

Intellectual Property Rights and Access to Medicines: International Trade Issues

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Summary

A patent, which is a form of intellectual property right (IPR), is a legal, exclusive right granted for the invention of a new product, process, organism, design, and plant. It allows the right holder to exclude others from making, using, or selling the protected invention for a period of 20 years. Patents constitute the most common method for governments to encourage research and development (R&D) in order to find pharmaceutical treatments and cures for diseases and other illnesses.

IPR protection and enforcement have evolved from an area primarily of national concern to an area of international trade policy. The World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) established minimum standards for IPR protection and enforcement.

The U.S. government considers the protection and enforcement of international IPR standards, including those for patents, to be an important goal of U.S. trade policy for economic, health and safety, and national security reasons. As such, the United States has pursued strong IPR regimes through multilateral, regional, and bilateral free trade agreement (FTA) negotiations and unilateral trade policy tools, namely the Special 301 process and the Generalized System of Preferences (GSP).

IPR provisions in trade policies are among the range of social, economic, and political factors that may affect public health, including the ability of countries to deliver health services to their populations. Patents, through their possible impact on innovation and drug prices, may affect access to existing medicines and the development on new medicines. According to the World Health Organization (WHO), about one-third of the world's population, primarily those residing in poorer parts of Africa and Asia, lacks regular access to essential medicines.

While the United States places priority on promoting a strong international IPR regime, some Members of Congress have expressed concern over how to balance the goals of providing long-term incentives for innovation through patents and addressing the short-term need to provide affordable access to medicines.

This report focuses on the relationship between IPR provisions in international and U.S. trade policy and access to medicines. This issue represents one component of a broader debate about the relationship between trade policy and public health. Possible issues of interest for Congress include incorporating public health concerns into the U.S. trade policy advisory process, developing new U.S. trade policy guidance on public health, considering the implications of the U.S. strategy on IPRs and trade for U.S. access to medicines, and reviewing the range of options utilized for expanding global access to medicines. This report will be updated periodically as warranted by events.

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Introduction

This report focuses on the relationship between intellectual property rights (IPRs) provisions pursued through international and U.S. trade policy and access to medicines.[1] Patents, a form of IPR, constitute the most common method for governments to encourage research and development (R&D) in order to find treatments and cures for diseases and other illnesses. A patent is a legal, exclusive right granted for the invention of a new product, process, organism, design, and plant that allows the right holder to exclude others from making, using, or selling the protected invention for a period of 20 years. By a granting temporary, exclusive right to the market for the protected product, a patent enables the right holder to generate profits to recover the costs for investment in R&D and to invest in future innovations. However, some express concerns that patents enable right holders to price drugs at levels that greatly surpass marginal costs of R&D and production, raising questions about the role of patents in affecting access to medicines and public health.

IPR protection and enforcement have evolved from an area primarily of national concern to an area of international trade policy. The World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) established minimum standards for IPR protection and enforcement. Countries have advanced IPR protection and enforcement efforts through multilateral, regional, and bilateral free trade agreements (FTAs) and unilateral trade policies. [2]

Congress makes and shapes U.S. trade policy by passing statutory authorities that authorize trade programs, governing trade policy in a range of issue areas, setting trade negotiating objectives into law, engaging in consultations with the Executive Branch on trade negotiations, and conducting oversight hearings on U.S. trade policy and programs.[3] Within Congress, there has been significant interest in promoting and protecting IPRs through trade policy for economic, health and safety, and national security reasons. IPR-based industries are viewed as an important contributor to U.S. innovation, productivity, economic growth, employment, and international trade. Advocates of a strong international IPR regime claim that counterfeiting and piracy inflict billions of dollars of revenue and trade losses annually on U.S. IPR-based industries. Some policymakers also have expressed concern about the health and safety implications of counterfeit goods, including pharmaceutical drugs.[4] Finally, some lawmakers contend that IPR infringement operations are tied to organized criminal syndicates and terrorist financing activities.

The Office of the U.S. Trade Representative (USTR) considers the protection and enforcement of international IPR standards to be a high priority for U.S. trade policy. As such, the USTR has pursued strong IPR regimes by participating in multilateral, regional and bilateral FTAs, as well

[1] This report builds on CRS Report RL33750, *The WTO, Intellectual Property Rights, and the Access to Medicines Controversy*, by Ian F. Fergusson.

[2] For an overview on IPRs and international trade issues in general, see CRS Report RL34292, *Intellectual Property Rights and International Trade*, by Shayerah Ilias and Ian F. Fergusson.

[3] CRS Report RL33944, *Trade Primer: Qs and As on Trade Concepts, Performance, and Policy*, coordinated by Raymond J. Ahearn.

[4] Related legislation introduced in the 111th Congress includes H.R. 759, the Food and Drug Globalization Act of 2009; H.R. 1450, the Counterfeit Drug Prevention Act of 2009; S. 80, the Pharmaceutical Market Access Act of 2009; and H.R. 1298, the Pharmaceutical Market Access and Drug Safety Act of 2009, and the Senate version, S. 525.

as through unilateral trade policy tools, namely the Special 301 process and the Generalized System of Preferences (GSP).

IPR provisions in trade policies are among the range of social, economic, and political factors that may affect public health. While patents may provide incentives for innovation, their granting of market exclusivities and impact on prices raise questions about the affordability of medicines, particularly for (but not limited to) low-income countries and their populations. Through their possible impact on innovation and drug prices, patents may affect the ability of countries to provide medicines to their populations and for populations in general to access medicines. For some observers, this may represent a conflict between free market and public health policies. While the commercialization of public health may promote innovation and efficiency, the laws of supply and demand may cause some people to be "priced out" of a given market.

According to the World Health Organization (WHO), about one-third of the world's population, primarily residing in poorer parts of Africa and Asia, lack regular access to essential medicines.[5] Infectious diseases are major contributors of illness, death, and poverty in the developing world. In 2007, an estimated 33 million people were living with HIV/AIDS in 2007, most of whom were in Africa. In addition to the HIV/AIDS pandemic, other infectious diseases, such as tuberculosis, malaria, and influenza, also present critical global health challenges.[6] Over one billion people, primarily among the world's poorest, also are afflicted with neglected tropical diseases, which largely are infectious parasitic diseases prevalent in "impoverished" environments.[7]

In 2000, the United Nations established eight Millennium Development Goals, to which the United States is a signatory, in an effort to end poverty by year 2015. One of the U.N. targets is to achieve universal access to treatment for HIV/AIDS by 2010 and to have halted and reversed the spread of HIV/AIDS, malaria, and other major diseases by 2015. While prevention is key to combating infectious diseases, access to treatment is also critical to controlling epidemics. As such, another MDG target is to cooperate with pharmaceutical companies to provide access to affordable essential drugs in developing countries. Access to medicines has improved dramatically over the past couple of decades. For example, access to certain anti-retroviral (ARV) treatment for HIV/AIDS rose by over 40% in 2007, largely attributable to financing from the Global Fund to Fight AIDS, Tuberculosis, and Malaria ("the Global Fund") and the U.S. President's Emergency Plan for AIDS Relief (PEPFAR).[8]

Although access to medicines is an important goal and is the focus of the discussion at hand, some public health professionals caution that "over-access" also can be a problem. Proponents of this view assert that that the availability of medicines due to lower prices may promote misuse, leading to the faster onset of drug resistance and shorter duration of the drug's usefulness.[9]

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[5] The WHO defines essential medicines as "those that satisfy the priority health care needs of the population. They are selected with due regard to public health relevance, evidence on efficacy and safety, and comparative cost-effectiveness."

[6] CRS Report RL33396, *The Global Fund to Fight AIDS, Tuberculosis, and Malaria: Progress Report and Issues for Congress*, by Tiaji Salaam-Blyther.

[7] World Health Organization, *Neglected Tropical Diseases: Frequently Asked Questions*, updated March 25, 2009, http://www.who.int/neglected_diseases/en/.

[8] United Nations, *High-level Event on the Millennium Development Goals*, associated fact sheets, New York, NY, September 25, 2006.

[9] Ramanan Laxminarayan, Mead Over, and David L. Smith, "Will a Global Subsidy of Artemisinin-Based Combination Treatment (ACT) for Malaria Delay the Emergence of Resistance and Save Lives?", World Bank, Policy (continued...)

There is ongoing debate within Congress about the impact that IPR provisions in international and U.S. trade policies may have on access to medicines and public health. At the center of the debate is the question of how to balance providing long-term incentives for innovation through patents and addressing the short-term need to provide affordable access to medicines. The debate over the role of patents and trade policy in affecting access to medicines often has been framed as one in which high-income, developed countries and innovator ("brand name") pharmaceutical companies are pitted against low-income, developing countries and global health advocates. However, the number of stakeholders is more diverse, and includes middle-income, industrializing countries and generic drug manufacturers. In addition, there is debate within the governments of countries about how to balance advancing economic interests and public health outcomes through trade policy.

The debate over IPRs and access to medicines represents one component of a broader debate over the relationship between international trade policy and global public health. Over time, these two arenas have shown increasing overlap. In some cases, the linkages have been clear. For instance, international trade in goods that contain dangerous pathogens or counterfeit substances presents clear threats to public health. In other cases, as in the debate at hand, the linkages may not be so clear-cutting, or trade issues may only form one component of the public health issue.[10]

Background

The global pharmaceutical industry is classified as a high-technology industry by the Organization for Economic Co-operation and Development (OECD). As a high-technology manufacturing industry, the pharmaceutical industry spends a high proportion of its revenues on research and development (R&D), which can lead to innovative solutions to treat global health problems.[11]

The pharmaceutical industry is heavily reliant on protection of intellectual property rights (IPRs), specifically patents. Patents are the most common way for governments to encourage R&D and to foster innovation. A patent is a time-limited, legal, exclusive right granted for the invention of new products, processes, organisms, designs, and plants that allows the right holder to exclude others from making, using, or selling the protected invention for a period of 20 years. A patent does not necessarily provide the right holder with the "right to sell" the protected invention, as the right holder may need to comply with other regulatory laws. For example, pharmaceutical drugs generally also must be reviewed by a regulatory body (in the case of the United States, the Food and Drug Administration, FDA) for other considerations, such as health and safety, before it may be sold to consumers.

(...continued)

Research Working Paper No. 3670, Washington, D.C., 2005. Cited by Carsten Fink, "Intellectual Property and Public Health: An Overview of the Debate with a Focus on U.S. Policy," Working Paper Number 146, June 2008.

[10] David P. Fidler, Nick Drager, and Kelley Lee, "Managing the Pursuit of Health and Wealth: The Key Challenges," *The Lancet*, vol. 373 (January 24, 2009), pp. 328-329.

[11] National Science Foundation, "*Science and Engineering Indicators 2008*, "Industry, Technology, and the Marketplace," NSB 08-01; NSB 08-01A, Arlington, VA, January 2008, p. 16.

Incentives for Innovation

By granting time-limited, exclusive monopolies on the market for a product, patents generate above-market financial returns that are believed to enable pharmaceutical inventors to recoup the costs of R&D and to invest in future innovations. According to one frequently cited statistic from the Pharmaceutical Researchers and Manufacturers of America (PhRMA), an industry advocacy organization, drug researchers and manufacturers spend $800 million in R&D to create a single medicine. Given the high costs and uncertainty associated with R&D, supporters of patents argue that they are critical for innovation in medicine by allowing right holders to recoup the costs of R&D, earn profits, and invest in future R&D.

Proponents maintain that financial incentives for innovation may be even more critical now with the global economic downturn. Some fear that tighter credit markets may compel pharmaceutical companies to reduce current R&D spending.[12] For example, the World Intellectual Property Organization (WIPO) reported a slowdown in international patent filings in 2008, due to the global economic downturn.[13]

Others are skeptical of the reportedly high estimates of the costs of R&D in the creation of new medicines. They argue that PhRMA's cost estimate includes both the actual expenditures and the economic opportunity costs of developing new drugs. They also contend that a growing proportion of the financial returns generated from patented drugs is not directed toward new innovations, but rather to commercial marketing and political lobbying activities.

Additionally, pharmaceutical companies often use publicly-funded research to develop drugs for commercialization.[14] For instance, in the United States, the National Institutes of Health (NIH) and the Centers for Disease Control (CDC) are important sources of health-related research. In general, the public sector funds R&D that is focused on basic scientific research. Pharmaceutical companies then build on this research to develop products that are patentable and commercially marketable.

R & D for "Developing Country Diseases"

While patents may provide incentives for innovation, some argue that the economic premise behind patents only holds in situations where markets offer sufficient financial incentives for a return on investment. Many developing countries may be unable to provide a profitable market for treatments against diseases that disproportionately affect their populations. The WHO "Global Strategy and Plan of Action of Public Health, Innovation and Intellectual Property" acknowledges that IPRs serve an important incentive function, but notes, "This incentive alone does not meet the need for the development of new products to fight diseases where the potential paying market is small or uncertain (WHA61.21.6)."

[12] IHS Global Insight, *Drugs: Industry Analysis*, January 2009.

[13] World Intellectual Property Organization (WIPO), "Global Economic Slowdown Impacts 2008 International Patent Filings," press release, January 27, 2009, http://www.wipo.int/pressroom/en/articles/2009/article_0002.html.

[14] Carsten Fink, *Intellectual Property and Public Health: An Overview of the Debate with a Focus on U.S. Policy*, Center for Global Development, Working Paper Number 146, June 2008, p. 22.

According to a classification system used by the WHO, there are three main types of diseases that vary in the level of market-based incentives they offer for R&D.

- **Type I** diseases ("chronic diseases"), such as cancer, diabetes, and cardiovascular disease, are prevalent in developed countries and increasingly in developing countries. Pharmaceutical companies have a strong financial incentive to invest in treatments for these diseases.
- **Type II** diseases are prevalent in developing countries. Pharmaceutical companies may have incentives to invest in such diseases if there is sufficient demand by high-income countries for research, as in the case of HIV/AIDS. For other Type II diseases, such as malaria and tuberculosis, high-income country demand for treatments is limited and consequently, market-based incentives are not sufficient for pharmaceutical companies to invest in R&D.
- **Type III** diseases, such as dengue fever and African sleeping sickness, are those that have virtually no developed country demand. These diseases (often referred to as "neglected tropic diseases"), largely are concentrated in impoverished areas in developing countries. Pharmaceutical companies have little financial incentive to invest in R&D for these diseases, but may have social motivations.[15] According to the WHO, there are fourteen neglected tropical diseases.

According to one commonly cited statistic, less than 10% of global expenditures on health research and development is directed toward the major health problems of 90% of the world's population (the so-called "10/90 gap").[16] Some point out that low rates of R&D investment in "developing country diseases" may be one of many factors affecting health conditions in impoverished areas. For instance, some neglected tropical diseases are prevalent due to poverty-related conditions such as unsafe water, poor sanitation, and lack of basic health care infrastructure.[17]

Some of the pharmaceutical needs of developed and developing countries are increasingly converging. For example, many Type I diseases, typically associated with high-income countries ("age" diseases), also now account for a growing share of the disease burden in developing countries as they experience economic growth and development.[18] The WHO estimates that "85% of the burden of chronic diseases is now concentrated in low- and middle-income countries."[19] Additionally, increasing outbreaks of infectious diseases, such as the H5N1 "avian influenza" and H1N1 "swine influenza," and growing resistance to highly infectious diseases, such as tuberculosis, may lead to R&D for diseases that affect all populations.

[15] WHO, *Public Health, Innovation and Intellectual Property Rights: Report of the Commission on Intellectual Property Rights, Innovation and Public Health*, 2006, p. 16.

[16] Ricki Lewis, *Fighting the 10/90 Gap*, Medecins San Frontiers (MSF), May 13, 2002.

[17] Phillip Stevens, *Diseases of Poverty and the 10/90 Gap*, International Policy Network, November 2004.

[18] Ibid, pp. 5-7.

[19] WHO, Epidemic and Pandemic Alert and Response, "Assessing the severity of an influenza pandemic," May 11, 2009.

Drug Pricing

Pharmaceutical patents are among the many factors that may affect the price of medicines. Other factors include the level of economic development, taxes, tariffs, efficiency of global supply and distribution chains, government procurement plans, national health policies, and national and industry pricing decisions. These factors also are potentially significant determinants of drug pricing, but are beyond the scope of this paper.[20]

By granting a time-limited monopoly on the sale of a pharmaceutical drug, patents may raise the cost of the drug by delaying the entry of generic competitors into the market. Although the time-limited, exclusive right may serve an incentive function, some public health advocates are critical of the prices charged for patented medicines, arguing that patents enable right holders to price drugs at levels that greatly surpass marginal costs of R&D and production.

Generic medicines—typically defined as copies of a patented drugs, predominantly of drugs whose patents have expired[21]—tend to lower the price of drugs in the global marketplace in a number of ways. In general, generic manufacturers do not have to repeat research and clinical trials conducted by name brand pharmaceutical companies in order to obtain regulatory approval, but rather only need to demonstrate the "bioequivalence" of their product to the patented, branded medicine. In the United States, the Drug Price Competition and Patent Restoration Act of 1984 (the "Hatch-Waxman Act of 1984"), among other provisions, permits the FDA to provide marketing approval for generics on the basis of "bioequivalence" data rather than more costly, clinical data.[22] Without this obligation, generic manufacturers are able to enter the market more quickly once patents have expired and to offer the drugs at lower prices.

By serving as market competitors, generics also encourage innovator pharmaceutical companies to lower the prices of their branded drugs. In addition, the entry of generic drugs into a market may encourage innovator companies to develop newer drugs, thus increasing the supply of medicines.[23]

Access to Essential Medicines

The public health landscape has changed dramatically over the past 30 years. The world has witnessed the emergence of the HIV/AIDS pandemic in the 1980s, as well as an increasing resistance to treatments against malaria, tuberculosis, and a host of bacteria over the past couple of decades. While the HIV/AIDS is a global pandemic, it disproportionately affects developing countries. In addition, many other communicable and infectious diseases have afflicted the developing world.

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[20] Commission on Social Determinants of Health, *Closing the Gap in a Generation: Health Equity Through Actions on the Social Determinants of Health*, World Health Organization, Final Report of the Commission on Social Determinants of Health, Geneva, 2008.

[21] World Trade Organization glossary.

[22] CRS Report RL30756, *Patent Law and Its Application to the Pharmaceutical Industry: An Examination of the Drug Price Competition and Patent Term Restoration Act of 1984 ("The Hatch-Waxman Act")*, by Wendy H. Schacht and John R. Thomas.

[23] GAO, *U.S. Trade Policy Guidance on WTO Declaration on Access to Medicines May Need Clarification*, GAO-07-1198, September 2007, p. 7

Public health outcomes depend on a wide variety of often inter-related social, economic, and political factors, one of which is access to medicines.[24] According to the U.N. Millennium Development Goals, to which the United States is a signatory, access to medicines is defined as "having medicines continuously available and affordable at public or private health facilities or medicine outlets that are within one hour's walk from the homes of the population."[25]

In discussing access to medicines, many public health advocates focus on "essential medicines." Given that national governments face resource constraints in providing health care, some argue that governments should rationalize their public health policy choices, including the provision of medicines. According to the WHO, essential medicines are

> those that satisfy the priority health care needs of the population. They are selected with due regard to public health relevance, evidence on efficacy and safety, and comparative cost-effectiveness. Essential medicines are intended to be available within the context of functioning health systems at all times in adequate amounts, in the appropriate dosage forms, with assured quality and adequate information, and at a price the individual and the community can afford. The implementation of the concept of essential medicines is intended to be flexible and adaptable to many different situations; exactly which medicines are regarded as essential remains a national responsibility.[26]

While progress has been made in several countries to promote access to essential medicines and treatments, such as those to combat HIV/AIDS, malaria, and tuberculosis, the WHO estimates that one-third of the world's population, particularly in poorer parts of Africa and Asia, continues to lack regular access to essential medicines.

For low-income countries and populations, pharmaceutical drug prices may constitute a significant barrier in accessing essential and other medicines. In most parts of the world, health services are offered through a combination of public and private health services. Oftentimes, in developing countries (and in some cases, developed countries such as the United States), consumers bear much of their health care costs directly. In contrast, some countries, such as Thailand, Japan, Turkey, and France, have more publicly-funded pharmaceutical markets, reducing the costs borne by consumers. However, in situations where the government is funding a larger share of health care, higher-priced drugs may add limits to the government's ability to provide public health care.

There is considerable debate on the extent to which patent protection affects access to essential medicines. The complexity is fueled by differing definitions of what is meant by "essential medicines" and "access to medicines." For instance, there often are no agreed-upon units of analysis for evaluating access to essential medicines. Since 1977, the WHO has maintained a Model Essential Medicines List (EML) to assist national governments to select medicines to address their public health needs and to develop national lists.[27] While the WHO EML often is

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[24] Commission on Social Determinants of Health, *Closing the Gap in a Generation: Health Equity Through Actions on the Social Determinants of Health*, World Health Organization, Final Report of the Commission on Social Determinants of Health, Geneva, 2008.

[25] United Nations, *Delivering on the Global Partnership for Achieving the Millennium Development Goals*, MDG Task Force Report, 2008, p. 35.

[26] WHO, http://www.who.int/topics/essential_medicines/en/, accessed April 6, 2009.

[27] WHO, *WHO Model List of Essential Medicines*, 15th List, March 2007, http://www.who.int/medicines/publications/essentialmedicines/en/.

used as a basis for analysis, some global health activists express concern that the EML may not be comprehensive. They argue that the EML may exclude essential medicines based on cost concerns. They contend that patents raise the cost of medicines, and that the EML includes very few medicines currently under patent. However, the EML notes that cost is not a reason to automatically exclude a medicine and points out that multiple criteria are considered in the decision process.

Moreover, some argue that the number of essential medicines under patent is under "constant flux" because patents will expire for existing medicines, new patents will be sought for new medicines, new medicines will be added to the WHO's Model Essential Medicines List, and others will be removed from the EML.

Quantifying Essential Medicines Under Patents

Despite data limitations, some studies have attempted to quantify how many essential medicines are patented. According to one study published in 2004, 1.4% of essential medicines were patented in 2003. The study quantified the frequency with which "essential medicines" as defined by the WHO's 13th Model Essential Medicines List (EML) are patented in 65 low- and middle-income countries and examined the data using statistical regression methods. Of the 349 products listed in the WHO EML, the study concluded that 17 essential medicines could be subject to patented in 2003. While the overall patent incidence rate for essential medicines may be low, the study noted that patents were more frequent for antiretroviral medicines (ARVs) for HIV/AIDS treatment. In addition, HIV/AIDS treatment often utilizes combination therapy (use of multiple drugs for a treatment), so that a patent on one medicine can limit access to "fully-generic based therapy."[28]

According to the study, inventors were more likely to seek patents for patentable drugs in larger, developed markets than in developing countries, whose markets may not provide sufficient financial incentives for inventors to incur the costs of seeking patents. The study found that patenting was more prevalent in large, middle-income countries, such as China, South Africa, and Mexico. Pharmaceutical companies also may choose to not seek patents in low-income countries due to social motivations to increase access to drugs in these countries or reputational concerns. In addition, pharmaceutical companies may not have had the option to apply for a patent if the developing country did not recognize patents. The study suggests that views of both health care activities and pharmaceutical companies are exaggerated: "Patents cannot cause essential medicines to be inaccessible in 'many' developing countries because they do not exist 98.6 percent of the time; similarly, patents cannot be a 'global' necessity of pharmaceutical business because companies forgo them 69 percent of the time."[29]

International Trade in Pharmaceuticals

Like many other IPR-sensitive industries, the pharmaceutical industry is heavily involved in international trade. IPR-sensitive products generally rank among the fastest-growing trade commodities. International trade in pharmaceutical products is heavily dominated by the developed world, both in terms of supply and demand.

The global pharmaceutical market is expected to grow by over 4% in 2009, a growth rate similar to 2008. However, the international economic downturn poses uncertainties may affect international demand for pharmaceuticals. Although demand for pharmaceutical products tends to be more price-inelastic than for other commodities, the global pharmaceutical market is not wholly insulated from factors affecting the global economy. The international economic slowdown may constrain performance in some pharmaceutical markets more so than others. For

[28] Amir Attaran, "How Do Patents and Economic Policies Affect Access to Essential Medicines in Developing Countries," *Health Affairs*, vol. 23, no. 3 (May/June 2004).

[29] Ibid., p. 159.

instance, the pharmaceutical markets of countries in which consumers bear a large degree of the cost of health care may be particularly susceptible to global economic changes.[30]

Supply of Pharmaceuticals

According to the most recent statistics compiled by the National Science Foundation (NSF), in 2005, the United States, European Union, and Asia supplied 90% of global value-added revenue of pharmaceutical manufacturing. The United States ranked as the largest single-country contributor to global value-added of the pharmaceutical industry, accounting for about 32% of the world market share. The European Union and Asia accounted for another 30% of the global market share each. The leading contributors to Asia's market share were Japan, China, and South Korea.[31]

The global pharmaceutical industry is comprised mainly of a small number of multinational corporations "who negotiate with buyers and set prices and volumes for drugs."[32] The top corporations are concentrated in the United States, the United Kingdom, Germany, Switzerland, and France. Industry consolidation among branded companies has become more prevalent as generic companies have made greater inroads into the global pharmaceutical market.

While high-income countries constitute the largest source of pharmaceuticals, industrializing countries have contributed to a larger share of the global value-added revenue of the pharmaceutical industry. For example, between 1995 and 2005, China's pharmaceutical industry's value-added revenue increased four-fold to 8% of the global market. During this time period, India's global market share of value-added doubled to 2%. India and China have become important exporters of generic drugs and active pharmaceutical ingredients. Several industrializing countries—primarily Brazil, China, Cuba, India, among others—also are developing innovative capacity for biomedical research.[33]

Demand for Pharmaceuticals

In terms of demand for pharmaceutical products, the multi-billion dollar global pharmaceutical market is highly polarized. The United States is the world's largest pharmaceutical market, and along with Japan and Europe, account for about 75% of global sales of pharmaceutical products.[34] In total, the thirty wealthiest countries in the OECD account for 80% to 90% of global sales of patented medications.[35] In contrast, the developing world, which comprises over 80% of the world's population, represents about 10% of global pharmaceutical sales.

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[30] Gary Gatyas and Clive Savage, "IMS Health Forecasts 4.5-5.5 Percent Growth for Global Pharmaceutical Market in 2009, Exceeding $820 Billion," *Business Wire*, October 29, 2008.

[31] National Science Foundation (NSF), "*Science and Engineering Indicators 2008*, "Industry, Technology, and the Marketplace," NSB 08-01; NSB 08-01A, Arlington, VA, January 2008, pp. 20-21.

[32] IHS Global Insight, *Drugs: Industry Analysis*, January 2009.

[33] WHO, *Public Health, Innovation and Intellectual Property Rights: Report of the Commission on Intellectual Property Rights, Innovation and Public Health*, Switzerland, 2006, p. 26.

[34] Richard D. Smith, Carlos Correa, and Cecilia Oh, "Trade, TRIPS, and Pharmaceuticals," *The Lancet*, vol. 373 (February 21, 2009).

[35] Kevin Outterson, "Patent Buy-Outs for Global Disease Innovations for Low- and Middle-Income Countries," *American Journal of Law & Medicine*, vol. 32 (2006), p. 160.

U.S. Trade in Pharmaceutical Products

For the United States, the pharmaceutical industry is an important contributor to U.S. economic growth and employment and is an internationally competitive industry that generates a significant volume of trade. For 2009, the U.S. pharmaceutical market is expected to experience lower levels of growth. Among other factors, the contraction of the U.S. economy and the global economic slowdown may constrain growth of the sector.[36]

Recent trends in international trade in the U.S. pharmaceutical industry are similar to those of U.S. high technology industries overall.[37] Through the 1980s and early 1990s, the U.S. high technology industries were net exporters. However, since the late 1990s, the United States has become a net importer of pharmaceuticals. [38]

For the U.S. pharmaceutical industry, total trade has grown as both exports and imports of pharmaceuticals have grown. However, imports have grown faster than exports, resulting in a U.S. trade deficit (see **Table 1**). Some observers question whether this is a signal of a decline in the U.S. pharmaceutical industry's competitiveness or simply an indication of the growing role of other countries in the global pharmaceutical industry. Also, these data do not reflect which pharmaceutical products traded by the United States are high-technology and which are low-technology.

Table 1. U.S. Trade in Pharmaceuticals, 1996-2008

U.S. Billions of Dollars

Trade Category	1996	2000	2004	2008
Exports	5.5	10.3	18.9	33.3
Imports	4.9	12.2	32.2	52.8
Total Trade[a]	10.4	22.5	51.1	86.1
Trade Balance[b]	0.6	-1.9	-13.3	-19.5

Source: U.S. International Trade Commission, CRS analysis.

Notes: Pharmaceutical data based on the U.S. Harmonized Tariff Schedule (HTS), Chapter 30.

a. Total trade is equal to exports plus imports.

b. The trade balance is exports less imports.

The U.S. Census Bureau tracks U.S. trade in advanced technology products (ATPs) in 10 different categories. Two categories, biotechnology and life science, may be most relevant to trade in U.S. trade in pharmaceutical products. While the products in these two ATP categories are not limited solely to pharmaceutical goods, their trade trends may be illustrative of U.S. pharmaceutical trade trends (see **Table 2**). In 2008, ATP trade in biotechnology products yielded a surplus, while ATP

[36] Gary Gatyas and Clive Savage, "IMS Health Forecasts 4.5-5.5 Percent Growth for Global Pharmaceutical Market in 2009, Exceeding $820 Billion," *Business Wire*, October 29, 2008.

[37] U.S. classification of technology industries differs from that of the OECD. While the OECD classifies technologies as "high-technology," "medium-technology," and "low-technology,"

[38] NSF, "*Science and Engineering Indicators 2008*, "Industry, Technology, and the Marketplace," NSB 08-01; NSB 08-01A, Arlington, VA, January 2008.

trade in life science products produced a deficit. The trade balance for the two ATP categories combined was negative, as was the overall trade balance in ATPs.

Table 2. U.S. Trade in Advanced Technology Products (ATPs), 2008

U.S. Billions of Dollars

Trade Category	Biotechnology[a]	Life Science[b]	Biotechnology and Life Science	All ATPs[c]
Exports	9.4	25.2	34.6	275.8
Imports	5.8	39.9	45.7	333.4
Total Trade	15.2	65.1	80.3	609.2
Trade Balance	3.6	-14.7	-11.1	-57.6

Source: U.S. Bureau of the Census, Foreign Trade Statistics.

Notes:

a. The ATP category "biotechnology" concentrates on "medical and industrial applications of advanced scientific discoveries in genetics to the creation of new drugs, hormones and other therapeutic items for both agricultural and human use."

b. The ATP category "life science" concentrates on "the application of scientific advances (other than biological) to medical science. Recent advances, such as nuclear resonance imaging, echocardiography, and novel chemistry, coupled with new production techniques for the manufacture of drugs have led to many new products for the control or eradication of disease."

c. The 10 different ATP categories are (1) biotechnology, (2) life science, (3) opto-electronics, (4) information and communications, (5) electronics, (6) flexible manufacturing, (7) advanced materials, (8) aerospace, (9) weapons, and (10) nuclear technology.

The WTO Agreement on Trade-Related Aspects of Intellectual Property Rights

Historically, IPRs have been a matter of U.S. national concern, but over time, have evolved into a cornerstone of international trade agreements. At the center of the present international IPR system is the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights ("TRIPS Agreement"). The conclusion of the Uruguay Round (1986-1994) of the General Agreement on Tariffs and Trade (GATT) resulted in the creation of the WTO, an international organization established in 1995 as the successor to the GATT. The Uruguay Round also culminated in numerous WTO agreements on trade in goods, services, investment and other non-tariff barriers to trade, one of which was the TRIPS Agreement.

The TRIPS Agreement sets minimum standards of protection and enforcement for patents, copyrights, trademarks and other forms of intellectual property.[39] The agreement is based on three core commitments of the WTO: minimum standards, national treatment, and most-favored-nation treatment. Adherence to the TRIPS Agreement is a prerequisite for WTO membership, and

[39] The North American Free Trade Agreement (NAFTA) signed in 1993 by the United States, Canada, and Mexico was the first international trade agreement to include minimum standards for IPR protection and enforcement. In many respects, the NAFTA served as a framework for the TRIPS Agreement.

provisions of the agreement can be enforced through the WTO's Dispute Settlement Understanding Mechanism (DSM).

Efforts by the United States, the European countries, and the IPR business community in the late 1980s were important in elevating IPR as a trade issue on the agenda of the Uruguay Round of the GATT. They argued that the prevailing international IPR regime, largely administered through "unenforceable" international treaties, was ineffective. U.S. industry criticized the lack of consistency in the promotion, protection, and enforcement of IPR across countries.[40] Others contended that IPR protection and enforcement should not be viewed as a trade issue. Among those who held this view, some may have agreed that the movement of counterfeit and pirated goods across national borders could be a trade issue, but may have questioned the inclusion of a wider-ranging set of IPR issues on the Uruguay Round agenda.

Among the debates about the implications of the TRIPS Agreement, one of the most controversial is its impact on public health. Prior to the TRIPS Agreement, developing country governments regulated public health with little involvement of international IPR regimes. This is because developing countries either did not have IPR systems in place or excluded pharmaceutical products from patents. Proponents of the TRIPS Agreement, mainly developed countries, argued that IPR protection and enforcement contribute to economic growth and development by promoting trade, investment, and technology transfer. Developed countries also asserted that patent protection is critical to public health because patents provide financial incentives for R&D to find pharmaceutical solutions for diseases.

In contrast, critics of the TRIPS, including many developing countries and civil society organizations, asserted that developed countries, which are the major producers of intellectual property, would be the prime beneficiaries of the TRIPS Agreement. Some also held the view that the TRIPS Agreement would raise the costs of IPR-sensitive goods, such as public health goods, constrain the ability of governments' to provide health services to their populations, and hinder innovation and economic development for low-income countries. In addition, many developing countries preferred to discuss IPR issues under the auspices of the World Intellectual Property Organization (WIPO) instead of the WTO. WIPO is a United Nations agency that administers all international IPR treaties with the exception of TRIPS.[41]

Ultimately, developing countries acceded to the TRIPS Agreement, after being granted delayed compliance periods and after negotiating goals on other issues in the Uruguay Round such as textiles and clothing. They also favored the prospect of operating under a rules-based trading system. [42] Nevertheless, many stakeholders continue to be critical of the TRIPS Agreement. They argue that the IPR regime's architecture is biased toward IP right holders. They also contend that, in negotiations, high-income countries had greater bargaining power than lower-income countries, which are often dependent on developed countries economically. In addition, some argue that the interests of such groups as IP users, consumers, small- and medium-sized manufacturers, and public health advocates were not sufficiently represented in the TRIPS Agreement negotiations.

[40] Keith E. Maskus, *Intellectual Property Rights in the Global Economy* (Institute for International Economics, 2000).

[41] Frederick M. Abbott and Jerome H. Reichman, "The Doha Round's Public Health Legacy: Strategies for the Production and Diffusion of Patented Medicines Under the Amended TRIPS Provisions," *Journal of International Economic Law*, vol. 10, no. 4, p. 925.

[42] Keith E. Maskus, *Intellectual Property Rights in the Global Economy* (Institute for International Economics, 2000).

Doha Declaration on Public Health

In agreeing to launch the Doha Round of the WTO trade negotiations, trade ministers adopted a "Declaration on the TRIPS Agreement and Public Health" (the "Doha Declaration") on November 14, 2001. The Declaration sought to alleviate developing country dissatisfaction with aspects of the TRIPS regime, confirming that the "TRIPS Agreement does not and should not prevent members from taking measures to protect public health." The Declaration committed member states to interpret and implement the agreement to support public health and to promote access to medicines for all.

Public Health Debates Surrounding the WTO TRIPS Agreement and the Doha Declaration

The provisions in the TRIPS Agreement and the Doha Declaration that affect pharmaceuticals continue to be the subject of ongoing debate. Issues of concern include the transitional implementation of the TRIPS Agreement, compulsory licensing provisions, parallel importing, and trade in counterfeit pharmaceuticals.

Transitional Implementation of the TRIPS Agreement

In many ways, the TRIPS Agreement was modeled on the IPR standards of developed countries. Many developing countries would have to devote more resources, to develop more technical expertise and capacity, and to make more significant changes to their laws and enforcement practices to become compliant with the TRIPS Agreement than developed countries. The Doha Declaration acknowledged the burden differential by allowing developing countries to delay implementation of the TRIPS Agreement until 2005, and allowing least developed countries (LDCs) to delay implementation until 2016. The WTO does not designate countries by level of development, and under the Doha Declaration, countries are able to self-identify themselves as developing countries.

The TRIPS Agreement does not apply to inventions that already were in the public domain during the time that the Agreement became effective. As such, pharmaceutical inventions that were open to generic competition prior to the implementation of TRIPS do not receive patent exclusivity under TRIPS. Some public health advocates express concerns about how full implementation of the TRIPS Agreement will affect international trade in generic medicines.[43] For example, in the case of HIV/AIDS treatment, most first-line (initial treatments) ARV treatments are off-patent, available through lower-priced generic suppliers, or are offered at significantly discounted prices by innovator pharmaceutical companies. However, second- and third-line (newer products, often developed due to increasing resistance to initial treatments) ARVs tend to be more recent innovations that are patentable under the TRIPS Agreement. In addition, observers point out that new pharmaceutical solutions for infectious diseases, such as malaria and tuberculosis, and non-

[43] Carsten Fink, *Intellectual Property and Public Health: An Overview of the Debate with a Focus on U.S. Policy*, Center for Global Development, Working Paper Number 146, June 2008.

communicable diseases such as coronary disease, cancer, diabetes, and asthma may be subject to patents.[44]

Critics of the TRIPS Agreement maintain that implementation of the agreement will affect countries with strong domestic generic drug industries. For example, in 2005, India began implementing its national patent law as part of its TRIPS Agreement requirements. Accordingly, India has started offering patents (including for the larger number of "mailbox" patent applications that were held during the transitional period) for pharmaceutical products. Some question how this provision of patents may affect India's generic supplies of future pharmaceuticals for second-line and third-line ARVS, as well as for new treatments of other diseases.

Some public health advocates express concern that full implementation of the TRIPS Agreement will affect the ability of countries to take advantage of generic goods from countries that serve as generic suppliers. For instance, the ability of Brazil and Thailand to provide HIV/AIDS treatments and other medicines to their nationals largely has been a result of access to India's low-priced generic supplies. [45] Others argue that full implementation of the TRIPS Agreement may not greatly change access to medicines, given that a multitude of other social, political, and economic factors affect access to medicines.

Others also point out that while many WTO signatories have been amenable to changing their laws to increase IPR protection, enforcement of these IPR laws has sometimes been weak or inconsistent.

Compulsory Licensing

Compulsory licenses are issued by governments to authorize the use or production of a patented item by a domestic party other than a patent holder (without the permission of the right holder). They are authorized by Article 31 of TRIPS, which places certain limitations on their use, scope, and duration in an attempt to balance promotion of pharmaceutical innovation and access to new medicines. A government can only issue a compulsory license under certain conditions intended to protect the right of the patent holder. The government must have "made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions." This requirement to first seek authorization can be waived in a time of "national emergency," "other circumstances of extreme urgency," "public non-commercial use," or to address anti-competitive practices (Article 31(b)). If a compulsory license is issued, then "the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization" (Article 31(h)). The TRIPS Agreement also predominantly restricts production authorized by compulsory licenses to the domestic market (Article 31(f)).

Some public health advocates view compulsory licenses as an important mechanism for national governments to provide access to medicines at affordable prices. Supporters of strong IPR regimes argue that, while compulsory licensing may increase short-term access to medicines in

[44] Frederick M. Abbott, "The WTO Medicines Decision: World Pharmaceutical Trade and the Protection of Public Health," *The American Journal of International Law*, vol. 99, no. 2 (April 2005), p. 320.

[45] Lisa Forman, "Trading Health for Profit: The Impact of Bilateral and Regional Free Trade Agreements on Domestic Intellectual Property Rules on Pharmaceuticals," in *The Power of Pills*, ed. Jillian Clare Coehn, Patricia Illingworth, and Udo Schüklenk (Ann Arbor: Pluto Press, 2006), p. 191.

developing countries, their widespread use may harm long-term access to medicines. Pharmaceutical companies may opt not to offer their products in countries that consistently break or threaten to break patents in the future. In addition, pharmaceutical companies may not be as willing to invest in finding cures for diseases prevalent in developing countries if their profits are undermined. Others contend that because developing country markets are small, issuing compulsory licenses in these markets does not markedly affect pharmaceutical industry profits or research directions.[46]

National Emergencies

Part of the controversy surrounding compulsory licenses centers on the definition of a "national emergency" under Article 31(b) of the TRIPS Agreement. According to the Doha Declaration, each WTO member country has the right to grant compulsory licenses and to determine the grounds upon which such licenses are issued, including defining what constitutes a national emergency or other cases of extreme urgency. The Doha Declaration cites crises related to HIV/AIDS, tuberculosis, malaria, and other epidemics as situations of potential national emergency or extreme urgency.

Case Study: Compulsory Licenses for Anti-Influenza Medicines

In response to recent concerns about the H1N1 "swine flu" outbreak in Mexico, the Mexican government issued a compulsory license for Tamiflu, the leading, brand name anti-influenza drug produced through efforts by the Swiss pharmaceutical company Roche and American pharmaceutical company Gilead. Mexico signed a deal with Cipla, an Indian generic pharmaceutical company, for the manufacture and export of a generic version of Tamiflu to Mexico. The generic version would be sold at a lower price. Roche, which holds the marketing license for Tamiflu, has opposed the decision, arguing that it "has confirmed its willingness to provide the Mexican government with Tamiflu in significant quantities in a timely manner and therefore sees no rationale for compulsory licensing."[47]

Limited Use of Compulsory Licenses By Low- and Middle-Income Countries

Low-income countries have issued compulsory licenses for pharmaceutical drugs under patents on a limited basis. Some speculate that the "underuse" of Article 31 of the TRIPS Agreement is due to the prospect of foreign trade sanctions and/or the threat of corporate litigation. While national governments and multinational companies have expressed support for the Doha Declaration, they reportedly often have opposed the "practical implementation" of compulsory licensing provisions under Article 31 of the TRIPS Agreement.[48] Others suggest that low-income countries may not issue compulsory licenses due to a dearth in administrative or legal resources. Some also suggest that low-income countries may be concerned that issuing compulsory licenses may raise concerns about their business environment and deter foreign investment.

In contrast, middle-income countries such as Brazil and Thailand, have threatened to issue compulsory licenses for pharmaceutical products in order to negotiate price reductions. Some

[46] Martin Foreman, *Patents, Pills and Public Health: Can TRIPS Deliver?*, The Panos Institute, London, 2002, pp. 28-29.

[47] Khomba Singh and Sushmi Dey, "Local drug cos may chip in to treat swine flu," *The Economic Times*, April 28, 2009. Andrew Jack, "Indian drug company set to sell cheap copy of Tamiflu," *The Financial Times*, May 14, 2009.

[48] Ellen F.m.'t Hoen, LL.M., *The Global Politics of Pharmaceutical Monopoly Power: Drug patents, Access, Innovation and the Application of the WTO Doha Declaration on TRIPS and Public Health* (AMB Publishers, 2009), p. 3.

assert that compulsory license threats may be a viable option limited to countries with sufficient manufacturing capacity and a sizeable market that can affect pharmaceutical companies' profits.

Case Study: Brazil's Issuance of Compulsory Licenses for HIV/AIDS Drugs

Brazil, a middle-income country, threatened to issue a compulsory license for an HIV/AIDS drug in 2001 following unsuccessful price negotiations with the Swiss pharmaceutical company Roche, citing the HIV/AIDS crisis as a national emergency. Brazil has a national healthcare program that offers free treatment to the entire HIV/AIDS population in Brazil. To that end, Brazil began domestically producing HIV/AIDS drugs, but Efavirenz, a drug produced by the Roche, constituted nearly 30% of the government's spending on HIV/AIDS at that time. Roche eventually conceded to dramatic price reductions, reportedly out of concerns that if Brazil issued a compulsory license, the company would lose out on a significant market.[49]

Utility of Compulsory Licenses

During the Doha Round of the WTO, the requirement under Article 31(f) of the TRIPS Agreement that compulsory licenses must be issued predominantly for the domestic market became a focal point of negotiations. In effect, Article 31(f) conveys the right of compulsory licensing only to countries with the capability to manufacture a given product and precludes countries without domestic manufacturing capability to take advantage of the flexibility. The Doha Declaration acknowledged 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." As such, the Declaration ("Paragraph 6") directed the WTO members to formulate a solution to address the use of compulsory licensing by countries with insufficient or inadequate manufacturing capability.

Prior to the Cancun Ministerial in August 2003, WTO members agreed on a decision to waive the domestic market provision of the TRIPS article on compulsory licensing (Article 31(f)) for exports of pharmaceutical products for "HIV/AIDS, malaria, tuberculosis and other epidemics" to LDCs and countries with insufficient manufacturing capacity. This decision was incorporated as an amendment to the TRIPS agreement at the Hong Kong Ministerial in December 2005. The amendment must be ratified by two-thirds of the 153 WTO member states. Until then, the 2003 waiver continues in force. To date, 47 countries (the United States, Switzerland, El Salvador, South Korea, Norway, India, the Philippines, Israel, Japan, Australia, Singapore, Hong Kong, China, the 27 countries of the European Union, Mauritius, Egypt, Mexico, Jordan, Brazil, Morocco, and Albania) have ratified the amendment. The deadline for ratification is December 31, 2009.

The system established by the WTO allows LDCs and countries without sufficient manufacturing capacity to issue a compulsory license to a company in a country that can produce such a good. After a matching compulsory license is issued by the producer country, the drug can be manufactured and exported subject to various notification requirements, quantity and safeguard restrictions. Under the safeguard provisions, the drugs issued must be specially marketed or packaged with identifiable characteristics, such as distinguishable colors or shapes "provided that such distinction is feasible and does not have a significant impact on price." It also declared that importing countries should take measures "within their means" to prevent trade diversion.

[49] Jillian Clare Cohen, "Expanding Drug Access in Brazil: Lessons for Latin America and Canada," *Canadian Journal of Public Health*, vol. 97, no. 6 (Nov/Dec 2006).

While the TRIPS Agreement waiver arguably represents a lowering of IPR standards, its supporters assert that the waiver effectively balances the need to promote innovation and protect IPRs with the need for countries with insufficient manufacturing capacity to access medicines through trade. For some public health advocates, the extensive safeguard provisions raise concerns about whether or not manufacturing companies will have sufficient financial incentives to develop such drugs. Moreover, developing countries may not have the resources to protect against the illegitimate export of such drugs to other countries. Some observers argue that the requirements may pose extreme burdens on developing countries that are politically unstable.[50] Some commentators also criticize the case-by-case, country-by-country nature of the notification requirements, which must be fulfilled for every request for parallel importing under a compulsory license. While several exporting countries have established laws and procedures for implementing this system, only Rwanda has availed itself to use the WTO system to import HIV/AIDS medicines from a generic manufacturer in Canada.[51]

An ongoing issue is the extent to "middle-income" countries, such as Brazil, Thailand, India, and China, can or should take advantage of TRIPS Agreement waiver.[52] Developing countries range from the poorest, least-developed, and low-income countries to industrializing, middle-income countries. Some supporters of a strong IPR regime argue that a hard line should be drawn between low-income and middle-income countries. Others hold that international trade policies on innovation should acknowledge the unique needs and capacities of middle-income countries. Some observers have expressed concern that compulsory licensing may be used as an "industrial policy" tool. Countries may issue compulsory licenses for pharmaceuticals in order to develop their domestic pharmaceutical industries.

Parallel Importation

Parallel ("grey market") imports are products marketed by the right holder or with the right holder's permission in one country and imported into another country without the approval of the patent owner. Supporters of parallel trade of pharmaceuticals argue that the practice enables public health providers to take advantage of international differences in the prices of patented drugs. For some countries, importing drugs may be a more cost-effective way of accessing lower-priced medicines than manufacturing them directly.[53] Others contend that parallel importing policies avoid addressing "root" problems in countries' national drug pricing strategies or manufacturing capacity. Some pharmaceutical companies that oppose parallel importation of pharmaceuticals allege that the practice prevents them from offering tiered-pricing for medicines within and among countries. For instance, some pharmaceutical companies may opt to charge lower prices for drugs in least developed countries compared to other countries. In addition, pharmaceutical companies express concern that, in the process, such drugs may be diverted to higher-income markets. Some also express concern about the impact of parallel importing on the supply of medicines in exporting countries.

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[50] Pooja Van Dyck, "Importing Western Style, Exporting Tragedy: Changes in Indian Patent Law and Their Impact on AIDS Treatment in Africa," *Northwestern Journal of Technology and Intellectual Property*, vol. 6 (2007-2008), p. 146.

[51] Daniel Pruzin, "Canadian Firm to Begin Exporting Generic Medicines Under WTO Deal," *International Trade Daily*, September 9, 2008.

[52] The World Bank classifies countries as high-, middle-, and low-income countries.

[53] Lisa Forman, "Trading Health for Profit: The Impact of Bilateral and Regional Free Trade Agreements on Domestic Intellectual Property Rules on Pharmaceuticals," in *The Power of Pills*, ed. Jillian Clare Coehn, Patricia Illingworth, and Udo Schüklenk (Ann Arbor: Pluto Press, 2006), p. 191.

In the United States, there has been an ongoing debate on parallel importing of pharmaceuticals. U.S. innovator pharmaceutical industries have tended to oppose U.S. imports of generic medicines. Due to concerns about the cost of prescription medicines in the United States, in the 111th Congress, two bills (H.R. 163, S. 80) have been introduced that would allow Americans to import prescription drugs from foreign countries. Pharmaceutical drug companies have raised concerns that allowing such importation may lead to health and safety threats based on counterfeiting concerns. Others argue that allowing such importation would reduce drug prices. Prescription drug costs in Canada and the United States may differ due to factors such as government price controls, purchasing power, and negotiating ability. Although "grey market" importation of pharmaceuticals is currently prohibited in the United States, Americans are able to do so through Internet pharmacies that enable such transactions. Prosecution of these individuals has been limited. Canada has expressed concerns that parallel importation has led to shortages. Because some drug companies reportedly restrict the supply of their products to Canada, the Canadian government has threatened to clamp down on the export of drugs to the United States.[54]

Debates about parallel trade raise a question of at what point of sale is the patent right exhausted. The TRIPS Agreement does not address the issue of IPR exhaustion.[55] The Doha Declaration further says that the TRIPS Agreement implies that WTO members can chose their own IPR exhaustion regime.

Patent Exhaustion Regimes

National exhaustion: Some countries, such as the United States and Switzerland, have a national exhaustion regime, meaning that the first sale of a patented good in the country exhausts the patent right in that country and the buyer of the patented good may resell the product without violating the patent right. Conversely, if the first sale of the patented good takes place in a foreign country, the patent may not be exhausted in the home country. As such, importing the patented good from the foreign country into the home country without the permission of the right holder may violate the patent.

Regional exhaustion: In contrast, the European Union subscribes to a regional exhaustion regime. Thus, the first sale of a patented product anywhere in the European Union allows parallel importing within the European Union. However, without the permission of the right holder, parallel importation with a country outside of the European Union is banned without a first sale.

International exhaustion: At the other extreme, some countries, such as China, subscribe to an international exhaustion regime, in which the first sale of a good internationally exhausts the patent right. Thus, a buyer of the patented good may resell the product anywhere in the world without violating the patent right. In this situation, parallel importing of a good after the first sale does not violate the patent.

Trade in Counterfeit Pharmaceuticals

In the international supply and distribution of pharmaceuticals, there are concerns about the quality of medicines traded. There is broad-based concern about trade in counterfeit pharmaceuticals, which are manufactured and/or sold with the intent to deceive consumers about their origin, legitimacy, and effectiveness. Examples of counterfeit drugs include those that are mislabeled, have no or incorrect active pharmaceutical ingredients (APIs), or have correct APIs but in incorrect quantities. According to previous estimates by the WHO, many countries in

[54] Alex Wayne, "Obama Wants to Permit Imports of Prescription Drugs," *CQ Today*, February 26, 2009.

[55] The TRIPS Agreements states that none of its provisions, aside from those concerning non-discrimination (i.e. national treatment and most-favored nation), can be applied to address the issue of exhaustion of IPRs in a WTO dispute.

Africa, Asia, and Latin America have areas where 10% to 30% of medicines sold are counterfeit. In contrast, in many developed countries, which tend to have stronger regulatory systems, the prevalence of counterfeit drugs is significantly lower.

Unlike counterfeit medicines, generic medicines are distinguished from counterfeit medicines in that they are legitimately produced, generally copies of off-patent drugs, and their sale or distribution is not intended to deceive consumers about their origin, authenticity, or effectiveness.[56] While generic medicines are legitimately produced, some innovator pharmaceutical companies and public health advocates express concerns that some generic medicines may be sub-standard.

Some industrialized countries have begun to detain shipments of generic medicines for inspection due to concerns that the drugs are counterfeit. On the one hand, increased IPR seizures may limit instances of counterfeit drugs, thus mitigating health and safety risks. On the other hand, confusion between counterfeit and legitimate generic goods may result in increased incidences of seizures of legitimate generics in transit and delay delivery of medicines. Some non-governmental organizations (NGOs) also assert that industrialized countries are using this strategy to discourage generic drug production and have urged the WTO and the WHO to take action to address this issue.

Case Study: Seizure of Generic Medicine Shipments in Transit from India to Brazil

In December 2008, Dutch customs authorities temporarily stopped a shipment of generic high-blood pressure medicines in transit from India to Brazil, reportedly based on concerns that the generic ingredients in the drugs were counterfeit. Previously, Dutch customs authorities temporarily halted shipments of generic medicines manufactured in India and in transit to Colombia and Peru via the Netherlands. Critics, including some non-governmental organizations, asserted that seizures of legitimate generic medicines in transit posit risks to public health by placing trade in generic medicines in peril. They claimed that the actions of the Dutch customs officials and European Union rules are designed to "disrupt the supply of legitimate generic medicines to developing countries" and that such actions set dangerous precedents. EU officials countered that the GATT permits customs officials to stop and inspect transit shipments.[57]

U.S. Trade Policies on Intellectual Property Rights

The U.S. government has placed significant priority on pursuing stronger international IPR protection and enforcement through U.S. trade policy. In addition to participating in multilateral trade policy negotiations regarding IPRs, the United States seeks stronger international IPR protection and enforcement through regional and bilateral free trade agreements (FTAs) and unilateral trade policy tools.

Free Trade Agreements

In pursuing IPR provisions in regional and bilateral FTAs, USTR is guided by three main goals: (1) to promote strong IPR protection and enforcement in FTAs; (2) to secure market access opportunities for U.S. businesses that rely on IPR protection; and (3) to respect the Doha

[56] WTO glossary.

[57] Daniel Pruzin, "Group Urges WHO, WTO to Prevent Seizure of Legitimate Generic Medicine Shipments," *International Trade Daily*, February 23, 2009.

Declaration on the TRIPS Agreement and Public Health.[58] Currently, the United States has two regional FTAs and nine bilateral FTAs in force. Three FTAs (Panama, Colombia, and Korea) have been negotiated and are pending congressional approval.

In negotiating FTAs, the USTR frequently has sought levels of protection that exceed the minimum standards of the TRIPS Agreement (the so-called "TRIPS-plus" provisions). For pharmaceutical-related IPR provisions in FTAs, the USTR generally has pursued requirements on data exclusivity, patent term extensions, and patent linkage. In some cases, the USTR also has sought provisions to limit the issuance of compulsory licenses and parallel importing, particularly when negotiating FTAs with middle-income countries.

TRIPS-Plus Provisions in U.S. FTAs

While the specific IPR provisions vary across FTAs, there are a number of typical "TRIPS-plus" provisions that the United States has pursued.

Data exclusivity: In general, data exclusivity requirements stipulate that "a generic company cannot obtain market approval based on the safety and efficacy of the innovator company for a period of at least five years from the data marketing approval was granted to the innovator." Consequently, this provision gives the patent holder five years "of effective marketing exclusivity, unless the generic firm produces its own safety and efficacy data with new drug trials."

Patent term extensions: Patent terms may be extended beyond 20 years in order to compensate for "unreasonable delays" in granting patent licenses or market approval.

Patent linkage: The FTAs may prohibit a country's drug regulatory authority from approving a generic drug for marketing while the brand-name drug is still under patent.

Compulsory licensing: The FTAs may limit the grounds on which to issue compulsory licenses. This is largely restricted to national emergencies, such as anti-competitive remedies and for public non-commercial use. Some question whether or not this restricts the ability of countries to issue compulsory licenses to protect public health in cases that are serious but may not be viewed as national emergencies. Prohibiting compulsory licenses for non-national emergencies may disallow compulsory licenses to promote generic competition on medicines.

Parallel importing: In some FTAs, patent holders can contractually prevent parallel importation.

The USTR asserts that strong IPR provisions ultimately promote access to medicines for developing countries by encouraging innovation. However, the adoption of "TRIPS-plus" provisions in FTAs has garnered much criticism from public health advocates and developing countries. Some critics contend that the FTAs and unilateral U.S. trade actions (discussed below) are eroding developing countries' abilities to exercise their legal rights to issue compulsory licenses and engage in parallel importing under the TRIPS Agreement. Public health advocates also express concerns that these TRIPS-plus standards run contrary to the spirit of the Doha Declaration; they "limit national strategies to provide affordable medicines and limit market access for generic medicines, irrespective of the country's level of development or disease burden."[59]

[58] U.S. Government Accountability Office (GAO), *U.S. Trade Policy Guidance on WTO Declaration on Access to Medicines May Need Clarification*, GAO-07-1198, September 2007, pp. 27-28.

[59] Lisa Forman, "Trading Health for Profit: The Impact of Bilateral and Regional Free Trade Agreements on Domestic Intellectual Property Rules on Pharmaceuticals," in *The Power of Pills*, ed. Jillian Clare Coehn, Patricia Illingworth, and Udo Schüklenk (Ann Arbor: Pluto Press, 2006), p. 190. Jamie Strawbridge, "NGOs Press USTR To Extend May 10 Deal On IPR To All Trade Pacts," *Inside U.S. Trade*, May 22, 2009.

In addition, some argue that U.S. rigidity regarding IPRs may take away from potential U.S. gains in other areas of trade negotiation. For, FTA negotiations between the United States and Thailand, initiated in 2003, reportedly have been hampered by U.S. concerns about deficiencies in Thailand's IPR regime and Thailand's concern about the impact that raising IPRs may have on public health in Thailand, including the government's ability to provide generic versions of HIV/AIDS medicines to its population.

Because U.S. trade partners have expressed reservations about the stringent IPR standards pursued by the United States, some question why countries would want to enter into FTAs with the United States. Some argue that for low-income and middle-income countries, "Securing favorable market access for exports has usually outweighed public-health priorities—even when benefits are likely to be short lived and eroded as tariffs decrease."[60]

In response to concerns that U.S. trade negotiations may affect public health in developing countries, among other concerns (including environmental issues and labor rights), there has been somewhat of a shift in U.S. trade policy regarding pharmaceutical IPRs. A May 10, 2007 bipartisan trade deal between former President George W. Bush and congressional leaders yielded changes to the provisions in the U.S. FTA template, which is the basic text with which the United States begins FTA negotiations.[61] The deal made optional the previously mandatory requirements for patent linkage and patent term extensions. In addition, the deal includes provisions that may shorten the period of data exclusivity used for providing marketing approval. The bipartisan trade deal scaled down IPR provisions for pharmaceutical patents in U.S. FTAs with Peru, Panama, and Colombia. The Obama Administration is reviewing U.S. trade policy, including IPRs and pharmaceuticals.

Unilateral Trade Policy

Domestic trade policy tools also are available for U.S. efforts to advance international patent protection and enforcement. Such trade policy tools are often effective in influencing developing countries' decisions because the United States is a significant market for some trade partners. However, the use of these tools has been criticized by various interest groups.

Special 301

The most prominent of these tools is the USTR "Special 301" Report. Pursuant to Section 182 of the Trade Act of 1974, as amended (P.L. 93-618), the USTR identifies countries with inadequate IPR protection and enforcement regimes in its yearly Special 301 Report. USTR Special 301 country identifications consider all forms of IPR and take into account a host of factors, including the level and scope of the country's IPR infringement; the impact of infringement on the U.S. economy; the strength of the country's IPR laws and enforcement of IPR laws; the progress made by the country in improving IPR protection and enforcement; and the sincerity of the country's commitment to multilateral and bilateral trade agreements. The USTR can identify a country as

[60] Kelley Lee, Devi Sridhar, and Mayur Patel, "Bridging the Divide: Global Governance of Trade and Health," *Lancet*, vol. 373 (January 22, 2009), p. 418.

[61] The text of the May 10, 2007 Bipartisan Trade Deal is available on the USTR website at http://www.ustr.gov/assets/Document_Library/Fact_Sheets/2007/asset_upload_file127_11319.pdf.

denying sufficient intellectual property protection even if the country is complying with its commitments under the TRIPS Agreement.

The USTR identifies countries through a three-tier system, depending on the severity of the country's IPR violations. If a country is named as a "Priority Foreign Country," the USTR must launch an investigation into that country's IPR practices, and the country is subjected potentially to trade sanctions, including the suspension of trade concessions or the imposition of import restrictions or duties.[62] "Priority Watch List" countries are those whose acts, policies, and practices warrant concern, but do not meet all of the criteria for identification as a Priority Foreign Country. "Watch List" countries have intellectual property protection inadequacies that are less severe than those on the Priority Watch List, but still warrant U.S. attention. Countries identified for "Section 306" are monitored for compliance with bilateral intellectual property agreements used to resolve investigations under Section 301. Oftentimes, USTR identification of countries on the Special 301 list prompts countries to take actions to change their IPR practices.

Case Study: Thailand's Issuance of Compulsory Licenses for Medicines

Thailand has a national health care program that includes HIV/AIDS treatment. As more patients have become resistant to the first-line ARVs, they have required treatment with newer, more expensive ARVs. In response to the rising cost of medicines, in 2006, Thailand issued compulsory licenses for two ARVs for HIV/AIDS, as well as a heart medication. Prior to issuing the compulsory licenses, the Thai government reportedly engaged in negotiations with pharmaceutical companies to lower the prices of medicines.

In 2007, the USTR identified Thailand as a Priority Watch List country in its Special 301 report, citing "a weakening of respect for patents" and a "lack of transparency and due process" in the issuance of compulsory licenses. Although the USTR did not specifically mention Thailand's issuance of compulsory licenses for HIV/AIDS drugs in 2006, several Members of Congress interpreted USTR's decision as retaliation for Thailand's recent actions. Members argued that Thailand's actions were consistent with the WTO TRIPS Agreement. They pointed out that no prior consultation with patent holders is required in cases of extreme urgency or public non-commercial use and that Thailand entered into pharmaceutical consultations, even though it was under no obligation to do so. Members also expressed concern that the USTR decision would be viewed as a warning by the public health community and would deter other countries from pursuing similar actions.[63] For 2008 and 2009, Thailand remained on the Priority Watch List.[64] In response to U.S. pressure, Thailand reportedly decided to not continue its compulsory licensing policy and to promote access to medicines in other ways.[65]

Generalized System of Preferences

Another domestic policy tool used to protect IPRs is the Generalized System of Preferences (GSP). The United States may consider a developing country's IPR policies and practices as a basis for granting preferential duty-free entry to certain products from the country, and can suspend GSP benefits if IPR protection is lacking. For 2008, the USTR was scheduled to continue evaluating IPR protection in Russia, Lebanon, and Uzbekistan on the basis of petitions by the International Intellectual Property Alliance (IIPA) for ongoing GSP reviews.[66] The citation of a country on the USTR Special 301 watch lists may be grounds for withdrawing GSP benefits from

[62] Among other factors, the imposition of trade sanctions depends on whether or not the country is a WTO member. If the country is a WTO member, then the United States must use the WTO Dispute Settlement Mechanism to resolve the issue.

[63] Letter from Henry A. Waxman, Member of Congress, et al. to Ambassador Susan C. Schwab, USTR, June 20, 2007.

[64] USTR, *USTR Special 301 Report 2008*, pp. 36-37.

[65] "Thailand: Government not to extend compulsory licensing policy," *BBC Monitoring Asia Pacific*, May 2, 2009.

[66] USTR, *GSP: 2008 Annual Review*, http://www.ustr.gov.

that country. Because it is trade preferences that are being withdrawn, countries are unable to raise the removal of trade concessions as a WTO violation.

Case Study: South Africa and Access to HIV/AIDS Drugs

During the 1990s, South Africa considered issuing compulsory licenses for HIV/AIDS drugs. The United States strongly opposed these measures, on the grounds that they would hurt pharmaceutical innovation. Subsequently, the United States refused South Africa's request for additional GSP concessions and also placed South Africa on its Special 301 Watch List. In addition, South Africa was faced with corporate litigation. Ultimately, due to international pressure, the United States dropped its opposition and the pharmaceutical companies dropped its lawsuit against South Africa. [67]

U.S. Trade Policy and Support for Public Health

The USTR holds the view that its pursuit of a strong international IPR regime advances U.S. economic interests while at the same time supports public health. However, the U.S. government does not necessarily view trade policy as the primary policy tool to promote public health. According to a recent GAO report, "Trade and IP efforts are only one small part of the larger U.S. government effort to increase access to medicines."[68]

U.S. government efforts directed at increasing access to medicines may be promoted through foreign, health, education, and other policy areas. There are a number of U.S. government initiatives specifically designed to increase developing countries' access to medicines. For instance, the U.S. Department of State "primarily makes an effort to balance IP rights and access to medicines through public health initiatives it coordinates with other agencies or administers itself ... ."[69]

The United States has advocated for greater availability of certain generic drugs in certain areas of the world. One example of this is through PEPFAR, the U.S. President's Emergency Plan for AIDS Relief.[70] This initiative "supports the increased availability of safe, effective, low-cost, and generic antiretroviral drugs (ARVs) in the developing world ... " To meet the need for such ARVs, the FDA introduced an expedited "tentative approval" process through which ARVs produced by any manufacturer, including of generic manufacturers, internationally could be reviewed quickly for quality standards and approved for purchase under PEPFAR.[71]

Issues for Congressional Consideration

Possible issues of interest for Congress include incorporating public health input into the U.S. trade policy advisory process, developing new U.S. trade policy guidance on public health,

[67] Anna Lanoska, "The Global Politics of Intellectual Property Rights and Pharmaceutical Drug Policies in Developing Countries," *International Political Science Review*, vol. 24, no. 2 (April 2003).

[68] U.S. Government Accountability Office, *U.S. Trade Policy Guidance on WTO Declaration on Access to Medicines May Need Clarification*, GAO-07-1198, September 2007, p. 53.

[69] Ibid., p. 53.

[70] For more information on PEPFAR, see CRS Report RL34569, *PEPFAR Reauthorization: Key Policy Debates and Changes to U.S. International HIV/AIDS, Tuberculosis, and Malaria Programs and Funding*, by Kellie Moss.

[71] The United States President's Emergency Plan for AIDS Relief, "Increasing the Availability of Safe, Effective, Low-Cost Generic Medications," press release, January 2009, http://www.pepfar.gov/press/108120.htm.

considering the implications of the U.S. strategy on IPRs and trade for U.S. access to medicines, and reviewing the range of options utilized for expanding global access to medicines.

Public Health Representation in U.S. Trade Policy Process

Some observers of the U.S. trade policy process assert that the protection of intellectual property has been given more emphasis than the protection of public health. Advocates of public health maintain that the United States has a legal and moral imperative to ensure that public health is safeguarded through trade policy. They point out that the United States is a signatory to the United Nation's International Covenant on Economic, Social and Cultural Rights. Among the human rights agreed upon in the covenant, Article 12.1 provides "the right of everyone to the enjoyment of the highest attainable standard of physical and mental health." Many human rights organizations view access to medicines as a critical component of the fundamental human right to health. Other observers of the U.S. trade policy process assert that protection of IPRs contributes to the protection of public health, and that U.S. trade policy is one of multiple policy arenas that support public health.

USTR Advisory Committee

Some proponents of greater public health representation in the U.S. trade policy process often direct their attention to the USTR Advisory Committee structure, the central mechanism through which the USTR consults with the private sector and civil society organizations regarding the U.S. trade policy agenda and negotiations. Critics argue that private sector interests are granted greater representation in the advisory system than public health or other civil society interests. They argue that this "privileged access to government policy makers" allows commercial interests to influence the formulation of U.S. trade negotiating positions, which in turn have affected the WTO's agenda.[72]

According to a recent Government Accountability Office (GAO) report, for the review period of the report (November 2006 through November 2007), there were 16 Industry Trade Advisory Committees (ITACs), two of which each had a single public health representative. These committees are the Intellectual Property Committee and the Chemicals, Pharmaceuticals, Health Science Products and Services Committee, which were composed of 20 and 33 members, respectively, during the review period. Defenders of the current advisory system argue that public health representation is included in the ITACs most relevant to public health. Furthermore, according to officials from the USTR, it was "not necessary to have two public health representatives on one committee representing the same view, and they said they did not find any other viable candidates with additional perspectives beyond the individuals selected."[73]

Some lawmakers have urged the USTR to reform the formal trade advisory committee system. Among the suggestions put forth are creating a new advisory committee that addresses public health issues, including issues pertaining to developing countries, or a committee focusing on

[72] Kelley Lee, Devi Sridhar, and Mayur Patel, "Bridging the Divide: Global Governance of Trade and Health," *Lancet*, vol. 373 (January 22, 2009), p. 418.

[73] GAO, *U.S. Trade Policy Guidance on WTO Declaration on Access to Medicines May Need Clarification*, GAO-07-1198, September 2007.

trade and development.[74] In the 111th Congress, H.R. 2293 (Van Hollen) was introduced and referred to the House Ways and Means Committee on May 6, 2009, to ensure that public health views are represented and accommodated in developing U.S. trade policy. Specifically, the bill would require the creation of a Public Health Advisory Committee on Trade, whose membership would be restricted to individuals with expertise in various trade and public health issues, including issues in access to affordable pharmaceuticals. Membership would exclude individuals who represent commercial interests in health services or regulations. This committee would be located in the second tier of the Trade Advisory Committee System. In addition, the bill would require non-governmental public health officials to be appointed to the Advisory Committee for Trade Policy and Negotiations, a first-tier committee.

In the 110th Congress, Representative Van Hollen also introduced legislation to reform the trade advisory system (H.R. 3204) that differed from H.R. 2293 in certain ways. Both pieces of legislation include provisions for creating a Public Health Advisory Committee on Trade. However, H.R. 3204 also would have required that each ITAC must have at least one representative of labor, consumer interest, and public health. This provision was not included in H.R. 2293 in the 111th Congress.

While many public health advocates applaud legislation to increase public health representation on advisory trade committees, some caution against creating a trade advisory committee that focuses solely on health issues as this may insulate trade policy discussions from public health concerns. For instance, critics express concern that the USTR may limit consultations with the proposed health committee to a narrow set of technical issues and not on the broader implications of trade policy for public health. Among industry advocates, some may be critical of legislation that would dilute industry representation on the ITACs. They may contend that the ITACs were created as a vehicle for the USTR to consult specifically with industry.

Other channels for input on FTA negotiations include the "USTR's formal public hearings and the Federal Register comments." While the public health input through these alternate mechanisms may be higher, some question the relative weight of such input compared to that received through the ITACs.[75]

Special 301

For some observers of the U.S. trade policy process, another area of concern is the USTR Special 301 report. USTR identification of countries also involves gathering information and analysis based on the USTR's annual trade barriers report, as well as consultations with a wide variety of sources, including government agencies, industry groups, other private sector representatives, congressional leaders, and foreign governments. Some observers express concern that U.S. industry interests, such as those of PhRMA, heavily influence USTR's country identifications and that there is limited input from public health advocates, generic drug manufacturers, and other groups. Although the Special 301 Report is regarded by some as an effective form of U.S.

[74] "Ways and Means Democrats Urge U.S. Trade Representative Schwab to Strike balance Between Patent, Public Health Issues in Upcoming Trade Negotiations," *U.S. Fed News*, June 6, 2008.

[75] GAO *U.S. Trade Policy Guidance on WTO Declaration on Access to Medicines May Need Clarification*, GAO-07-1198, September 2007, pp. 56-57.

political pressure on trading partners, others express concern that disproportionate representation of industry interests may limit the legitimacy of the Special 301 trade policy tool.[76]

U.S. Trade Policy Guidance

In 2002, Congress granted Trade Promotion Authority (TPA) to then President Bush. The TPA included a commitment to ensure that U.S international trade agreements respected public health. Should Congress decide to renew Trade Promotion Authority (TPA) for President Obama, Members may choose to consider what, if any, public health mandate should the TPA include.

Another issue that Congress may choose to consider is the extent to which the May 10, 2007 bipartisan trade deal between then President George W. Bush and congressional leaders will serve as a template for the IPR provisions in future FTAs. Some also question whether or not this FTA template will be used for all future FTAs, or if will it be used according to the income status of a country. For instance, the template's scale-down in patent requirements was incorporated into the recently negotiated FTAs with Peru, Panama, and Colombia, which are considered low-income countries. They were not incorporated into the FTA with South Korea, which is considered to be a middle-income country. Some also question whether or not the May 10, 2007 bipartisan trade deal's changes to FTA patent provisions will be applied to existing FTAs.[77]

Some stakeholders encourage Congress to revisit the IPR provisions in the May 10, 2007 bipartisan trade deal. Among those stakeholders, some innovator pharmaceutical industry representatives hope that the Administration will decided to reverse the previous scale-down in patent provisions. For instance, the National Association of Manufacturers (NAM) believes that the pharmaceutical industry was unfairly singled out in the trade deal. However, others express concern that revisiting the deal may lead to re-evaluation of previously resolved issues. Global health advocates and generic pharmaceutical companies likely would resist changes to the IPR portions and could encourage further weakening of patent provisions in an effort to increase access to medicines.[78]

Implications of U.S. Strategy on IPR and Trade for U.S. Access to Medicines

Given that the United States is a primary producer of patents, some argue that a strong international IPR regime is economically beneficial to the United States. However, some observers question whether continually seeking higher standards of IPR will always be in the U.S. interest. Situations may arise in which the United States may wish to issue compulsory licenses to address global health or security threats. For instance, when the anthrax scare occurred in 2001, the United States and Canada considered issuing compulsory licenses for Cipro, a drug produced by the German company Bayer, so that their populations could access the drug at affordable prices. Some viewed U.S. and Canadian action as hypocritical, considering that these two

[76] Richard D. Smith, Carlos Correa, and Cecilia Oh, "Trade, TRIPS, and Pharmaceuticals," *The Lancet*, vol. 373 (February 21, 2009). Oxfam International, *US Bullying on Drug Patents: One Year After Doha*, Briefing Paper 33.

[77] Jamie Strawbridge, "NGOs Press USTR To Extend May 10 Deal On IPR To All Trade Pacts," *Inside U.S. Trade*, May 22, 2009.

[78] Erik Wasson, "Drug Firms Eye Revisit of IPR Template for Future Trade Deals," *Inside U.S. Trade*, March 6, 2009.

countries had pledged to "opt out" of using the TRIPS Agreement flexibilities and had pressured other countries to do the same. Some observers saw the incident as a cautionary example of how limiting flexibilities in patent regimes may be detrimental to U.S. interests. Another example is the H5N1 "avian influenza" crisis of 2005. The United States threatened to issue a compulsory license for the production of Tamiflu, the anti-viral drug produced by the Swiss company Roche. The United States was concerned that Roche lacked the production capacity to meet global demand for the medication. Roche ultimately agreed to ramp up production for Tamiflu by sub-licensing the patent to other manufacturers.[79]

Higher vaccine and drug prices associated with IPR protection and enforcement may reduce incentives for developing countries to share virus samples with the WHO in order to find cures for diseases. For instance, during the H5N1 "avian influenza" pandemic, Indonesia limited sharing H5N1 virus samples with WHO researchers. Indonesia expressed concerns that the vaccines would be patented and then offered for purchase at marked-up prices unaffordable for Indonesia and other developing countries. In March 2007, Indonesia began sharing virus samples again under the condition that an international agreement would be negotiated for more equitable, affordable sharing of vaccines.[80]

As China, India, and other industrializing countries continue to develop, a larger proportion of global patents may originate from these countries. Although the United States ranked as the leading source of applications under WIPO's Patent Cooperation Treaty (PCT) in 2008, U.S. patent filings fell by 1% from the previous year. In contrast, the growth rate in patent filings stood at about 12% for both China and South Korea. These shifts in the concentration of patents and the pharmaceutical marketplace may have implications for the cost of medicines for the United States and other developed countries. [81]

Non-Patent Options for Expanding Access to Medicines

Some public health advocates argue that the public should play a greater role in the provision of pharmaceutical solutions for diseases. Some suggest that U.S. strategies to address public health needs through trade policy should expand beyond patenting and compulsory licensing. The WHO Global Strategy on Public Health, Innovation and Intellectual Property calls for an exploration of a range of incentive mechanisms. In addition to patents, other methods of incentivizing the private sector to target R&D toward addressing public health needs of developing countries may include advance market commitments, patent pools, and innovation prizes. While such mechanisms may direct pharmaceutical R&D toward meeting the needs of developing countries, they may require governments to bear a greater share of the risks associated with R&D.[82]

[79] For an in-depth analysis, see CRS Report RL33159, *Influenza Antiviral Drugs and Patent Law Issues*, by Brian T. Yeh.

[80] Tim Wilson, "Spread the Flu Virus to Stop It," *The Asian Wall Street Journal*, May 1, 2009.

[81] NSF, "*Science and Engineering Indicators 2008*, "Industry, Technology, and the Marketplace," NSB 08-01; NSB 08-01A, Arlington, VA, January 2008, pp. 20-21.

[82] Carsten Fink, *Intellectual Property and Public Health: An Overview of the Debate with a Focus on U.S. Policy*, Center for Global Development, Working Paper Number 146, June 2008, pp. 22-23.

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