qatar, Singapore, Chinese Taipei, Turkey, United Arab Emirates."

The Chairman's Statement Was a Key Condition to U.S. Support of the Paragraph Six Solution

USTR officials emphasized that the United States ultimately conditioned its consensus with a paragraph six solution on a statement by the chairman of the General Council that signaled that diversion was a key issue.[22] WTO members generally agreed diversion should be prevented to ensure that drugs provided under the paragraph six solution went where intended. The separate statement by the General Council chairman was designed to alleviate fears that the decision might be abused and undermine patent protection or not effectively prevent drugs from being diverted. The General Council chairman stated that, before adopting the decision, he wanted to place on the record "this Statement which represents several key shared understandings of Members regarding the Decision to be taken and the way in which it will be interpreted and implemented." He went on to state that members recognize that the purpose of the decision would be defeated if products were diverted from the markets for which they were intended, and that all reasonable measures should be taken to prevent such diversion. In addition, the chairman listed the WTO members that had agreed to opt out of using the system as importers.

USTR Believes the 2003 Council Decision Was a Positive One, but Some WTO Members Have Expressed Concerns since the Decision

Ultimately, the outcome of the nearly 2-year debate over a paragraph six solution was the adoption of the 2003 General Council Decision in light of the General Council chairman's statement. The decision waived the prohibition in TRIPS article 31(f) against exporting under a compulsory license to countries that cannot manufacture the pharmaceuticals themselves. USTR officials told us they considered it a positive outcome in that it provided a solution to the problem identified in paragraph six of the Doha Declaration, while preserving TRIPS rules and obligations.

Other WTO members initially supported the outcome, but expressed some concern later. For example, the African Group suggested at a March 2005 meeting of the WTO TRIPS Council that the burden of using the decision was the reason why, up to that point, the 2003 Council Decision had not been used by a country to waive TRIPS rules and import generic versions

[22]For the purposes of this report, diversion is the importation and resale of pharmaceuticals intended for use in another country. A typical example might involve pharmaceuticals donated to a relief organization in a poorer country that make their way into developed nations for sale at a substantial markup. Diversion presents its practitioners with opportunities to generate illegitimate profits by diverting drugs from their intended recipients whenever pharmaceutical companies distribute high value drugs at below market prices.

of patented drugs under a compulsory license. One WTO representative told us more recently that he considered the waiver too complicated, calling the packaging and labeling requirements costly and draconian because of the need to change production lines.

Under the waiver, countries can produce generic copies of patented products under compulsory licenses to export to eligible importing countries, subject to certain requirements and safeguards. The terms of the waiver are summarized below:

Importing members:

- Notify TRIPS Council: names, expected quantities, of drug.
- Other than least developed countries, establish insufficient or no manufacturing capacities for the product in question.
- Take reasonable measures within their means, with possible assistance from developed country members, to prevent exportation elsewhere (diversion).
- If product is patented in its territory, must grant or intend to grant a compulsory license in compliance with TRIPS Article 31.
    - Remuneration waived if product is provided by exporting country.
    - Make a determination of a national emergency, other circumstances of extreme urgency, or a case of public noncommercial use.

Exporting members:

- Export only amount necessary to meet needs of eligible importing member.
- Export entirety of product produced under compulsory license to the eligible importing member(s) that has notified the TRIPS Council.
- Label product to identify it as being produced under the system established by the decision.
    - Package and color uniquely, provided such distinction is feasible and does not significantly affect price.

- Publicize on a designated Web site distinguishing features and quantities of medicine exporting.

- Notify TRIPS Council: name of licensee, products, country to be supplied, and duration of license.

- Adequately remunerate patent holder in the exporting member.

All WTO members:

- Ensure the availability of effective legal means to prevent the importation of products produced under the system established by the decision and diverted to their markets.

According to USTR, in July 2004, the United States and Canada agreed to suspend applications, as between themselves, of a provision of the North American Free Trade Agreement (NAFTA) that parallels Article 31 (f) of the TRIPS agreement in order to ensure that Canada could export drugs under the terms of the 2003 Council Decision without violating NAFTA. The first and only WTO member to date to notify the WTO TRIPS Council of its intent to use a paragraph six solution was Rwanda, in July 2007.

General Council Issued 2005 Decision to Consider Amending the TRIPS Agreement, after Some Difficulties

Debate at the WTO over the 2003 Council Decision still continued for another 2 years. In response to a call by some WTO members, principally driven by the African Group, to express the 2003 Council Decision in an amendment to TRIPS as a more permanent solution, the 2003 Decision also called for WTO members to prepare an amendment to replace the decision. As a result, the General Council issued a decision on December 6, 2005, adopting a protocol amendment that is open for members to accept. It will become effective once the amendment is accepted by two thirds of the WTO membership. Thus far, eight WTO members have accepted the amendment, including the United States, Switzerland, El Salvador, the Republic of Korea, Norway, India, the Philippines, and Israel.

The drafting of the amendment turned into another 2-year struggle. According to USTR, the United States wanted to ensure that agreements made under the 2003 Council Decision were not changed in the amendment. To do this, USTR proposed to include the chairman's statement as a footnote to the amendment. WTO members discussed the possible legal weight of a footnote. According to USTR, some members felt attaching the chairman's statement as a footnote might give it too much legal weight. In addition, some members wanted to make changes to

the original 2003 Decision in the amendment. Eventually, the footnote was dropped and the members agreed to have the chairman's statement read orally, similar to the scenario followed in adopting the 2003 Council Decision. Despite losing the footnote, the United States believed it had achieved the delicate balance of preserving the solution agreed to under the 2003 Council Decision while promoting access to medicine with safeguards against diversion.

USTR Has Maintained Its Pursuit of High IP Standards and Made Some Allowances for Doha Flexibilities in Negotiating FTAs

In negotiating FTAs, USTR said it balances respect for the Doha Declaration with its other two IP negotiating objectives in TPA by consistently promoting high standards of IP protection similar to U.S. law, while making allowances for the two specific flexibilities mentioned in the declaration. For example, USTR makes concessions to developing countries on compulsory licensing and parallel importing provisions specifically cited in the declaration. However, USTR has continued to pursue other pharmaceutical-related IP provisions that it does not see as relevant or contrary to the Doha Declaration in all of its FTAs, such as data exclusivity, patent term extensions, and patent linkage. Reactions to USTR's approach have been mixed. The pharmaceutical industry supports the inclusion of these protections in FTAs because it believes they are central to maintaining incentives for investment in research and development of new drugs. Some experts and public health advocates have raised concerns that USTR's approach hinders generic competition, reducing access to medicines and thus violating the principles of the declaration. Finally, certain Members of Congress have expressed concern over the pharmaceutical-related IP provisions in FTAs with developing countries, and this concern was recently addressed through a bipartisan compromise between Congress and the administration.

USTR Believes That Strong IP Protection and Increased Market Access Promotes Public Health, and Thus Respect for the Doha Declaration

USTR has three principal negotiating objectives related to IP rights when negotiating FTAs with other countries. The Trade Act of 2002, which granted the President Trade Promotion Authority (TPA), contains guidance from Congress on U.S. negotiating objectives for trade agreements, including three goals on IP rights:[23]

1. to further promote adequate and effective protection of IP rights, including through ensuring that the provisions of any multilateral or

[23] 19 U.S.C. §3802.

bilateral trade agreement governing IP rights that is entered into by the United States reflect a standard of protection similar to that found in United States law;

2. to secure fair, equitable, and nondiscriminatory market access opportunities for United States persons that rely upon IP protection; and

3. to respect the Doha Declaration on the TRIPS Agreement and Public Health, adopted by the World Trade Organization (WTO).

USTR officials explained that USTR believes it can simultaneously pursue policies that advance the first two objectives of promoting IP rights and securing market access, while fulfilling the third objective to respect the Doha Declaration. Specifically, the officials noted that in order to pursue the first two objectives in FTAs, USTR officials have negotiated high levels of IP protection in FTAs that reflect standards of protection similar to U.S. law, and build on the minimum standards in TRIPS. USTR officials stated that they pursue the second objective of securing market access for persons who rely on IP protection by ensuring that products benefit from the increased protection and market access in the FTAs. For example, USTR officials noted that FTAs with more developed countries have regulatory provisions for pharmaceuticals and medical devices on market approval, price controls, and reimbursement policies. USTR sees no inherent conflict between active pursuit of TPA's first two objectives of promoting IP protection similar to U.S. law and market access opportunities, and the third objective of respecting the Doha Declaration, but rather considers these objectives complementary. USTR officials stated that USTR's view is that IP rights ultimately enhance public health by promoting innovation for new medicines and that therefore this approach is consistent with the Doha Declaration.

USTR Pursues a Menu of Pharmaceutical-Related IP Provisions in FTA Negotiations

In response to the objectives laid out in TPA, USTR officials noted that they have pursued a menu of pharmaceutical-related IP provisions in its FTAs, including restrictions on compulsory licensing and parallel imports, and requirements to provide data exclusivity, patent term extensions, and patent linkage. Some of these pharmaceutical-related IP provisions go beyond the minimum levels of protection outlined in TRIPS, provoking complaints from some that they violate the principles and spirit of the Doha Declaration. However, USTR considers them consistent with its interpretation of the declaration's intent and meaning and with TPA guidance.

The FTA pharmaceutical-related IP provisions, to the extent that they are similar across the FTAs, have been summarized below. However, it is important to note that variations across the provisions exist and have not been presented in these summaries. Moreover, not every FTA reviewed contained every provision summarized below.

Compulsory Licensing: Generally, provisions on compulsory licensing limit the ability of a country to issue a compulsory license to a few specific scenarios: to remedy anticompetitive practices in cases of public noncommercial use, in cases of national emergency, or other circumstances of extreme urgency.

Parallel Imports: Generally, provisions on parallel importation require the country to preserve the patent owner's exclusive right to sell or import its product in the country in a variety of contexts.

Data Exclusivity: Generally, data exclusivity provisions state that a generic company cannot obtain marketing approval based on the safety and efficacy data of the innovator company for a period of at least 5 years from the date marketing approval was granted to the innovator. Thus, this provision provides the innovator 5 years of effective marketing exclusivity, unless the generic firm produces its own safety and efficacy data with new drug trials.

Patent Term Extensions: Generally, patent term extension provisions require the country to provide a patent term extension to the patent owner to compensate for unreasonable delays in granting the patent, or for unreasonable curtailment of the effective patent term as a result of the marketing approval process.

Patent Linkage: Generally, provisions on patent linkage establish a relationship between the market approval process of generic drugs and the patent status of the originator product. Under this relationship, the governmental body responsible for granting market approval prevents third parties from making or selling copies of patented products without the authorization of the patent holder by withholding marketing approval until either the expiration of the patent or a determination by a governmental body, either executive or judicial, that the patents are either not infringed, invalid or unenforceable. In addition, the identity of the generic company requesting marketing approval must be made available to the patent owner.

Patent term extensions and patent linkage are two examples of pharmaceutical-related IP provisions the United States negotiates for in FTAs that go beyond the minimum obligations in the TRIPS agreement. TRIPS article 33, which lays out the term of protection for a patented product, states that "the term of protection available shall not end before the expiration of a period of twenty years counted from the filing date." There is no mention of patent term extensions to make up for delays in the patent or marketing approval process in the TRIPS agreement. Nevertheless, these patent term extension provisions exist in U.S. law[24] and according to USTR officials are negotiated by USTR in FTAs. In addition, there is no mention of coordination between the health regulatory authority and the patent granting office, known as patent linkage, in the TRIPS agreement. However, U.S. law does establish linkage between the FDA drug approval process of generics and the patent status of the originator product,[25] and USTR believes that such linkage is important to restrict marketing of infringing copies of patented drug products.

Whether FTA provisions on data exclusivity go beyond TRIPS is less clear. TRIPS article 39(3) states that members who require the submission of undisclosed test data as a condition of marketing approval for a pharmaceutical or agricultural chemical product shall protect the data from unfair commercial use and disclosure.

TRIPS Article 39(3)

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 a considerable effort, shall protect such data against unfair commercial use. In addition, Members 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.

There are different interpretations of the obligations under TRIPS 39(3), and exactly what practices can be considered a fulfillment of this obligation. One interpretation of TRIPS 39(3) requires members to grant the originator of the data a period of exclusive use similar to that provided by data exclusivity laws in the United States. Under this interpretation,

[24]*See* 35 U.S.C. § 156.

[25]*See* 21 U.S.C. § 355.

FTA provisions do not go beyond TRIPS. Others do not believe that Article 39(3) of TRIPS confers exclusive rights, but instead simply requires countries to prevent third parties from using the originators' data for unfair commercial purposes. This interpretation suggests that the FTA provision goes beyond the TRIPS requirement.

USTR Has Made Limited Concessions on Doha Declaration Flexibilities

USTR officials stated that they did not change the initial demands USTR makes in FTA negotiations as a result of the Doha Declaration. However, they argued that USTR follows TPA guidance to respect the Doha Declaration by making concessions during negotiations with what it considers to be developing countries on the two TRIPS flexibilities specifically mentioned in the declaration. USTR officials told us that when developing country trading partners raise concerns during FTA negotiations about provisions that would restrict the use of parallel imports or compulsory licensing, USTR ultimately backs off and removes them from the proposed text; however, they stated that no such concessions were made for countries that USTR considered developed countries. A USTR official said that developed countries have more tools and resources with which to deal with public health situations and that they should not have to revert to such extraordinary measures outside of the cases specified in FTA provisions, such as national emergencies. Restricting these concessions to developing countries is in line with USTR's belief that the Doha Declaration is intended to apply primarily to developing countries with limited resources.

USTR also attaches side letters on public health to FTAs with developing countries.[26] Our analysis in figure 2 shows that 7 of the 11 agreements include a side letter or understandings on public health.[27] USTR officials

[26]The side letters on public health generally state that the obligations under the IP chapter do not affect a Party's ability to take necessary measures to protect public 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. The side letters also generally state that the obligations under the IP chapter do not prevent the effective utilization of the TRIPS/health solution. For specific wording, see the Colombia, Bahrain, Oman, Morocco, CAFTA-DR, Peru, and Panama free trade agreements and associated side letters.

[27]Not captured in this number are other statements on public health in the FTAs such as in the preamble of the Chile FTA IP chapter that states, "*Recognizing* the principles set out in the Declaration on the TRIPS Agreement on Public Health, adopted on November 14, 2001, by the WTO at the Fourth WTO Ministerial Conference, held in Doha, Qatar." According to USTR officials, such a statement is part of the interpretive context of an FTA.

noted that they use the side letters to further clarify that the provisions of the agreement leave intact a series of methods a country can use to respond to public health emergencies.[28] However, according to a USTR official, these side letters do not create exceptions to the provisions in the FTA.

Figure 2: FTA Pharmaceutical-Related IP Provisions and Side Letters Matrix

FTA	FTA status (signed/ implemented)	Compulsory licensing	Parallel importing	Data exclusivity	Patent extension	Patent linkage	Side letter on public health	Per capita income
Chile	Implementing Leg. signed Sept. 03	○	○	●	●	●	◑	$12,983
Singapore	Implementing Leg. signed Sept. 03	●	●	●	●	●	○	$32,867
Australia	Implementing Leg. signed Aug. 04	●	●	●	●	●	○	$32,938
Morocco	Implementing Leg. signed Aug. 04	○	●	●	●	●	●	$4,956
CAFTA-DR	Implementing Leg. signed Aug. 05	○	○	●	●	●	●	$5,895
Bahrain	Implementing Leg. signed Jan. 06	○	○	●	●	●	●	$23,604
Oman	Implementing Leg. signed Sept. 06	○	○	●	●	●	●	$18,841
Peru	Agreement signed Apr. 06	○	○	●	●	●	◑	$6,715
Colombia	Agreement signed Nov. 06	○	○	●	●	●	◑	$8,091
Panama	Agreement signed June 07	○	○	●	●	●	◑	$8,389
Korea	Agreement signed June 07	○	○	●	●	●	◑	$23,926

○ Indicates that the provision is NOT present in the FTA

◑ Indicates that language on the Doha Declaration and public health was incorporated into the body of the agreement

● Indicates that the provision is present in the FTA

Source: GAO analysis, International Monetary Fund (IMF), and United Nations (UN).

Note: Per capita income based on purchasing power parity (PPP) exchange rate is from International Monetary Fund's staff estimates for 2006. Per capita income for CAFTA-DA is an average for the region, which is total PPP-based Gross Domestic Product (GDP) for the region divided by total population for the region using UN estimates.

[28]The side letter on public health constitutes a formal understanding that forms part of the interpretive context of a signed/implemented FTA as described in the Vienna Convention on the Law of Treaties, Article 31.

USTR told us that some differences in the IP provisions among FTAs represented accommodations made to countries raising specific concerns during negotiations. For instance, USTR officials stated that, in the Central America-Dominican Republic-United States Free Trade Agreement (CAFTA-DR), a transition period was included for the implementation of patent term extensions. In the CAFTA-DR agreement, USTR dropped a proposal for data exclusivity protection on new uses of previously discovered chemical entities, and instead left data exclusivity in place only for new chemical entities. In addition, USTR revised the proposed provision on patentable subject matter in the Oman agreement in order to exclude plants and animals from patent protection in response to Oman's concerns. USTR officials said that most concerns raised during negotiations regarding data exclusivity and patent linkage were not couched as health concerns, but rather as unease related to administrative burden or implementation concerns. When these types of implementation concerns are raised during negotiations, USTR said it consults with the U.S. agencies responsible for implementing those provisions in the United States, PTO, and FDA.

USTR officials stated that USTR considers the remaining pharmaceutical IP provisions on data exclusivity, patent linkage, and patent term extension a central part of its strategy of pursuing the first two IP negotiating objectives, while it does not see these provisions as being specifically addressed by the Doha Declaration. Therefore, USTR officials noted that these three provisions are pursued universally by USTR in all of its FTAs. USTR officials noted that these provisions are very important for providing protection similar to that found in U.S. law and for maintaining incentives for the pharmaceutical industry. USTR officials explained that USTR does not believe that these three provisions are considered flexibilities under the Doha Declaration, and therefore sees no conflict between pursuing them and respecting the Doha Declaration. USTR officials noted that USTR maintains that these provisions do not restrict a country's ability to protect public health.

The pattern of IP provisions negotiated in the 11 FTAs completed to date confirms USTR's stated negotiating strategy. Figure 2 demonstrates that data exclusivity, patent term extension, and patent linkage provisions are found in all 11 of the FTAs concluded under TPA, regardless of the development level in the country. Pursuing these provisions also confirms USTR's stated strategy of seeking high IP standards related to pharmaceuticals in trade negotiations. On the other hand, figure 2 indicates that IP provisions on compulsory licensing are found in only 2 of 11 completed FTAs, those with Singapore and Australia, both of which

USTR considered developed countries. Only 3 of 11 FTAs—Singapore, Australia, and Morocco—contain provisions on parallel imports. Although Morocco is considered a developing country, USTR officials explained that Morocco decided in 2000, well before the onset of negotiations, not to permit parallel imports. Therefore, USTR officials stated that the parallel importation provision reflected what was already provided in Moroccan law.

The Pharmaceutical Industry Supports USTR's Insistence on Data Exclusivity, Patent Linkage, and Patent Term Extensions, but Others Contend These Provisions Contradict the Principles of the Declaration

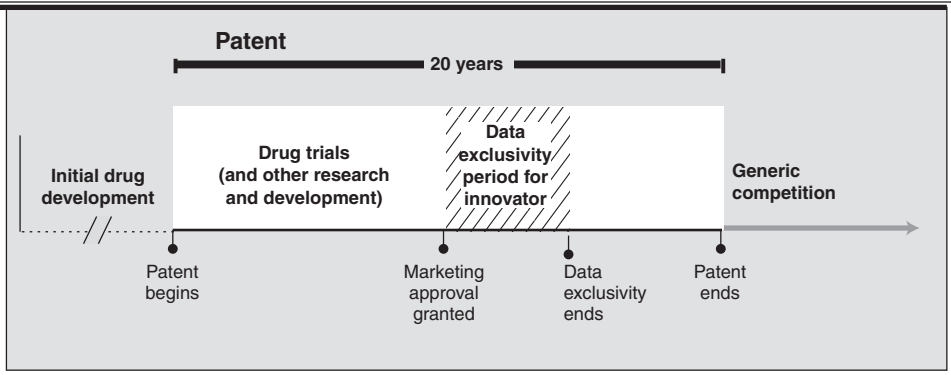
Reactions to USTR's approach to pursuing its TPA objectives in negotiating FTAs have been mixed, with controversy centered on the three key provisions of data exclusivity, patent linkage, and patent term extensions. The pharmaceutical industry stated that it supports the inclusion of these provisions in FTAs because it believes they maintain incentives for research and development. However, some experts and public health advocates have raised concerns that USTR's approach delays generic competition and reduces access to medicines. Therefore, they believe that USTR's strategy violates the principles and goal of the Doha Declaration.

The Pharmaceutical Industry Considers Data Exclusivity, Patent Linkage, and Patent Term Extensions Key Provisions

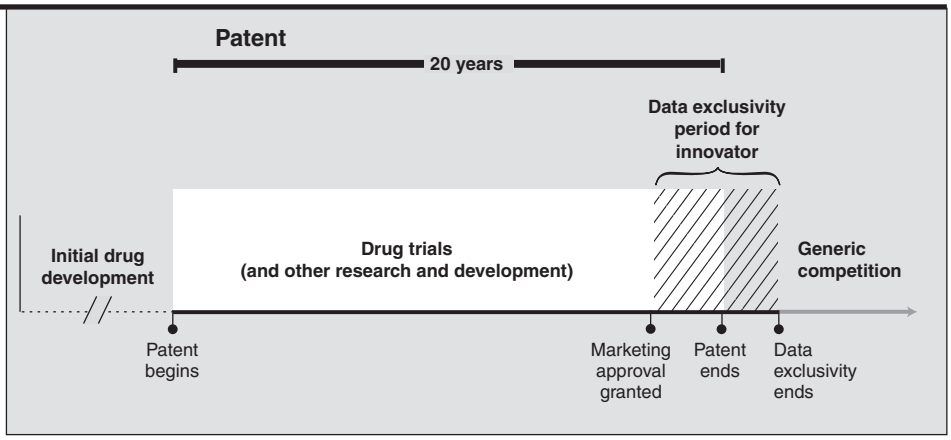
Pharmaceutical industry representatives stated that data exclusivity is a very important IP protection that provides incentives to innovate and invest in certain markets. Data exclusivity grants a company the exclusive use of its safety and efficacy test data, necessary to obtain marketing approval, for a fixed period after the marketing launch. Data exclusivity is one method by which the innovator company can recoup the costs involved with conducting clinical tests necessary for marketing approval, as well as the considerable costs associated with developing a new drug. Industry representatives explained that they consider patent protection and data exclusivity to be separate but complementary protections. Both can generally provide a period of exclusivity. Consequently, data exclusivity may effectively grant another layer of market exclusivity for the new product. Figure 3 contains three scenarios of how the periods of data exclusivity and patent protection can interact to create market exclusivity under U.S. law.

Figure 3: Data Exclusivity and Patent Protection, Three Possible Scenarios

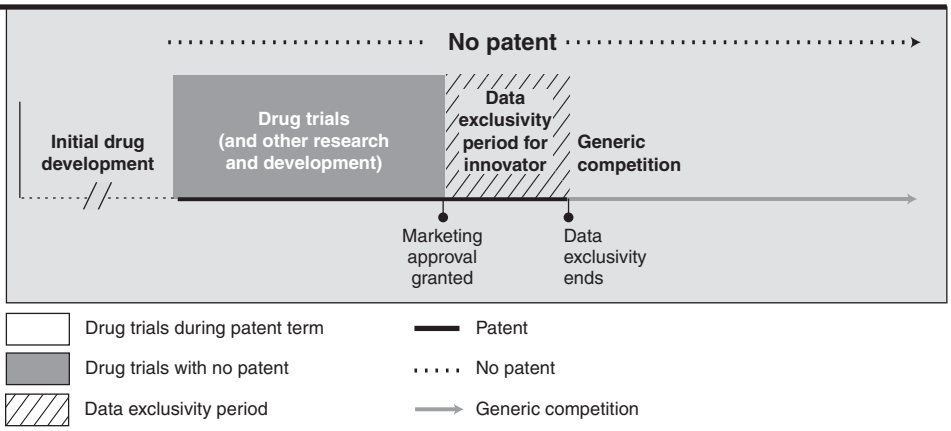
Scenario 1:
Marketing approval is granted about 8-10 years into the 20 year patent term and therefore the 5-year data exclusivity for new chemical entities runs concurrently with patent term. Most typical scenario for a new drug in the U.S.



Scenario 2:
Data exclusivity extends beyond the end of the patent term because marketing approval is granted so far into the patent period that less than 5 years remain on the patent when the patent holder enters the market.



Scenario 3:
No patent is obtained by the innovator company, therefore data exclusivity provides 5 years of marketing exclusivity for new chemical entities for the innovator company. This scenario is more likely in countries where patents have not been obtained or are poorly enforced.



Source: GAO analysis.

Some time after the initial drug development takes place, the company applies for a patent and the 20-year patent term begins. During the patent term, the company completes all of the drug trials necessary to obtain the safety and efficacy data needed for marketing approval by the FDA. After approval is granted, the company can begin marketing its drug, and the set period of data exclusivity period begins. Industry representatives noted that the data exclusivity period generally is concurrent with the patent period and therefore does not add any additional period of effective market exclusivity, as shown in the first scenario in figure 3. However, as shown in the second scenario, if marketing approval is obtained further into the patent term, the 5-year data exclusivity period, which begins when marketing approval is granted, can extend beyond the term of the patent. As shown in the third scenario, when no patent protection exists, data exclusivity effectively provides the entire market exclusivity period.

Pharmaceutical industry representatives stated that the first scenario is the most typical, with the data exclusivity running concurrently with patent protection. However, they noted that there are many instances in which companies do not obtain patents on their products (particularly for small markets), or patent protection is inadequate or poorly enforced. In these situations, data exclusivity ensures the innovator company a 5-year period of market exclusivity. The pharmaceutical industry believes that, in cases in which there is no patent or very little patent life remains when the drug first enters the market, data exclusivity is critical because without an effective market exclusivity period, incentives to research and develop new drugs are diminished.

Pharmaceutical industry representatives have also advocated for patent term extensions in FTAs. It is common for a substantial portion of the patent life to be spent running drug trials. Therefore, the industry argues that patent term extensions ensure that innovators get enough time to recoup their costs and maintain the incentives for future innovation. In addition, industry representatives noted that, in many developing countries, the delays associated with getting a patent or obtaining marketing approval for a new drug can be far more extensive than in the United States. They argue that, under these circumstances, it is even more critical that a safeguard mechanism exists to ensure that these delays do not undermine the intentions of patent protection.

Patent linkage is also considered important by the pharmaceutical industry. Patent linkage provisions in the FTAs provide for delay of marketing approval if a generic drug product is covered by an unexpired patent. Pharmaceutical companies claim that generic companies routinely

launch patent-infringing products during the life of a patent in many developing countries and that patent linkage would help to minimize this problem.

Some Experts and NGOs Believe USTR's Continued Promotion of Data Exclusivity, Patent Term Extensions, and Patent Linkage Conflicts with the Principles of the Doha Declaration

Some experts and NGOs believe that these provisions impair access to medicines and therefore are contrary to the "spirit" of the Doha Declaration and TPA guidance. These NGOs, academics, and generic pharmaceutical producers believe that these provisions limit generic competition, thereby maintaining high prices for pharmaceutical products, ultimately impairing access to medicines. These concerns have been extensively discussed and documented by academics, international organizations, think tanks, NGOs, and public health groups. Since many FTA partners implemented these pharmaceutical-related IP provisions for the first time very recently, it is difficult to identify the tangible effect of these provisions. However, these groups believe that the inclusion of these provisions has the potential to decrease public health and therefore is contrary to the spirit and principles and goal of the Doha Declaration.

Many NGOs argue that the data exclusivity provisions included in U.S. FTAs will damage access to medicines and public health and worry that there might be instances where the data exclusivity period could extend beyond the length of the patent term, as in figure 3, scenario 2. This data exclusivity period effectively delays entry of generics onto the market, thereby maintaining monopoly prices for a longer period of time. While some NGOs recognize that it would be rare for the data exclusivity period to extend beyond the patent term, they are worried that if this situation occurs, generic competition will be delayed because of the presence of data exclusivity. In addition, where the innovator of a new drug did not obtain a patent in that country, either because it did not apply or because the new drug was not patentable, data exclusivity will effectively give the innovator a patent-like period of marketing exclusivity for the entire period of data exclusivity, from the time marketing approval is granted (see figure 3, scenario 3). NGOs are also concerned that data exclusivity provisions might prevent the marketing of generic drugs produced under a compulsory license. For instance, if a compulsory license is granted to a generic producer, but that producer is not able to rely on the data generated by the innovator company to obtain needed marketing approval, it will not be possible to distribute the drugs under a compulsory license.

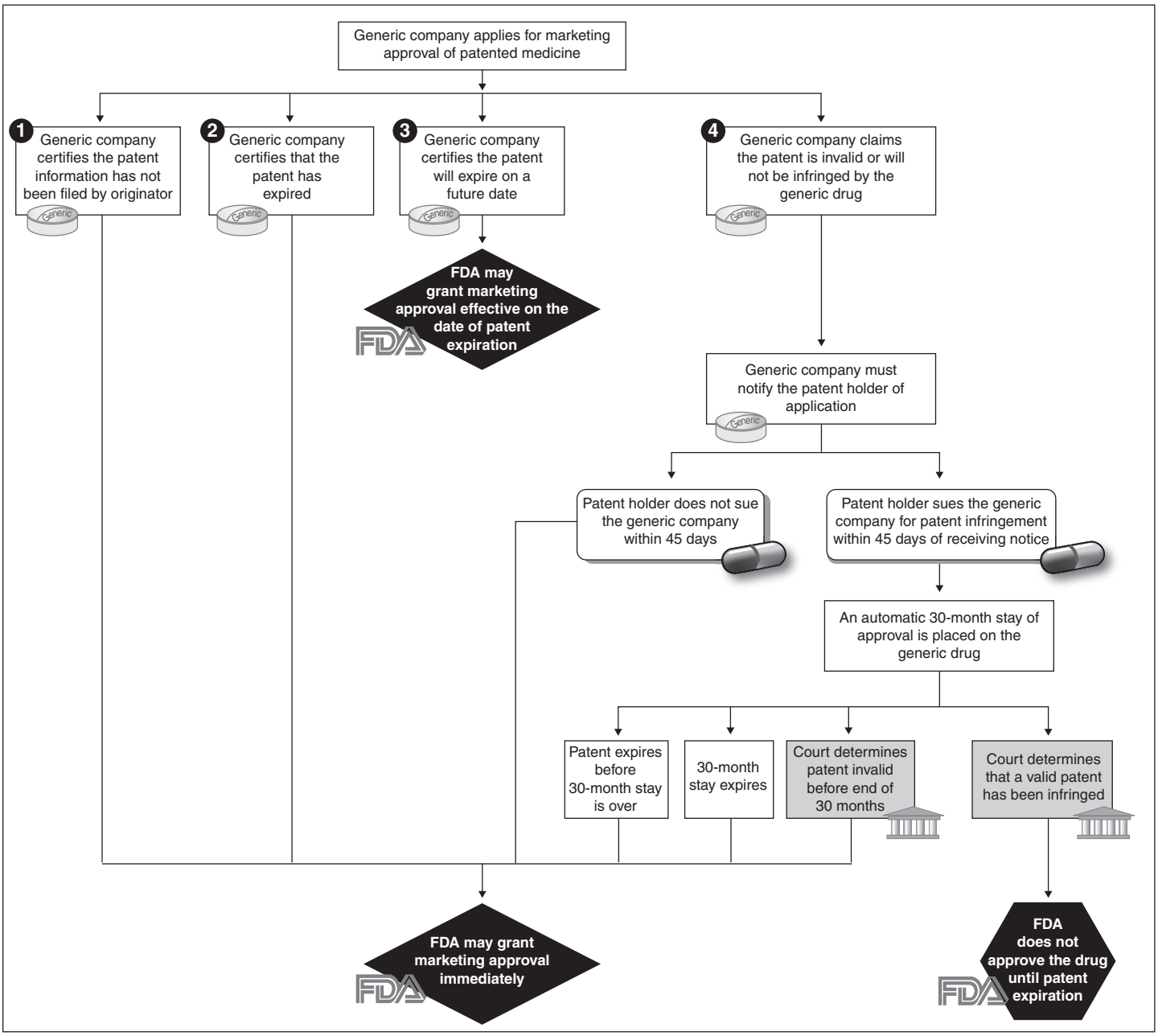
Some experts and NGOs are also concerned that variations in the data exclusivity periods across countries could further delay generic entry. An FTA partner country must normally provide 5 years of data exclusivity to the innovator once the product receives marketing approval.[29] If the innovator waited to apply for marketing approval in the FTA partner country, thereby delaying the start date of its market exclusivity period, it would effectively extend the overall market exclusivity period beyond the intended 5 years. Some FTAs have addressed this issue by specifying that a country may require the innovator to apply for marketing approval in its country within a specified period of time. For instance, in the CAFTA-DR agreement, at their request, a Party may require that the innovator seek marketing approval in that Party within 5 years after obtaining marketing approval in any other territory in order to receive data exclusivity. This way, the innovator company can only delay the start date of its data exclusivity period by a fixed period of time.

Patent term extension provisions in FTAs have also led to questions about their effect on access to medicines. Many NGOs and generic pharmaceutical producers believe that the 20-year patent term in TRIPS creates a balance between access and innovation and that extending the patent period would have a detrimental effect on generic competition. They are also concerned that the patent term extension provisions in U.S. FTAs do not contain the same limits present in U.S. law. For instance, under U.S. law, innovators cannot receive more than 14 years of patent protection through a patent term extension after they have received market approval, and in any case, the maximum period of extension determined on the basis of the regulatory review period cannot exceed 5 years. This limit on patent term extensions is not present in FTAs.

Some also assert that patent linkage might negatively affect access to medicines. The patent linkage process in the United States involves numerous steps and actors, designed to enable resolution of patent disputes before marketing approval is granted for a generic drug product. As shown in figure 4, this linkage system places the burden on the private companies, not the regulatory authority, to monitor the patent system.

[29]The Chile, Singapore, Australia, Morocco, Bahrain, CAFTA-DR, Oman, and Republic of Korea FTAs state that 5 years of data exclusivity are to be provided. The Peru, Colombia, and Panama FTAs will require the provision of data exclusivity for a reasonable amount of time and state that a reasonable amount of time normally means 5 years.

Figure 4: Patent Linkage Process in the United States



Source: GAO analysis.

Specifically, the U.S. patent linkage system puts the onus on the generic company producer to provide information on the applicability of an existing patent to the drug product for which it is seeking marketing approval. If the generic company decides to challenge the patent, it must notify the patent holder within a specified period of time in order to give the patent holder the chance to sue and defend the patent in the courts. When the patent litigation is resolved, the FDA can grant marketing approval to the generic company if the patent is overturned, and may be obliged to wait until the patent expires if the generic drug product is found to infringe the patent and the patent is not found to be invalid. NGOs and generic pharmaceutical producers are concerned that developing countries do not have the same set of protocols laid out in the FTA agreement or in their laws, and that this will ultimately affect access to medicines. Generic pharmaceutical representatives argue that countries might experience regular abuses and delays in the introduction of generic drugs if they are unable to institute an effective linkage process.

Congressional Concern over IP Provisions and Access to Medicines Addressed in Bipartisan Trade Deal

Certain Members of Congress have expressed concern over the pharmaceutical-related IP provisions in FTAs with developing countries, and this concern was recently addressed through a bipartisan compromise between Congress and the administration. Through letters and correspondence with USTR, certain Members emphasized the need to better balance IP protection for pharmaceuticals with the promotion of access to affordable medicines, including through robust generic competition. These Members expressed unease over the balance achieved in the FTAs negotiated by USTR to date—specifically, the impact of the pharmaceutical-related IP provisions in FTAs on developing countries. These Members urged USTR to ensure that the FTA provisions do not restrict the availability of generic competition and put affordable health care at risk. In response to these concerns, in May 2007, Members of the congressional leadership agreed on a bipartisan compromise with the administration to revise four of the recently negotiated FTAs, in order to alter provisions pertaining to a variety of areas, including IP provisions and access to medicines.

The bipartisan trade deal reached between Congress and the administration in May 2007 stipulated that certain disputed IP provisions in FTAs with Peru, Colombia, Panama, and Korea be revised prior to submission of the agreements for congressional approval, by USTR and

the trading partners.[30] According to USTR officials, the agreement preserves a strong overall level of IP protection in the FTAs, while incorporating flexibilities aimed at ensuring that trading partners are able to achieve the appropriate balance between innovation and promoting access to medicines. Specifically, USTR revised the FTAs with Peru, Colombia, Panama, and Korea to include a reference to the Doha Declaration and the ability of each country to protect public health in the body of the agreement, instead of in a side letter. In addition, the data exclusivity provision in each of these agreements was revised to provide an exception for public health.

The agreements with Peru, Colombia, and Panama were revised further to alter the language of provisions on patent term extensions, patent linkage, and data exclusivity. A USTR official stated that USTR and Congress decided that these additional changes would not be applied to the Korea FTA in view of Korea's relatively higher level of economic development. These additional changes to the Peru, Colombia, and Panama agreements revised the provisions on patent term extensions and patent linkage in order to provide more flexibility for trading partners in implementing these provisions. In addition, the data exclusivity provision was revised further to ensure that, in some circumstances, the data exclusivity period in those countries would not extend beyond the period of data exclusivity provided in the United States. These changes were renegotiated and finalized by USTR in June 2007.

[30]The bipartisan trade deal also included agreements and amendments on a variety of other areas in these FTAs, including labor standards, environmental standards, government procurement, port security, and investment.

USTR Is Implementing and Overseeing Trade Agreements in a Manner Consistent with Its Overall Approach of Promoting High Standards concerning IP Rights

USTR's approach to implementing and overseeing pharmaceutical-related IP provisions is consistent with its overall negotiating strategy pursued in FTAs. Before a signed FTA can go into force, the President determines, with USTR's advice, whether the FTA partner has met all obligations, including, when appropriate, changes in laws and regulations. As part of this process of advising the President on the determination that he is required to make under U.S. implementation legislation for FTAs, USTR has vigorously pursued FTA partners' implementation of pharmaceutical provisions related to data exclusivity, patent term extension, and patent linkage. In fact, in some cases, USTR has continued to work with countries after the agreement has entered in force. For example, USTR is still working with Chile to ensure that its data exclusivity provisions are implemented in a manner consistent with the Chile FTA.

In its broader role of annually identifying countries that deny adequate and effective protection of IP rights, USTR has frequently raised data protection and patent linkage, in keeping with its strategy of gaining high levels of IP protection for pharmaceutical products, similar to U.S. law. With regard to the Doha Declaration flexibilities, USTR has not generally pressed for restrictions on compulsory licensing and parallel imports in its Special 301 reports. Furthermore, USTR has had a measured response to cases to date of countries actually issuing compulsory licenses. For example, when Thailand recently issued a compulsory license, USTR acknowledged its right to do so and thus far is restricting its criticism to a lack of transparency in the process.

USTR Reviews Compliance with FTA Obligations before Agreements Enter into Force

One USTR official noted that USTR oversees FTA partners' implementation of the pharmaceutical-related IP provisions agreed to in the FTA in order to ensure that the negotiated standards are implemented as intended. In order for an agreement to enter into force, the President determines with the advice of USTR whether the FTA partner has met all obligations. A USTR official explained that USTR works with the trading partner to ensure that its IP laws are aligned with the provisions agreed to in the FTA. The USTR official further explained that, at the start of the implementation process, the trading partner provides USTR a comprehensive list of its laws related to each provision in the IP chapter of the FTA. The trading partner also provides USTR a list detailing the intended legal changes necessary to bring its laws into compliance with the agreement. USTR reviews the laws and proposed changes and provides the trading partner with comments regarding their degree of compliance. USTR monitors the changes in the other country, and has numerous exchanges with the trading partner on any legal changes

necessary. One USTR official stated that they are careful to ensure that the agreement is implemented exactly as it was negotiated. For example, in response to Guatemala's proposal to have an exception to data exclusivity written into its laws, USTR insisted that this exception undercut the original obligations, and it was therefore unwilling to accept the change.

A USTR official explained that when the legal changes are complete and USTR is comfortable with the new legislation, USTR makes a recommendation to the President for the agreement to enter into force. The administration then makes a determination about the legal compliance before the agreement can officially enter into force. USTR and other agencies also provide technical assistance on implementing related IP provisions to FTA partner and nonpartner governments. (See appendix II.)

USTR Vigorously Pursues Implementation of Data Exclusivity, Patent Term Extension, and Patent Linkage

USTR focuses on a wide range of IP provisions including data exclusivity, patent term extensions, and patent linkage during the FTA implementation phase to ensure that U.S. trading partners are properly implementing and enforcing pharmaceutical-related IP provisions. In 2005, Chile reformed its data protection regime; however, a USTR official stated that USTR has continued to monitor Chile's implementation of data exclusivity in response to concerns raised by the pharmaceutical industry. Specifically, USTR officials noted that Chile had added a requirement that, in order to receive data exclusivity, companies must apply for marketing approval within a year of doing so in other countries. USTR is also monitoring Chile on specific issues with regard to the implementation of patent linkage and patent term extensions. In particular, USTR is responding to concerns that the Chilean health authorities issued a number of marketing approvals of generic versions of drugs still under patent. Chile appears to have no provision that would prevent such an approval from being issued during the patent term. In addition, USTR noted that Chile has yet to implement a law that would enact patent term extensions to compensate for delays in marketing approval.

USTR Has Focused Attention on Data Protection and Patent Linkage in Its Special 301 Report

USTR officials noted that USTR regards the Special 301 report, which is subject to different statutory requirements distinct from TPA,[31] as an important tool for overseeing and evaluating the implementation and adequacy of IP protection worldwide. USTR officials explained that USTR considers all items that are related to the effectiveness and adequacy of IP protection in its Special 301 report. They noted that in the Special 301 report there are considerations relevant to adequacy and effectiveness that sometimes go beyond the minimum standards laid out in TRIPS. In fact, there are many examples of situations discussed in the Special 301 reports that are not specifically part of TRIPS. Thus, the Special 301 report tracks progress of WTO member implementation of TRIPS and trading partner implementation of FTAs, as well as how adequately countries are protecting IP rights overall. While the Special 301 report focuses on a wide range of IP protection issues related to copyrights, patents, and trademarks, including piracy, counterfeiting, and enforcement, our analysis focuses only on the pharmaceutical-related issues discussed in this report. Thus, this analysis focuses only on the countries listed on the Special 301 report for which pharmaceutical-related issues were mentioned as a concern, which represent only a subset of the issues discussed and the total number of countries listed in the Special 301 reports over the years 2000-2007. (See table 1.)

[31]See 19 U.S.C. §§ 2242, 2412. Special 301 is a congressionally mandated report that requires USTR to identify, within 30 days of the submission of the annual National Trade Estimates report, foreign countries that (1) deny adequate and effective protection of IP rights or fair and equitable market access to U.S. persons that rely on IP protection, and (2), of those countries identified in (1), priority countries. Priority countries, as defined by law, are countries (1) that have the most onerous or egregious acts, policies, or practices that deny adequate and effective IP rights with the greatest adverse impact on the relevant U.S. goods, and (2) that are not entering into good faith negotiations or making significant progress in bilateral or multilateral negotiations to provide adequate and effective IP protection. In making these identifications, USTR takes into account the history of IP laws and practices of the foreign country and the history of efforts of the United States, and the response of the foreign country, to achieve adequate and effective protection and enforcement of IP rights.

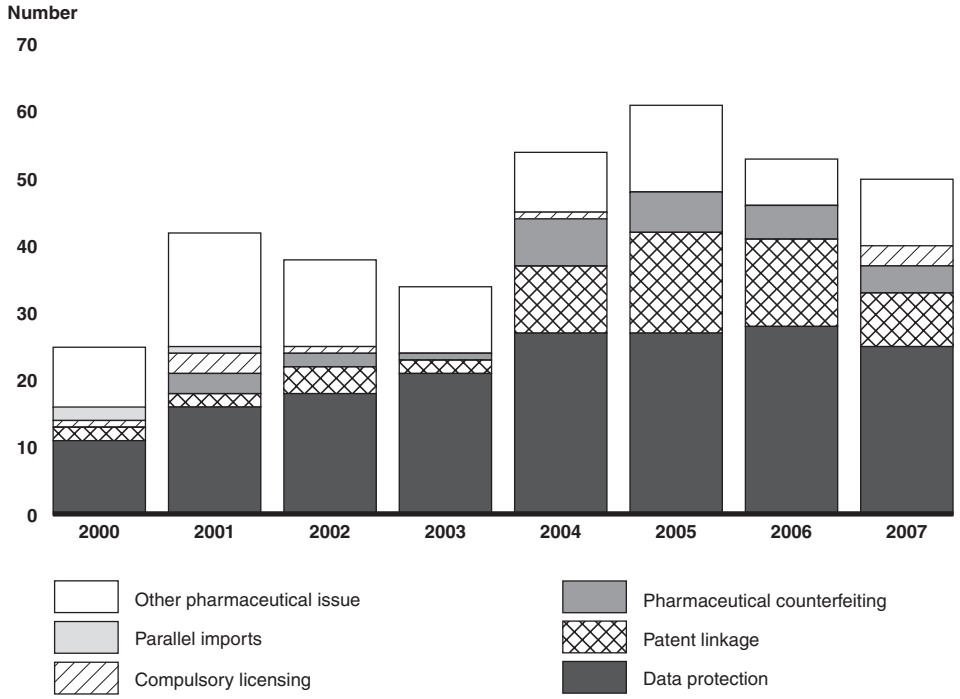
Table 1: Countries Listed in the Special 301 Report with Mention of Pharmaceutical-related Issues Compared to All Countries Listed (2000-2007)

	2000	2001	2002	2003	2004	2005	2006	2007
Total countries listed with mention of pharmaceutical-related issues	17	21	21	23	37	32	31	27
Total countries listed for all issues	56	50	51	50	51	52	48	43

Source: GAO analysis of Special 301 Reports.

Consistent with its emphasis in FTAs, our analysis of the Special 301 reports indicates that USTR focuses heavily on data protection in its annual Special 301 reports. For countries listed in the Special 301 reports over the period 2000 through 2007 for whom pharmaceuticals was cited as an issue of concern, data protection was mentioned in almost every case. In fact, data protection is the most frequently mentioned of all pharmaceutical issues in the Special 301 reports over that 8-year period, appearing a total of 173 times. (See figure 5.)

Figure 5: Number of Pharmaceutical Provision Mentions in Special 301 Reports (2000-2007)



Source: GAO analysis of Special 301 reports.

USTR's focus on patent linkage is also similar to its negotiating strategy in FTAs. The second most frequently mentioned pharmaceutical provision in Special 301 reports from 2000 through 2007 is patent linkage, which is mentioned 56 times. Pharmaceutical counterfeiting is also discussed somewhat regularly in the Special 301 reports over this period, but not as frequently as data protection or patent linkage.

USTR Has Only Infrequently Mentioned Compulsory Licensing or Parallel Imports in Special 301 Reports

There is limited mention of compulsory licensing or parallel imports in the Special 301 reports. In the Special 301 reports from 2000 through 2007, compulsory licensing regarding pharmaceuticals is only mentioned nine times, while parallel importing related to pharmaceuticals is mentioned only three times. While the IP objectives in TPA do not control the coverage of the Special 301 reports, USTR's approach to these two provisions referenced in the Doha Declaration seems similar. USTR officials explained that USTR recognizes that the TRIPS agreement allows

countries some flexibility regarding the use of compulsory licenses and parallel imports when protecting public health. By not mentioning these provisions frequently in the Special 301 report, USTR acknowledges the existence of these flexibilities, as highlighted in the Doha Declaration. However, USTR officials also noted that the infrequency with which these provisions are mentioned is due to the fact that the trading partners rarely make use of these flexibilities.

USTR Has Acknowledged Thailand's Right to Issue a Compulsory License, but Criticized Its Lack of Transparency

Thailand recently issued a compulsory license on a pharmaceutical product, citing a public health need. In November 2006, Thailand issued a compulsory license on a drug for treating HIV/AIDS, followed by two more compulsory licenses issued in early 2007 for another HIV/AIDS drug and a heart disease medication. These compulsory licenses are government-use licenses issued under Thai law. The government of Thailand announced that these decisions were aimed at improving access to essential medicines and public health in Thailand. In addition, Brazil issued a compulsory license for one of the same HIV/AIDS drugs in May 2007.

Public reaction to Thailand's and Brazil's actions has been mixed, with some defending their right to issue a compulsory license and others criticizing their actions as irresponsible. For instance, the pharmaceutical industry believes that the compulsory licenses were unnecessary and will ultimately negatively affect drug innovation, and is concerned the licenses will set a precedent for similar actions. However, many NGOs stated that they support countries like Thailand and Brazil using their right to issue compulsory licenses in order to improve access to medicines in their countries.

USTR's response to Thailand's and Brazil's issuance of compulsory licenses has been more measured. USTR officials told us that in all speeches, letters, and private conversations, USTR tried to recognize and convey that Thailand has the ability to issue compulsory licenses. However, they noted that, when issuing a compulsory license, it is important that the issuer engage with all of the affected stakeholders, including patient groups and patent holders, about the best way to meet public health needs. In both the Brazil and Thailand cases, USTR has tried to focus on the procedures and processes followed by the governments, rather than on the validity of the licenses. USTR officials noted that, in general, they are reluctant to insert themselves into price negotiations between governments and the pharmaceutical industry, but that they will advocate for transparency.

Although USTR mentioned both the Thai and possible Brazil cases of compulsory licensing in the 2007 Special 301 report, the report limited its criticism to issues of good governance. USTR officials noted that, at the time the report was issued, all three compulsory licenses had already been issued by Thailand, and that they believed the Brazilian compulsory license was imminent. For example, in the Thai case, USTR was careful in its report to recognize a country's ability to issue compulsory licenses subject to WTO rules and the country's domestic laws. However, it expressed concern about what it considered to be the lack of transparency exhibited in Thailand, and emphasized the need for such transparency in discussions with all relevant stakeholders in Brazil.

USTR officials stated that the decision to elevate Thailand from the watch list in its 2006 Special 301 report to the priority watch list in 2007 was based on broad IP concerns, not solely on its compulsory license decision. They explained that there were many major IP concerns in Thailand and many complaints that fueled their decision. In addition, they noted that, while Thailand was raised to the priority watch list, Brazil, which was also about to issue a compulsory license at the time, was lowered from the priority watch list to the watch list. They said that Brazil's standing improved due to impressive work in other areas of IP enforcement, and that the imminent compulsory license did not alter USTR's decision to improve Brazil's standing. Nevertheless, in its 2007 Special 301 report, USTR noted that it will conduct an out-of-cycle review to evaluate Brazil's progress in other areas and encourage additional progress in areas of outstanding concern.

Public Health Input on IP Rights Has Been Limited in U.S. Trade Negotiations

Since TPA, public health input into U.S. trade negotiations has been limited. In negotiating trade agreements under TPA, the President must seek advice and information from executive departments and the public and private sectors.[32] Although U.S. agencies generally support USTR's negotiations approach, interagency input on U.S. trade negotiations has not addressed the public health implications of IP pharmaceutical provisions negotiated under TPA and has been primarily technical in nature. For instance, HHS, the lead U.S. agency on global public health and social welfare issues, endorses USTR's negotiating approach that strong IP protection promotes public health and access to medicines. However, HHS advice during trade negotiations has generally concentrated on technical

[32]19 U.S.C. §§ 2152, 2155.

advice from one of its subagencies, the Food and Drug Administration (FDA), to ensure that FTA provisions related to pharmaceuticals do not violate U.S. law and are consistent with U.S. health regulations. HHS has not addressed policy questions related to whether FTA provisions might affect public health in FTA partner countries. Within the formal private sector advisory system, two public health representatives were recently added to two private sector Industry Trade Advisory Committees (ITACs) after USTR had concluded nine trade agreements. These two committees are respectively composed of 20 and 33 private sector representatives from the pharmaceutical and other industry sectors. USTR has obtained some public health perspectives from stakeholders through other formal and informal means, including public hearings, *Federal Register* comments, and written correspondence.

The Departments of Health and Human Services and State Endorse the View that IP Protection Supports Access to Medicine

HHS officials told us they support the USTR position concerning the Doha Declaration and agree with USTR's view that strong IP protection promotes innovation and access to medicines. The agency supports the administration's vision for both global health and overall U.S. foreign policy, and HHS's Office of Global Health Affairs (OGHA) is the U.S. focal point for policy coordination across multilateral health and science organizations. According to OGHA officials, the FDA's generic drug preapproval process is a key example of HHS efforts to balance high IP standards and access to medicines. Officials stated that the FDA generic drug preapproval process exhibits HHS support for creating a market for high quality generics that meet international standards. The agency has also supported USTR's interpretation of TRIPS flexibilities in multilateral discussions about IP and public health, such as those held at WHO. According to officials, HHS's OGHA coordinates U.S. policy inputs and interests as they pertain to IP rights and public health in WHO, ensures that the U.S. policy position at WHO meetings reflects administration priorities, and works with USTR and other U.S. agencies to advance U.S. IP and public health interests internationally. Most recently, HHS hosted the newly formed WHO Commission on Intellectual Property Rights, Innovation, and Public Health, and has been the lead federal agency in coordinating the U.S. response across agencies, including USTR, to a 2006 WHO report on IP rights and public health.

State Department officials also support the USTR's view that IP protection is important for promoting access to medicines. However, State Department officials said they principally demonstrate the U.S. strategy to balance IP rights and public health through various programs and initiatives. For example, State's Office of the Global AIDS Coordinator

(OGAC) works with several other agencies, including HHS, to implement the President's Emergency Plan for AIDS Relief (PEPFAR), which has programs in over 120 countries and a special focus on 15 countries that are primarily located in sub-Saharan Africa. OGAC and USAID also worked with the FDA to develop the generic drug preapproval process to support the purchase of low priced, high quality drugs for the PEPFAR program. This effort resulted in the preapproval of over 50 generic antiretrovirals (ARV) to date and almost $2 million in savings on generic drug purchases in 2006. In addition, USAID developed a centrally managed contract, the Partnership for Supply Chain Management, in order to work with generic companies to address drug supply chain challenges and increase research and development for a steady supply of ARVs in developing countries.

Interagency IP Rights and Public Health Perspective Is Limited to Technical Advice

USTR has obtained some input on IP rights and public health in trade negotiations through the formal interagency trade policy process, but public health perspectives on USTR's negotiating approach to pharmaceutical issues in FTA negotiations are primarily technical in nature and have not included an examination of the public health impacts of FTA provisions.[33] USTR coordinated with HHS when it first began to formulate its basic policy goals for negotiating FTAs, and HHS has had the opportunity to review draft FTA texts through the interagency advisory system. However, HHS has had limited involvement in the actual trade negotiations.[34] According to USTR, most public health issues are worked out in advance of the negotiations. HHS and USTR occasionally convene an interagency working group to discuss IP rights and public health issues that arise at WHO or in other multilateral fora.

[33]HHS, USAID, Commerce, and State, among others, participate in varied levels of the interagency advisory process through the Trade Policy Review Group (TPRG) and the Trade Policy Staff Committee (TPSC), in which agency officials may review the texts of FTAs and make comments. TPSC and TPRG are administered and chaired by USTR, and the groups are composed of 19 executive agencies and offices. The TPSC is the primary operating group, with representation at the senior civil service level, and if policy agreement is not reached in the TPSC, or if significant policy questions are being considered, issues are taken up by the TPRG, with representation at the Deputy USTR/Under Secretary level.

[34]During the TRIPS and public health debates at the WTO, USTR officials consulted with HHS officials, as well as with State and PTO officials, and HHS's Office of Global Health Affairs (OGHA) was very involved in developing the U.S. proposals for the paragraph six solution.

Although USTR routinely briefs HHS after each round of FTA negotiations, OGHA officials stated that the health agency's role in trade, IP rights, and the negotiation of pharmaceutical-related IP provisions in FTAs has primarily involved providing technical expertise through its subagencies when requested by USTR. For example, FDA officials stated that their overall mission is generally not related to trade, but instead focuses on regulatory matters as they affect public health. The agency offers technical advice to USTR during negotiations to ensure that FTA provisions related to pharmaceuticals do not violate U.S. law and are consistent with U.S. health regulations. For instance, the FDA has provided a perspective on regulatory issues in FTAs to ensure that provisions do not have implications for U.S. regulatory programs. HHS officials also stated that they have no role in assisting countries in pursuing objectives of the Doha Declaration. Although they have good working relationships with the health ministries of many countries, conversations generally focus on technical advice with regard to regulatory issues. For example, subagencies such as the FDA may provide regulatory advice and guidance to FTA partners, during negotiations or FTA implementation, on the regulatory responsibilities associated with various IP provisions, the manner in which provisions function in the United States, and how U.S. regulatory systems operate.

OGHA officials told us they are satisfied with HHS's role and input in the interagency advisory process and the public health considerations provided in U.S. trade negotiations and policy, and the office does not believe IP provisions in FTAs restrict access to medicines. However, there is little evidence that USTR consulted with HHS or OGHA regarding FTA partner countries' concerns about the potential impact on public health of specific pharmaceutical provisions in FTAs since the Doha Declaration and the Trade Promotion Authority Act of 2002 were agreed upon, although the HHS OGHA's mission includes promoting the health of the world's population. OGHA officials noted that USTR has never approached them to discuss such country concerns about public health. According to USTR officials, USTR does not generally talk to HHS about countries' concerns about the public health impact of FTA provisions, but instead relies on the countries themselves to raise concerns, since developing countries know their own public health systems and needs better than any U.S. agency would. Similarly, HHS has not been asked by USTR to conduct analyses of the impacts of FTA provisions on regulatory institutions in partner countries, and HHS has not provided such an assessment. There is also little evidence that the agencies have determined whether the FTAs affect public health, either positively or negatively, and HHS officials stated they do not have the technical capacity to do so.

Similarly, the PTO Office of International Affairs is involved in the FTA negotiations process as a technical advisor under its statutory authority regarding IP issues. The office advises USTR on WTO issues and FTAs, meets with USTR to discuss strategy before each round of FTA negotiations, and participates in the negotiations. For example, USTR may ask PTO's opinion about the use of a particular technical term. PTO also provides technical advice and training to FTA partner countries on pharmaceutical IP provisions during FTA negotiations, and provides clarification on the interpretation of negotiated provisions. For instance, in the CAFTA-DR negotiations, partner countries asked PTO to explain data exclusivity in further detail and how the provision functions in the United States. According to officials, PTO never states that the U.S. method of implementing a particular provision is the only way to implement or fulfill a particular FTA obligation, but instead simply provides U.S. examples.

The State Department is also involved in interagency coordination on trade and public health through the interagency advisory system as well as during FTA negotiations, but agency officials stated that trade and IP efforts are only one small part of the larger U.S. government effort to increase access to medicines. USTR consults with State through the formal interagency advisory review process, and State officials are included in all discussions of IP chapters in the FTAs. However, the agency primarily makes an effort to balance IP rights and access to medicines through public health initiatives it coordinates with other agencies or administers itself, such as PEPFAR. USAID has extensive global health programs and had some involvement in policy discussions at the time of the Doha Declaration. The development agency has had little or no involvement in such discussions since, however.

Public Health Representatives Were Recently Added to the Industry Trade Advisory Committees

In January 2007, public health representatives were added to the two technical ITACs most relevant to pharmaceuticals and IP rights—the chemicals committee (ITAC-3) and the IP committee (ITAC-15)—where multiple brand-name pharmaceutical companies serve. However, by the time that USTR and the Department of Commerce had appointed one public health representative to each of these two committees, USTR had concluded nine FTAs.

According to Commerce officials, the appointments were prompted by an April 2005 request by an NGO for public health perspectives in several of

the industry trade advisory committees. Within 3 months, Commerce and USTR agreed to consider adding public health representatives to the industry advisory system, but the appointments were delayed until 2007.[35] Although USTR and Commerce indicated at least one public health representative would be appointed to both the IP committee and the chemicals committee in December 2005, a coalition of NGOs filed a lawsuit against USTR during the same month for public health representation on six other ITACs in the trade advisory committee system as initially requested in 2005.[36] The lawsuit is pending an appeal, after an initial ruling dismissing the case on the grounds that the court could not find any meaningful standards in the Trade Act of 1974 under which it could judge the balance of the membership of the trade advisory committees.[37] Due to the ongoing litigation relating to the composition of the trade advisory system, we do not make any judgments about the appropriateness of a particular committee's composition.

USTR maintains that representatives in other trade advisory committees provided public health input on FTAs. For instance, USTR noted that Trade and Environment Policy Advisory Committee (TEPAC) members had access to the secure private sector advisory Website, and that some groups in that committee had expressed concern about provisions in several FTAs. Specifically, some environmental and consumer group NGOs on the committee have submitted concerns to USTR in committee reports on the FTAs about the impacts certain FTA provisions have on public health and access to medicines. In an alternative opinion attached to several committee reports, the minority group of TEPAC representatives maintained that U.S. FTAs are inconsistent with the Doha Declaration on TRIPS and Public Health and that FTA provisions on data

[35]Department of Commerce officials cited the Doha negotiations, the rechartering of the industry trade advisory committees, and the time required to send out notices of position openings, vet applicants, and obtain security clearances.

[36]*Ctr. for Policy Analysis on Trade and Health (CPATH) v. Office of the United States Trade Representative*, No. 05-05177 MJJ (N.D.Cal. June 30, 2006), appeal docket, No. 06-16682 (9th Cir. Sept. 14, 2006). The industry advisory committees cited in the lawsuit are ITAC-4 (Consumer Goods), ITAC-5 (Distribution Services), ITAC-8 (Information and Communications Technologies, Services and Electronic Commerce), ITAC-10 (Services and Finance Industries), ITAC-14 (Customs Matters and Trade Facilitation) and ITAC-16 (Standards and Technical Trade Barriers).

[37]Pursuant to Federal Advisory Committee Act, an advisory committee's membership must be "fairly balanced in terms of the points of view represented and the functions to be performed by the advisory committee." 5 U.S.C. App. 2 § 5.

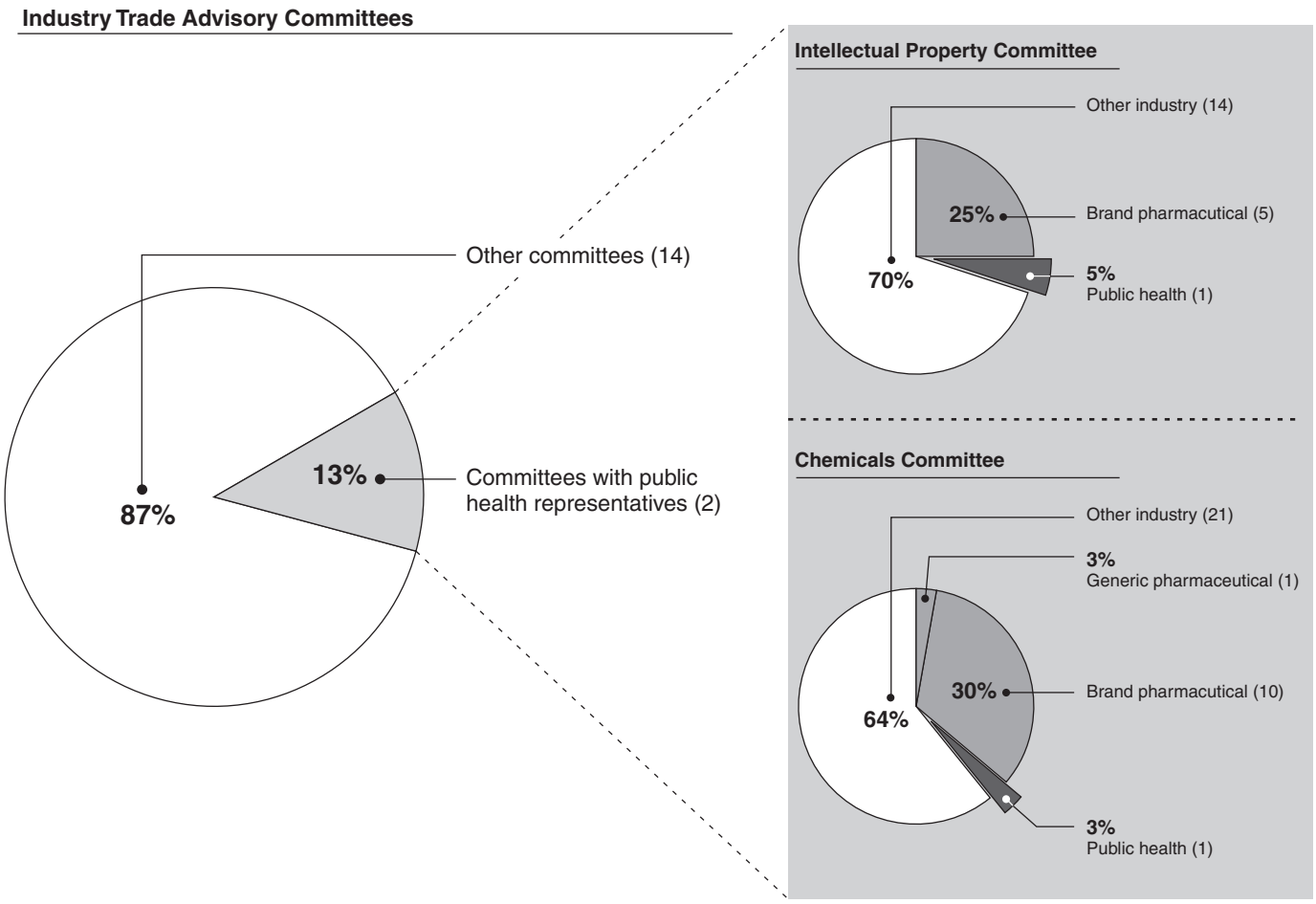
exclusivity and patent linkage, as well as limitations on the use of compulsory licensing, reduce access to medicines. They recommended that Congress not approve some FTAs and requested Congress to take their public health concerns into account when considering other FTAs.

There is little evidence that USTR discussed the concerns submitted about the public health impact of FTAs with U.S. health agencies or other members of the public health community. A member of the TEPAC committee also noted that although the environmental advisory committee reports provided to USTR include the committee members' recommendations or concerns about public health in FTAs, there is little dialogue between USTR and committee members on these issues. In the member's opinion, this is because the advisory consultations are not integrated into the FTA negotiations process, which limits the ability of members to advise USTR on the issues that arise during negotiations, including public health concerns, as opposed to after a draft has been developed. However, USTR notes that the concerns have been raised and discussed by the USTR personally during TEPAC meetings.

The Committees on Which Public Health Representatives Participate Are Composed of a Majority of Other Private Sector Industry Stakeholders

The two individuals that were appointed as public health representatives on the ITACs individually serve on committees that are respectively composed of a total of 20 and 33 private sector representatives from the pharmaceutical and other industry sectors. (See figure 6.) Commerce officials explained that, in selecting among the 10 applicants who responded to the *Federal Register* notice, they considered candidates' backgrounds to determine if the candidates understood both relevant IP issues and which public health concerns would be relevant to the intersection of public health, international trade, and IP rights or pharmaceuticals, respectively, as relevant to the work of the committees. According to these officials, the selection committee also tried to ensure that the representatives would make meaningful contributions to the committees and have the weight necessary to challenge the committees when necessary. Commerce officials did not believe it was necessary to have two public health representatives on one committee representing the same view, and they said that they did not find any other viable candidates with additional perspectives beyond the individuals selected. However, Commerce officials stated that the *Federal Register* notice announcing the positions on the ITACs remains open. If additional qualified public health candidates applied would contribute another perspective to either of these two committees applied, they said the agency would consider adding additional public health representation.

Figure 6: Public Health Representation on Industry Trade Advisory Committees



Source: GAO analysis of USTR documents.

USTR Has Received Public Health Input through Other Formal and Informal Means

Our review showed that, although USTR has received limited input on public health through formal advisory system communications channels, it has received public health input through other formal and informal processes, including input from the pharmaceutical industry and the public health community. Pharmaceutical Research and Manufacturers of America (PhRMA), the pharmaceutical industry trade group, has submitted annual reports to USTR on industry concerns about IP rights globally for the agency to consider in developing its Special 301 report. Both pharmaceutical industry representatives and public health community members have also provided input on IP rights and public

health concerns for several FTAs that have been concluded through USTR's formal public hearings and the *Federal Register* comments. In addition, USTR has received and responded to congressional correspondence regarding members' public health concerns about the impact of FTAs. According to USTR officials, while there are some minor modifications to FTA texts during each negotiation, the public health community is aware of the provisions the United States proposes to be included in each agreement, given past FTAs implemented, and may also provide public health input through more informal mechanisms. For example, USTR has received and responded to some informal input on public health in trade negotiations through correspondence with NGOs. Moreover, USTR officials noted that they have an open door policy and will meet with anyone who requests a meeting, including NGOs, public health representatives, and generic industry representatives. Both USTR and private sector representatives, including NGOs, have confirmed that private sector representatives have provided informal input to USTR on public health concerns, in particular FTAs, through phone calls or requested meetings. However, input USTR receives through such channels may lack the weight of formal private sector input on public health issues in trade agreements, such as trade advisory committee reports on proposed trade agreements that are transmitted to the administration and Congress.

Conclusions

USTR has followed a consistent approach in negotiating, implementing, and monitoring its trade agreements under TPA—namely, by protecting the minimum standards of IP rights provided in TRIPS and promoting high IP standards similar to U.S. law. Other than making concessions on compulsory licensing and parallel importation provisions, and on side letters that state that the IP chapter does not affect a country's ability to take necessary public health measures, USTR has not changed its uniformly high demands with regard to IP protection in its FTAs. The degree to which USTR's policy has achieved the right balance of IP protection and attention to public health, and more specifically whether it has respected the Doha Declaration as called for under TPA, depends in part on the stakeholder asking the question. This reflects a fundamental tension between protecting IP rights in order to allow companies to recoup investment and encourage innovation for the long term, and allowing competitors to sell lower cost drugs for short term public health needs. As Congress contemplates renewal of TPA, there are ongoing questions about the overall balance of IP rights and public health.

Matter for Congressional Consideration

If Congress disagrees with USTR's interpretation and implementation of TPA guidance with regard to IP rights and public health, it should specify more clearly its intentions for U.S. trade policy and public health policy input related to balancing public health concerns and the negotiation of IP rights in trade agreements.

Agency Comments and Our Evaluation

We provided the U.S. Trade Representative; the Secretaries of the Departments of Commerce, Health and Human Services, and State; the Administrator of the U.S. Agency for International Development; and the Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office with a draft of this report. The U.S. Trade Representative; the Secretaries of the Departments of Commerce, Health and Human Services, and State; and the Administrator of the U.S. Agency for International Development chose to provide technical comments. We modified the report where appropriate.

As agreed with your offices, unless you publicly announce the contents of this report earlier, we plan no further distribution of it until 30 days from the date of this letter. At that time, we will send copies of this report to the U.S. Trade Representative; the Secretaries of the Departments of Commerce, Health and Human Services, and State; the Administrator of the U.S. Agency for International Development; and the Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office. We also will make copies available to others upon request. In addition, the report will be available at no charge on the GAO Web site at http://www.gao.gov.

If you or your staff has any questions concerning this report, please contact me at (202) 512-4128 or at yagerl@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff members who made major contributions to this report are listed in appendix IV.

Sincerely yours,



Loren Yager
Director, International Affairs and Trade

Appendix I: Scope and Methodology

To evaluate how the U.S. has interpreted the intent and meaning of the Doha Declaration, we performed document reviews on agency documentation and correspondence as well as WTO documents, and conducted interviews. We also reviewed academic studies, pharmaceutical industry reports, position papers, and media reports. Specifically, we examined relevant WTO legal documents, including the declaration on TRIPS and Public Health; the 2003 General Council Chairperson's statement; the August 30, 2003, General Council Decision on the Implementation of Paragraph 6 of the Doha Declaration on TRIPS and Public Health; the December 6, 2005, General Council Decision on the Amendment of TRIPS; and relevant articles of the TRIPS agreement. We reviewed WTO TRIPS Council minutes and other official documents, reviewed USTR official documents, interviewed USTR officials in Washington and Geneva, and interviewed WTO officials and WTO country representatives in Geneva.

To investigate how the United States negotiates and oversees implementation of IP provisions related to pharmaceuticals in its trade agreements, we interviewed USTR officials, reviewed agency documents, and examined the text of the FTAs negotiated since the Trade Act of 2002. We spoke to USTR officials about their views on the three IP negotiating objectives in TPA and their overall approach for pursuing these objectives. Specifically, we learned about the pharmaceutical provisions pursued by USTR in the IP chapter of its FTAs, and how the pursuit of these provisions relates to their negotiating approach. We also reviewed agency documentation of negotiating policy, draft texts of FTAs, and other types of documentation in order to further examine the IP negotiating policy pursued by USTR. In order to analyze the patterns and results of USTR's stated approach, we reviewed the text of each of the 11 FTAs negotiated under TPA. We evaluated the pharmaceutical-related IP provisions in each agreement and catalogued which related provisions were present in the final text of each agreement. Using this information, we were able to identify patterns and thereby confirm USTR's stated policy regarding the pursuit of these provisions. We did not assess the reliability of the per capita income data contained in figure 2 because we are providing them as background information only.

In addition, we interviewed officials from Department of State, Department of Health and Human Services (HHS), Department of Commerce, the Patent and Trademark Office (PTO), and the U.S. Agency for International Development (USAID) in order to obtain their perspectives on the pharmaceutical provisions pursued in the FTAs. We performed literature reviews of articles and studies documenting the

multiple opinions regarding these provisions pursued by USTR. From this literature review and from agency meetings, we identified numerous stakeholders and experts to speak with, including pharmaceutical industry representatives, public health groups, NGOs, academics, and IP experts. These groups include Pharmaceutical Research and Manufacturers of America (PhRMA), Generic Pharmaceutical Association, (GPhA), The International Federation of Pharmaceutical Manufacturers & Associations (IFPMA), Oxfam, Doctors without Borders (MSF), Essential Information, Consumer Project on Technology,[1] Health Global Access Project (GAP), Health Action International, Center for Policy Analysis on Trade and Health (CPATH), Access to Drugs Initiative (ADI), Third World Network, Center for International Environmental Law (CIEL), International Center for Trade and Sustainable Development (ICTSD), Drugs for Neglected Diseases Initiative (DNDI), as well as three academics, two intellectual property lawyers, and three public health experts specializing in this area. We interviewed these stakeholders and experts in order to gather a complete perspective on USTR's negotiating strategy and the pharmaceutical-related IP provisions present in the FTAs. We also traveled to Geneva, Switzerland, to meet with officials from the U.S. Mission in Geneva; World Trade Organization (WTO); World Health Organization (WHO); World Intellectual Property Organization; The Joint United Nations Program on HIV/AIDS; United Nations Development Program; the Global Fund to Fight AIDS, Tuberculosis and Malaria, as well as NGOs from the pharmaceutical sector and public health community.

In order to examine how USTR implements and oversees its trade agreements, we interviewed USTR officials, reviewed agency documentation, and analyzed USTR's annual Special 301 reports. We spoke to USTR officials and reviewed agency documentation about their approach to implementing and overseeing its trade agreements. In addition, we examined trends and patterns of citations found in USTR's annual Special 301 reports in order to analyze how USTR oversees its trade agreements with respect to IP provisions related to pharmaceuticals. We reviewed each Special 301 report from 2000 to 2007 in order to identify every mention of a pharmaceutical-related issue for all countries listed on

[1]Name recently changed to Knowledge Ecology International.

the priority watch list,[2] the watch list,[3] and the Section 306 list[4]. For each country listed in the report in every given year, we noted whether the report mentioned anything related to a pharmaceutical issue or concern. We reviewed the reports using decision rules we developed to identify the most frequently discussed pharmaceutical issues in Special 301 reports over this period. To enhance the accuracy and soundness of our review, two GAO staff members conducted independent reviews of the reports. These staff members had a high degree of concurrence in the pharmaceutical issues they identified and were able to reconcile the instances where they differed initially. We also interviewed USTR officials about some of the factors considered during the Special 301 process in order to determine limitations to our analysis. Limitations to our analysis include the inherent selection bias in the USTR reports, since the Special 301 report does not capture each IP concern in every country. Also, there are numerous factors governing a country's inclusion, but USTR generally focuses on countries with relatively higher levels of development. The analysis is also limited to only pharmaceutical-related issues raised in the Special 301 report over this period and does not capture the weight of each concern. In addition, pharmaceutical counterfeiting may be undercounted in this analysis due to the fact that it may be subsumed into more general references to trademark counterfeiting and inadequate enforcement. We also obtained and compared the input provided to USTR by U.S. embassies and the pharmaceutical industry. Additionally, we spoke to USTR officials about the factors taken into account for the 2007 Special 301 report, specifically regarding the decision of Thailand and Brazil to issue compulsory licenses on pharmaceutical products.

[2]Countries that have the most onerous or egregious acts, policies, or practices and whose acts, policies, or practices have the greatest adverse impact (actual or potential) on the relevant U.S. products must be designated as "Priority Foreign Countries." Countries placed on the Priority Watch List are the focus of increased bilateral attention concerning the problem areas.

[3]Placement of a trading partner on the Priority Watch List or Watch List indicates that particular problems exist in that country with respect to IP rights protection, enforcement, or market access for persons relying on intellectual property (IP).

[4]Any country that was previously designated a Priority Foreign Country but entered into good-faith negotiations and/or is making progress is placed under Section 306 monitoring. Under Section 306, USTR monitors a country's compliance with bilateral IP agreements that are the basis for resolving an investigation under Section 301.

To investigate how USTR assists other countries in implementing FTAs and TRIPS obligations, we interviewed agencies involved in providing technical assistance to FTA partner and nonpartner countries, including USTR, HHS, PTO, and USAID. We spoke with agency officials about the type of technical assistance they provide on the FTAs, Doha Declaration flexibilities, and public health and about the audience receiving the assistance. We also reviewed technical assistance and training-related documents and correspondence to corroborate the testimonial evidence.

In order to evaluate the extent of formal and informal IP and public health input into USTR's trade agreement negotiations, we examined the formal interagency advisory process, the formal industry advisory committee process, and several informal means for providing input to USTR. To examine the level of interagency consultation on trade, IP, and public health issues between USTR and the Department of State, HHS, Department of Commerce, PTO, and USAID, we reviewed documentation of interagency discussions related to the TRIPS Doha Declaration and FTAs. Limited documentation was available. We also interviewed USTR, Commerce, HHS, State, PTO, and USAID officials about their roles in the interagency advisory process and the public health input they provided or received during WTO discussions on the TRIPS and Public Health Declaration and during FTA negotiations.

To evaluate the type and extent of public health input USTR received through the industry trade advisory process, we reviewed industry advisory committee reports for the IP and chemicals committees, as well as the trade and environment committee. We also evaluated the membership of the IP and chemicals industry advisory committees to determine the composition of industries and interests represented. However, we did not make any judgments about the appropriateness of any particular committee's composition. In addition, to better understand the selection and appointment process for the public health representatives on the IP and chemicals industry advisory committees, we interviewed USTR, Commerce, and HHS officials and reviewed documentation related to the representatives' appointments. We also spoke with the primary NGO involved in the initial request for public health representation on the industry advisory committees, as well as several other NGO and academic members of the public health community, about their views on the public health representative appointments. Moreover, we interviewed selected members of the trade and environment committee, to obtain perspectives on the advisory process and public health input provided to USTR through it. Furthermore, we reviewed records of USTR's public hearings on FTAs,

Federal Register notice comments, and congressional and private sector correspondence with USTR on the FTAs and the issues of IP rights and public health. We also spoke with several NGOs about public health input they provided to USTR through meetings and phone calls.

Appendix II: Technical Assistance on IP Rights and Public Health

Technical assistance on IP rights and public health to FTA partner and nonpartner governments has been limited and provided mostly upon host country request. According to USTR officials, U.S. negotiators review each FTA provision in the text with the signatories, at which time they may also ask for technical assistance. Also, FTA partner countries always have the option of requesting trade-capacity building assistance from the United States at the conclusion of negotiations. However, USTR has never had a request for TCB on the Doha Declaration, and only on IP matters related to enforcement. USTR does not initiate technical assistance on FTA provisions and the use of TRIPS flexibilities, but responds to country requests, which it forwards to the appropriate agency. U.S. agencies tend to provide technical advice to FTA partner governments on regulatory issues, rather than public health issues. For example, the FDA has provided technical assistance to partner countries in developing implementing regulatory measures. Similarly, technical assistance activities conducted by USAID and PTO include conferences, workshops, capacity-building cooperation agreements, and patent program certificate programs on topics such as international IP standards in TRIPS, drafting trade reform legislation, and enforcement of IP rights. Specific IP issues discussed include data exclusivity, patent extensions, and implications of FTA IP rights commitments.

According to USAID officials, USAID can provide technical assistance if the host country has requested assistance in a particular area. Although FTAs have helped promote training in the area of intellectual property and public health, the agency has not done much work on those topics. USAID officials said that most training occurs during FTA negotiations, but FTA partner countries often receive the training from WTO or another third party in order to gain a more objective training or perspective than they believe they would receive from the United States. Similarly, according to PTO officials, most requested PTO training is with respect to FTA agreements and primarily focuses on the implementation and enforcement of FTA provisions, and the audience is generally patent examiners conducting enforcement activities. The PTO Global IP Academy, established in 2005, is another example of PTO's technical assistance on IP matters to other countries, whereby PTO trains foreign officials on IP enforcement. The agency also advises countries on drafting implementing legislation and the development of compliance regulations.

Agencies also provide general technical assistance to countries on TRIPS obligations. For example, Commerce's Commercial Law Development Program, which receives some funding from USAID, has provided training to Pakistan on TRIPS and the role of U.S. agencies in domestic patent and

data protection. However, according to USTR, most requests related to TRIPS IP issues fall in nonpharmaceutical IP areas, such as trademark registration, enhancing patent processing, or enforcement capacity. PTO officials stated that they offered a course on biotechnology that covered all aspects of patent, copyright, and trademark WTO provisions. The State Department has also provides a standard training on IP rights to U.S. Foreign Service Officers through the Foreign Service Institute (FSI), which includes basic information on patents, data protection, and other U.S. and TRIPS IP provisions. The training also provides an overview of the Doha Declaration and TRIPS flexibilities, including the use of compulsory licenses, as well as a summary of the U.S. government's objectives for access to medicines.

While there has been no proactive agency effort to assist countries in using the Doha Declaration TRIPS flexibilities, agencies have developed and provided some information upon request. USAID has worked closely with USTR to develop such U.S.-sponsored training that is TRIPS compliant and has recently added discussion about the Doha Declaration and the implementation of compulsory licensing into training on the use of TRIPS flexibilities. For instance, USAID funded a presentation in Lebanon on TRIPS implementation in response to requests for assistance with its WTO accession. In addition, USAID technical assistance projects were implemented in Egypt related to IP rights and public health, including a conference on IP and pharmaceuticals that covered TRIPS, the Doha Declaration, compulsory licensing, and data exclusivity, under the auspices of the prime minister and minister of health. Similarly, USAID presented in Uganda a workshop on Developments at Doha, including TRIPS and public health, as part of assistance taking place in December 2001 and January - February 2002. USTR stated that Honduras also conferred with the United States about how to use the paragraph six waiver to issue a compulsory license, but the drug was not under patent and training was ultimately not necessary. PTO has also conducted training on relevant IP provisions, including on U.S. laws and regulations related to data exclusivity and patent linkage, in response to country requests. PTO officials emphasized, however, that it is not PTO's role to ensure that these countries implement the provisions in the same manner as the United States. In fact, PTO makes an effort to understand the country's legal context and capacity so that its advice is appropriate to its circumstances.

In addition, U.S. agencies offer some assistance related to technology transfer, which is referred to in paragraph seven of the Doha Declaration on TRIPS and Public Health. For example, HHS provides significant

assistance to developing countries though its technology transfer activities. The National Institutes of Health (NIH) has developed innovative programs to improve how technologies are transferred to developing countries, particularly by identifying those biomedical research companies and institutions that have the interest and capacity to receive and develop new biomedical products. According to HHS officials, NIH has one of the largest biomedical technology transfer offices in the world. NIH's Office of Technology Transfer (OTT) has successfully transferred technologies, mostly for infectious disease diagnosis, treatment and prevention, to institutions in developing countries such as India, Mexico, Brazil, China, Egypt, and South Africa and currently is working with institutions in other developing countries. NIH OTT has also initiated a limited international technology transfer capacity building program to train scientists and managers from institutions in developing countries about intellectual property management and other technology transfer-related matters. Similarly, USAID is involved in some technology transfer assistance. According to agency officials, USAID recently established a technology transfer program in Columbia to assist the local generic industry.

Appendix III: GAO Contact and Staff Acknowledgments

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Staff Acknowledgments

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