

Intellectual Property Rights and International Trade

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Summary

This report provides background on intellectual property rights (IPR) and discusses the role of U.S. international trade policy in enhancing IPR protection and enforcement abroad. IPR are legal rights granted by governments to encourage innovation and creative output by ensuring that creators reap the benefits of their inventions or works and they may take the form of patents, trade secrets, copyrights, trademarks, or geographical indications. U.S. industries that rely on IPR contribute significantly to U.S. economic growth, employment, and trade with other countries. Counterfeiting and piracy in other countries may result in the loss of billions of dollars of revenue for U.S. firms as well as the loss of jobs. Responsibility for developing IPR policy, engaging in IPR-related international negotiations, and enforcing IPR laws cuts across several different U.S. Government agencies.

Promoting the enforcement of IPR is an important component of U.S. international trade policy. Since the 1995 Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) at the World Trade Organization (WTO), trade policy has been used to enforce IPR abroad. The United States and several trading partners recently announced plans to pursue a multilateral anti-counterfeiting agreement that would surpass TRIPS Agreement commitments.

The United States also pursues international IPR support through regional and bilateral free trade agreements (FTAs), which often include IPR commitments by U.S. partners exceeding their TRIPS Agreement obligations. However, for the Peru, Panama, and Colombia FTAs, the Administration agreed to scale back some IPR requirements to bolster bipartisan support for the FTAs. Other trade policy tools also are available for U.S. efforts to advance international IPR. Pursuant to Section 182 of the Trade Act of 1974 as amended (P.L. 93-618), the Office of the U.S. Trade Representative (USTR) identifies countries providing inadequate IPR protection in its annual "Special 301" report. Section 337 of the amended Tariff Act of 1930 authorizes the U.S. International Trade Commission (ITC) to prohibit U.S. imports of infringing products. Additionally, under the Generalized System of Preferences (GSP), the United States may consider a developing country's IPR policies and practices as a basis for offering preferential duty-free entry to certain products from the country, and can suspend GSP benefits if IPR protection is lacking.

IPR protection and enforcement bring up several key issues for Congress. A central issue is the appropriateness of FTAs as a vehicle for promoting IPR. Congress also faces the challenge of balancing the need for IPR protection and enforcement with the goals of the Doha Declaration on Public Health. Additionally, there has been concern about the effectiveness of the current U.S. IPR enforcement structure. In the 110th Congress, Legislation (P.L. 110-403) was enacted to establish a new structure to coordinate federal IPR enforcement activities. This report will be updated as warranted by events.

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Introduction

Intellectual property rights (IPR) traditionally have been matters of national concern. Individual nation states have developed IPR regimes reflecting their national needs and priorities. Over time, intellectual property protection and enforcement have come to the forefront as a key international trade issue for the United States, figuring prominently in the multilateral trade policy arena and in regional and bilateral U.S. free trade agreements (FTAs).

The protection and enforcement of IPR in the United States and abroad is of key interest to Congress. Intellectual property is an increasingly critical component of the U.S. economy. Industries that rely on intellectual property protection in the United States claim to lose billions of dollars each year due to overseas IPR infringement. There is also concern about the potential health and safety consequences of counterfeit pharmaceutical drugs and other products, as well as the link between terrorist groups and traffic in counterfeit and pirated goods. The role of Congress in addressing IPR and trade-related issues stems from the U.S. Constitution, which provides Congress with the power to regulate international trade. While authority to negotiate trade agreements has been delegated periodically to the President, Congressional action is needed to bring the agreements into force.

In promoting IPR through international trade policy, Congress may choose to consider whether or not FTAs are an appropriate vehicle for boosting intellectual property protection and enforcement. Congress may also balance IPR protection and enforcement with other public policy goals such as access to medicine in poor or developing countries. Another issue that is before Congress is the effectiveness of the current U.S. coordinating structure for promoting international IPR support. In the 110th Congress, legislation was enacted to establish a new entity to coordinate intellectual property activities within the federal government. Legislation was also introduced calling for greater U.S. international IPR enforcement efforts and increased prioritization of resources devoted to such activities.

This report discusses the different kinds of IPR; forms of IPR infringement; importance of IPR to the U.S. economy; estimated losses associated with IPR infringement; organizational structure of IPR protection in multilateral, regional, bilateral arenas; U.S. government agencies involved with IPR and trade; and issues for Congress regarding IPR and international trade. This report will be updated as events warrant.

Intellectual Property Rights Basics

This section provides definitions of the various kinds of intellectual property rights (patents, trade secrets, copyrights, trademarks, and geographical indications) and intellectual property rights misappropriation (infringement, piracy, and counterfeiting).

Types of Intellectual Property

IPR are legal rights granted by governments to encourage innovation and creative output. They ensure that creators reap the benefits of their inventions or works and may take the form of patents, trade secrets, copyrights, trademarks, or geographical indications. Through IPR, governments grant a temporary legal monopoly to innovators by giving them the right to limit or

control the use of their creations by others. IPR may be traded or licensed to others, usually in return for fees and or royalty payments. Although the World Trade Organization's (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) provides minimum standards for IPR protections, such rights are granted on a national basis and are, in general, enforceable only in the country in which they are granted. However, countries are obliged to abide by WTO rules and their IPR enforcement practices can be challenged by other countries at the WTO.

Patents

The Patent Act (35 U.S.C. 101 *et seq*) governs the issuance and use of patents in the United States. Patents are granted for inventions of new products, processes, or organisms (known as utility patents). Patents may also be granted for designs and plants. For an invention to be patentable, it must be new, "non-obvious" (involving an inventive step), and have a potential industrial or commercial application. The patent provides the holder with the exclusive right to sell the invention for a period of 20 years, or to prevent the incorporation of the invention into other products without the permission of the rights-holder. The patent right is based on the proposition that inventors must be granted a temporary monopoly over their invention in order to encourage innovation and to promote the expenditure of money on research and development. The patentholder recoups his up-front costs through a temporary monopoly over sale of the invention. In return for this economic rent, the patentholder must disclose the content of the patent along with test data and other information concerning the invention. This is meant to spur further creativity by those seeking to build on the patent after its expiration. Domestically, patents are granted by the Patent and Trademark Office (PTO) of the Department of Commerce.

Trade Secrets

A trade secret is any type of valuable information, including a "formula, pattern, compilation, program device, method, technique, or process," that derives independent economic value from not being generally known or readily ascertainable and is subject to reasonable efforts by the owner to maintain its secrecy.[1] Examples of trade secrets include blueprints, customer lists, and pricing information. While protection of patents and copyright is a matter of federal law, trade secret protection is found also in state law. However, most states subscribe to the Uniform Trade Secret Act (UTSA).

There are important differences between trade secrets and patents. Individuals do not have to apply for trade secret protection as they would do with patents. Protection of trade secrets originates immediately with the creation of the trade secret; there is no process for applying for or registering trade secrets. Trade secret protection does not expire unless the trade secret becomes known. In contrast, patent applicants must disclose information about their innovation to the PTO in order to acquire a patent. Patents offer rights holders stronger protection but for a limited period of time. While applying for a patent can be a costly and lengthy process, patents are valuable if the confidentiality of the innovation is fragile or if the area of research is highly competitive.

[1] Uniform Trade Secret Act, §1(4).

Copyright

Protection of copyrights in the United States is based on the Copyright Act (17 U.S.C. 101, *et seq*). Copyrights protect original expressions of authorship. Such protections include literary or artistic works such as books, music, sound recordings, movies, paintings, architectural works, and computer software and databases (though not individual bits of data). Traditionally, copyrights differed from patents in that there was no claim to industrial applicability or novelty of the idea. The expression of the idea, not the underlying idea, was being copyrighted. While some of the criteria for copyrights differ from those of patents, the objective is the same; investments of time, money, and effort to create work of cultural, social and economic significance should be protected to encourage further creativity. U.S. law protects authorship for life plus 70 years for personal works, or 120 years from creation (or 95 years from publication) for corporate works. Copyrights may be registered by the Copyright Office of the Library of Congress, or acquired through creating and fixation of the work of authorship.

Trademarks

Trademark protection in the United States is governed jointly by state and federal law. The main federal statute is the Lanham Act of 1946 (15 U.S.C. 1051, *et seq*). Also known as service marks, trademarks permit the seller to use a distinctive name, mark, or symbol to identify and market a product, service, or company. The trademark allows quick identification of the seller's product, and for good or ill, can become an indicator of a product's quality. If for good, the trademark can be valuable in the introduction of new products by conveying an instant assurance of quality. The trademark is designed to prevent other companies with similar merchandise from free-riding on the association of quality with the trademarked item. Thus, a trademarked good may command a premium in the marketplace because of its reputation. For trademarks, distinctiveness is at a premium because a trademark must capture the consumer's imagination to be effective as generic names of commodities cannot be trademarked. Trademark rights are acquired through use or through registration with the PTO.

A related concept to trademarks is the **geographic indication,** which is also protected by the Lanham Act. The geographic indication acts to protect the quality and reputation of a distinctive product originating in a certain region; however, the benefit does not accrue to a sole producer, but rather the producers of a region. Geographic indications are generally sought for agricultural products, or wines and spirits. Protection for geographical indications is acquired in the United States by registration with the PTO, through a process similar to trademark registration.[2]

Infringement of Intellectual Property

In the case of patents, infringement of a patent owner's exclusive rights (as afforded by patent laws) involves a third party's unauthorized use of the patented device. As relates to international trade, the greatest challenge to the patent right is infringement in foreign countries, or non-observance by WTO member states to the minimal standards of the TRIPS Agreement. Copyright infringement occurs when a third party engages in one of the acts requiring the copyright owner's

[2] For information on geographical indications and international trade negotiations, see CRS Report RS21569, *Geographical Indications and WTO Negotiations*, by Charles E. Hanrahan.

permission without his consent, including reproducing, performing, making sound or visual recordings of, and broadcasting the copyrighted work.

Piracy

The term "piracy" has applications to both copyrights and trademarks. The major challenge facing copyright protection is piracy, either through physical duplication of the work, illegal dissemination of copyrighted material (such as computer software, music, or movies) over the Internet, and/or participation in commercial transactions of copyrighted materials without the consent of the copyright owner. With respect to trademarks, piracy involves the registration or use of a famous foreign trademark that is not registered in the country or is invalid because the trademark has not been used.

Counterfeiting

An imitation of a product is referred to as a "counterfeit" or a "fake." Counterfeit products are manufactured, marketed, and distributed with the appearance of being the genuine good and originating from the genuine manufacturer.[3] The purpose of counterfeit goods is to deceive consumers about their origin and nature. Counterfeiting and copying of original goods is a major challenge for trademarked products. The counterfeited product can be sold for a premium because of its association of the original item, while reducing the sales of the original items. Furthermore, consumer experience with a counterfeited good of inferior quality, can damage the reputation of the trademark product. Popular examples of counterfeit products in fake fashionwear, such as Louis Vuitton bags or Rolex watches, or fake pharmaceutical products, such as popular brand-name prescription medicines.

A related issue is the imitation of labels and packaging of trademarked goods. In this situation, the imitator uses a trademark that is confusingly similar to a well-known trademark in order to benefit from the reputation of the product with which he is competing.

Global Intellectual Property Holdings

Intellectual property holdings that are protected by international agreements are concentrated in firms headquartered in the United States and other developed economies. The United States continues to be the source of the world's largest number of patent filing applications under the Patent Cooperation Treaty (PCT), an international patent filing system administered by the World Intellectual Property Organization (WIPO). The United States, along with Germany and Japan, accounted for about 60% of all patent applications filed in 2008 under the PCT (see **Table 1**).

In comparison, developing countries tend to be net importers of intellectual property and represented only 8% of all PCT international patent filings in 2006.[4] Given that developing

[3] Counterfeit goods should be distinguished from generic goods, i.e., in the case of generic forms of pharmaceutical medicines.

[4] WIPO, "Record Year for International Patent Filings with Significant Growth from Northeast Asia," press release, February 8, 2007, http://www.wipo.int/pressroom/en/articles/2007/article_0008.html. Statistics on patent applications filed and patents granted by country office are available on the WIPO website, http://www.wipo.org.

countries accounted for about 78% of signatories to the PCT, WIPO has engaged in efforts to ensure that developing countries also are able to take advantage of intellectual property. However, patent filings levels are not uniform among developing countries. In 2008, Korea and China continued to be among the top fifteen countries of origin for PCT international applications. Both countries had double-digit growth rates in patent filings from the previous year. Korea and China, along with India, Brazil, South Africa, Turkey, Mexico, and Malaysia, represented the majority of all patent filings from developing countries.

The total number of patent filings received by the PCT in 2008 represented the highest number in a single year. However, international growth in patent filings slowed to 2.4% in 2008, compared to an average growth rate of 9.3% for the previous three years. Some observers express concern that the slowdown in filings is associated with the global economic downturn, which may be affecting investment and spending on research and development.[5]

Table 1. Global Intellectual Property Filings Through the PCT, 2006-2008

Country	2006	2007	2008		
	Filings	Filings	Filings	% of Total	% Change from 2007
United States	50,941	54,086	53,521	32.7	-1.0
Japan	27,033	27,744	28,744	17.5	3.6
Germany	16,732	17,818	18,428	11.3	3.4
Korea	5,944	7,061	7,908	4.8	12.0
France	6,242	6,568	6,867	4.2	4.6
China	3,951	5,441	6,089	3.7	11.9
United Kingdom	5,090	5,539	5,517	3.4	-0.4
Netherlands	4,529	4,355	4,349	2.7	-0.1
Sweden	3,316	3,657	4,114	2.5	12.5
Switzerland	3,577	3,778	3,832	2.3	1.4
Canada	2,566	2,847	2,966	1.8	4.2
Italy	2,716	2,946	2,939	1.8	-0.2
Finland	1,845	1,995	2,119	1.3	6.2
Australia	2,001	2,053	2,028	1.2	-1.2
Israel	1,589	1,746	1,882	1.1	7.8
All Others	11,084	12,252	12,947	7.6	2.0
Totals	**149,156**	**159,886**	**163,800**	**---**	**2.4**

Source: World Intellectual Property Organization.

[5] 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.

Contribution of Intellectual Property to U.S. Economy

Intellectual property is an important source of comparative advantage for the United States. Numerous industries in the United States rely on intellectual property for their businesses. Among the industries that are dependant on patent protection are the aerospace, automotive, computer, consumer electronics, pharmaceutical, and semiconductor industries. Copyright-based industries include the software, data processing, motion pictures, publishing, and recording industries. Other industries that indirectly benefit from IPR protection include retailers, traders, and transportation businesses, which support the distribution of goods and services derived from intellectual property.[6]

According to a 2004 study, U.S. industries that rely on intellectual property accounted for close to 40% of total growth achieved by the U.S. private sector in 2003. These industries comprised about 20% of the private sector's contribution to the U.S. gross domestic product (GDP) that same year. With almost 18 million workers, the intellectual property industries are one of the largest source of jobs in the United States; employees receive notably higher wages than individuals in other sectors.[7] More broadly, IPR-intensive industries also contribute positively to the U.S. economy through productivity gains and other spillover effects.

The intellectual property industries contribute positively to the overall U.S. trade balance through royalties and licensing fees. Rights-holders may authorize the use of technologies, trademarks, and entertainment products that they own to entities in foreign countries, resulting in revenues through royalties and license fees.[8] In 2006, U.S. receipts from cross-border trade in royalties and license fees (relating to patent, trademark, copyright, and other intangible rights) amounted to $63.4 billion and payments totaled $26.4 billion. This resulted in a surplus of $37.0 billion, a 6% percent increase from the previous of year.[9]

Industry-specific figures also demonstrate the importance of the intellectual property to the U.S. economy. For example, the business and entertainment software, motion pictures, recording, and publishing industries, which rely on copyright protection, was estimated to constitute about $819 billion or about 7% of U.S. GDP in 2005. These industries accounted for nearly 13% of U.S. economic growth and 4% of U.S. employment (5.4 million workers) in 2005. Foreign sales and exports from these industries amounted to $110.8 billion in 2005.[10]

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[6] Stephen E. Siwek, "Engines of Growth: Economic Contributions of the US Intellectual Property Industries," commissioned by NBC Universal, 2005, p. 2.

[7] Ibid., p. 3.

[8] Amanda Horan, Christopher Johnson, and Heather Sykes, *Foreign Infringement of Intellectual Property Rights: Implications for Selected U.S. Industries*, U.S. International Trade Commission, Office of Industries Working Paper, October 2005, p. 4.

[9] Jennifer Koncz, Michael Mann, and Erin Nephew, "U.S. International Services," *Survey of Current Business*, U.S. Bureau of Economic Analysis (BEA), October 2007, pp. 53-54. This measure of cross-border trade in royalties and license fees by U.S. companies include transactions with both affiliated and unaffiliated foreign companies.

[10] Stephen E. Siwek, *Copyright Industries in the U.S. Economy: The 2006 Report*, prepared for the International Intellectual Property Alliance (IIPA), November 2006, http://www.iipa.com, pp. 3-5.

The pharmaceutical industry, which is dependent on patents, provides another illustration of intellectual property contributions to the U.S. economy. Domestic sales by research-based pharmaceutical companies that are members of Pharmaceutical Researchers and Manufacturers of America (PhRMA) were an estimated $189.6 billion in 2007, a 6.7% increase from the previous year ($177.7 billion). PhRMA company sales abroad increased by 10.0% from $76.8 billion in 2006 to $81.9 billion in 2007.[11] The U.S. pharmaceutical industry maintains a strong global position, accounting for over 30% of value added in the global pharmaceutical market place in 2005.[12]

Prevalence and Economic Consequences of IPR Infringement

Several factors contribute to the growing problem of IPR infringement. While the costs and time for research and development are high, IPR infringement is associated with relatively low costs and risks and a high profit margin. For instance, based on a survey of ten pharmaceutical companies, the Tufts Center for the Study of Drug Development estimated that the cost for developing a new drug cost was over $800 million on average.[13] According to PhRMA, it takes about 10 to 15 years of research and development to create a new drug. Pharmaceutical companies collectively spent an estimated $44.5 billion for research and development in 2007.[14] In contrast, drug counterfeiters can lower production costs by using inexpensive, and perhaps dangerous or ineffective, ingredient substitutes. The development of technologies and products which can be easily duplicated, such as recorded or digital media, has led to an increase in counterfeiting and piracy. Increasing Internet usage also has contributed to the distribution of counterfeit and pirated products. Additionally, civil and criminal penalties often are not sufficient deterrents for piracy and counterfeiting. The United States is especially concerned with *foreign* IPR infringement of U.S. intellectual property. Compared to foreign countries, IPR infringements levels in the United States are estimated to be relatively low.

Seizures

Because of the secretive, illicit nature of IPR infringement, it is difficult to estimate the magnitude of its impact on U.S. producers and exporters. However, data on seizures of counterfeit and pirated goods can be obtained from customs authorities. One study by the Organization for Economic Cooperation and Development (OECD) indirectly extrapolated available customs data on seizures to conclude that worldwide trade in counterfeit and pirated goods may have amounted to $200 billion in 2005. In particular, the study used the customs information to estimate the probability that imports of particular goods from particular countries would be pirated or counterfeit. The OECD estimate does not include the counterfeit and pirated goods produced and consumed within a country and does not include infringing goods distributed

[11] PhRMA, *Pharmaceutical Industry Profile 2008*, Washington, D.C., March 2008, http://www.phrma.org.

[12] National Science Foundation (NSF), "Science and Engineering Indicators 2008," *Chapter 6: Industry, Technology, and the Global Marketplace*, 2008, http://www.nsf.gov/statistics/seind06/, p. 21.

[13] J.A. DiMasi, "Tufts Center for the Study of Drug Development Pegs Cost of a New Prescription Medicine at $802 Million," press release, November 30, 2001. The study is available at http://csdd.tufts.edu/. Some contend that the study overestimates actual research and development costs for creating a new drug; Public Citizen offers a critique, accessible at http://www.publiccitizen.org.

[14] PhRMA, *Pharmaceutical Industry Profile 2008*, Washington, D.C., March 2008, http://www.phrma.org.

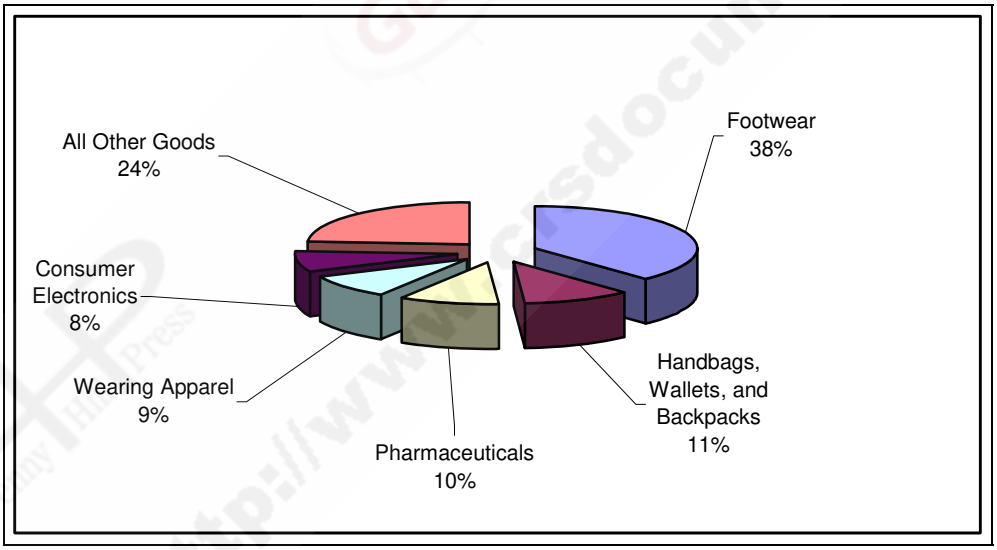
over the Internet. If these figures were included, the trade estimate undoubtedly would be higher.[15]

Data on pirated and counterfeit seizures at the U.S. border, provided by the U.S. Department of Homeland Security (DHS), shed light on U.S. trade in IPR infringement problem within the United States (see **Figure 1**). In 2008, the Customs and Border Protection (CBP) and Immigration and Customs Enforcement (ICE) agencies of the DHS made 14,992 IPR-related seizures, a nearly 10% increase from 2007. The domestic value of seizures totaled $272.7 million in 2008, a roughly 40% increase from 2007 ($196.7 million).[16]

A top priority for the CBP is seizing counterfeit imports that endanger the health and safety of consumers, such as fake healthcare products, pharmaceutical products, and consumer electronics.[17] IPR-related seizures of commodities that represent potential safety and security risks increased from $27.8 million in 2007 to $62.5 million in 2008. Pharmaceutical goods accounted for the majority of goods posing health and safety risks.[18]

DHS provides data on counterfeit goods seized by category. Counterfeit footwear ranked as the top commodity seized, representing $102.3 million in domestic value. Other popular items by domestic value included handbags, wallets, and backpacks ($29.6 million); pharmaceuticals ($28.1 million); wearing apparel ($25.1 million); and consumer electronics ($22.9 million).[19]

Figure 1. 2008 Border Seizures of Counterfeit and Pirated Goods



Sources: U.S. Customs and Border Protection and U.S. Immigration and Customs Enforcement.

[15] OECD, *The Economic Impact of Counterfeiting and Piracy*, 2007, p. 4, http://www.oecd.org/dataoecd/13/12/38707619.pdf.

[16] U.S CBP and U.S. ICE, *Intellectual Property Rights Seizure Statistics: FY2008*, January 2009.

[17] NIPLECC, " NIPLECC, *Report to the President and Congress on Coordination of Intellectual Property Enforcement and Protection*, January 2008, p. 74.

[18] U.S Customs and Border Protection and U.S. Immigration and Customs Enforcement, *Intellectual Property Rights Seizure Statistics: FY2008*, January 2009.

[19] Ibid.

Of all U.S. trading partners, China continues to account for the majority of counterfeits intercepted at the U.S. border. In 2008, seizures of goods originating from China represented 81% of all seizures and $221.6 million in value. Other top trading partners from which IPR-infringing goods were seized include India, Hong Kong, Taiwan, and Korea. [20]

Sectoral Infringement

U.S. industries that rely on IPR protection claim to lose billions of dollars in revenue annually due to piracy and counterfeiting. In 2002, the CBP estimated that counterfeit goods cost U.S. companies and industries about $200 billion in revenue loss and 750,000 in job loss each year.[21] Also in 2002, the U.S. Federal Bureau of Investigation (FBI) estimated that counterfeiting and piracy resulted in U.S. business revenue losses between $200 million and $250 million annually.[22] Given the above estimates, the Coalition Against Counterfeiting and Piracy (CACP) asserts that a conservative estimate for U.S. businesses' annual revenue loss due to counterfeiting and piracy is about $225 billion.[23] More recent comprehensive estimates of the total losses experienced by U.S. businesses due to all types of IPR infringement are not available. However, two intellectual property-based sectors that have calculated the extent of infringement in their industries and related costs are copyrights and pharmaceuticals. A discussion of estimated losses from these two sectors follows.

Copyright Industry

The International Intellectual Property Alliance (IIPA), a coalition of seven member associations representing over 1,300 U.S. copyright-based companies, provides annual estimates of U.S. trade loss associated with copyright infringements in selected countries.[24] For 2007, the IIPA claimed that copyright infringements in 43 countries resulted in an estimated $18.3 billion in trade losses for the United States (see **Table 2**). China was the leading culprit in terms of trade losses due to copyright piracy, contributing to at least $3.5 billion in trade losses in 2007. Russia was the second largest source of trade losses, totaling nearly $2.6 billion that year.[25]

[20] Ibid.

[21] CBP, "U.S. Customs Announces International Counterfeit Case Involving Caterpillar Heavy Equipment," press release, May 29, 2002. Cited by LECG, LLC, *Economic Analysis of the Proposed CACP Anti-Counterfeiting and Piracy Initiative*, November 27, 2007.

[22] FBI, press release, July 17, 2002, http://www.fbi.gov/pressrel/pressrel02/outreach071702.htm. Cited by LEG, LLC, *Economic Analysis of the Proposed CACP Anti-Counterfeiting and Piracy Initiative*, November 27, 2007.

[23] LEG, LLC, *Economic Analysis of the Proposed CACP Anti-Counterfeiting and Piracy Initiative*, November 27, 2007.

[24]The IIPA member associations are: Association of American Publishers (AAP), Business Software Alliance (BSA), Entertainment Software Alliance (ESA), Independent Film and Television Alliance (I.F.T.A.), Motion Picture Association of America (MPAA), and Recording Industry Association of America (RIAA).

[25] IIPA, "2008 'Special 301 USTR Decisions: IIPA's 2006 and 2007 Estimated Trade Losses Due to Copyright Piracy (in millions of U.S. dollars) and 2006-2007 Estimated Levels of Copyright Piracy," June 17, 2008, http://www.iipa.com.

Table 2. Estimated U.S. Trade Losses Due to Copyright Piracy, 2006-2007

(Millions of U.S. dollars)

Copyright Industry	2006	2007
Business software	9,141.0	13,004.0
Records and music	2,293.3	2,182.5
Motion pictures	Not available	Not available
Entertainment software	1,891.3	2,578.0
Books	548.5	525.0
Totals	13,873.6	18,289.5

Source: IIPA "Special 301" Report.

IIPA predicts that U.S. trade losses due to copyright infringement may be higher than reported because its estimates do not account for Internet piracy, which IIPA contends is an important contributor to copyright piracy.[26] There is a possibility that such IPR infringement loss estimates actually may overestimate the extent to which sales of pirated and counterfeit goods displace legitimate sales. The basic economic model employed in such estimates assumes that there is perfect substitutability between pirated and legitimate goods, which would equate sales of pirated goods to revenue losses of legitimate U.S. copyright businesses. Some analysts suggest that legitimate firms face a competition threat *only* if the individuals purchasing counterfeit products would be able and willing to purchase the legitimate product at the price offered when piracy is not present.[27] For consumers in poor developing countries, especially, this assumption may not be tenable.

There is not always a direct relationship between IPR infringement rates and the costs to U.S. firms. The size of a country's market and U.S. industries' access to the market affect the extent to which infringement rates translate into costs to U.S. IPR-based industries. For instance, the United States had the lowest software piracy rate in the world in 2006 (21%). However, the United States was also the largest contributor to piracy losses for the U.S. business software industry because of the significant size of the domestic computer software market. Losses to the software industry from U.S.-based piracy totaled $7.3 billion in 2006. By contrast, countries with higher software piracy rates, nevertheless, had lower infringement costs to U.S. software firms (see **Table 3**). The smaller sizes of the markets in these countries contributed to lower piracy-related absolute losses stemming from these countries. The worldwide software piracy rate was 35%, with global piracy amounting to $39.6 billion in losses for the U.S. business software industry.[28]

[26] IIPA, "The Copyright Industries in the International Intellectual Property Alliance (IIPA) Submit to USTR their 2007 Report on Piracy in 60 Countries/Territories," press release, February 12, 2007, http://www.iipa.com.

[27] Robert G. Picard, "A Note on Economic Losses Due to Theft, Infringement, and Piracy of Protected Works," *Journal of Media Economics*, 17(3), 207-217, 2004.

[28] BSA, *Fourth Annual BSA and IDC Global Software Piracy Study*, May 2006, http://www.bsa.org/globalstudy/, pp. 10-11.

Table 3. 2006 Software Piracy Rates and Losses to U.S. Business Software Companies From Selected Countries

Country	Piracy Rate	Piracy Loss (millions of U.S. dollars)
Zimbabwe	91%	$2
Vietnam	88%	$96
Pakistan	86%	$143
China	82%	$5,429
Russia	80%	$2,197
Canada	34%	$784
Denmark	25%	$183
United States	21%	$7,289

Source: Business Software Alliance.

Motion Picture Piracy Losses: A Closer Look at the Numbers

Recent studies have focused on the economic damages sustained by specific copyright industries. A study conducted by LEK Consulting for the MPAA asserted that the direct economic losses to major U.S. movie companies due to motion picture piracy was approximately $6.1 billion in 2005.[29] Conversely, this figure can be viewed as an estimate of the future gains that the could be obtained if piracy was reduced substantially.

The study found that 80% of U.S. motion picture studio losses resulted from piracy overseas, while 20% resulted from piracy in the United States. China had the greatest motion picture piracy rate, with an estimated 90% of the motion picture market considered to be illegitimate. U.S. film companies lost an estimated $244 million in revenue from piracy in China. At 80%, Russia and Thailand had the second highest motion picture piracy rates, with losses totaling $266 million and $149 million respectively. In terms of dollars losses, however, the leading sources of potential dollar losses for U.S. businesses were Mexico ($483 million), the United Kingdom ($406 million), and France ($322 million), which had significantly lower rates of piracy than the former countries.

A subsequent study found that in addition to the direct losses faced by the motion picture industry, there are also losses sustained by "downstream" industries, such as motion picture theatrical exhibitors or the home-video industry. Accounting for these losses, the motion picture industry experiences $20.5 billion annually in lost output. Using economic multipliers, the study estimated that 141,030 jobs would have been created in the United States annually if motion picture piracy did not occur. This translates into $2.7 billion in lost earnings each year by U.S. workers. The federal, state, and local governments would lose at least $422 million in tax revenues annually from lost personal income, corporate income, and production taxes. This analysis is based on a Regional Input-Output Modeling System (RIMS), which is maintained by the U.S. Bureau of Economic Analysis (BEA).[30] The study appears to be based on the assumption that the extra revenue that would be obtained absent piracy would be directed toward increased film production.

[29] Analysis prepared by LEK, *The Cost of Movie Piracy*, MPAA, p. 5, http://www.mpaa.org.

[30] Stephen E. Siwek, *The True Cost of Motion Picture Piracy to the U.S. Economy*, Institute for Policy Innovation, Policy Report #186, September 2006, pp. 4-6, 8-9, http://www.ipi.org.

Pharmaceutical Industry

The World Health Organization (WHO) estimates that many countries in Africa, Asia, and Latin America have areas where between 10% and 30% of medicines sold are counterfeit.[31] In the United States and many other developed countries, with relatively strong regulatory systems, the prevalence of counterfeit drugs is low. According to U.S. customs data, in FY2008, pharmaceuticals accounted for 45% ($28 million in domestic value) of all commodities seized at U.S. borders that posed potential safety and security hazards.[32] There continues to be concern about the vulnerability of the U.S. medicine supply and distribution chain, especially in light of recent high-profile cases about counterfeit drugs entering the United States.

PhRMA provides annual estimates of U.S. pharmaceutical industry losses from foreign violations of data exclusivity and patent protection.[33] In its 2007 Special 301 submission to the USTR (covering the period of October 2005 to September 2006), PhRMA contended that its member companies sustained damages totaling an estimated $21.7 million from data exclusivity and patent violations in 24 countries (see **Table 4**).[34] Damages reported in the 2007 submission were nearly double those reported in the prior year's submission (covering October 2005 to September 2005). While the total loss associated with IPR infringement grew, damages as a percentage of sales declined from the 2006 submission to the 2007 submission.[35] At the time of reporting for 2008 Special 301 submissions, PhRMA was not able to provide damage estimates due to trade barriers associated with intellectual property protection and market access.[36]

Table 4. Estimated Damages for PhRMA Member Companies From Data Exclusivity and Patent Protection Violations

	Oct. 2004 - Sept. 2005	Oct. 2005 - Sept. 2006
Total Damages	$13.9 million	$21.7 million
Total Sales	$74.6 million	$172.1 million
Damages as a Percentage of Sales	19%	13%

Source: PhRMA 2006 and 2007 Special 301 Submissions.

[31] WHO, "Counterfeit Medicines," fact sheet, revised November 14, 2006, http://www.who.int/mediacentre/factsheets/fs275/en/index.html.

[32] U.S CBP and U.S. ICE, *Intellectual Property Rights Seizure Statistics: FY2008*, January 2009. Because of the costs and resources required to conduct physical inspections, many counterfeit products escape inspection, making it difficult to determine the fraction of pirated goods caught. As a result, seizure statistics from the DHS agencies do not reflect on the overall size of the counterfeit market and total losses.

[33] PhRMA's calculations of damage due to violations of data exclusivity are based on a five-year data protection period; any sales not made by the patent holder within the data exclusivity period were regarded as data exclusivity damages. For damages from patent protection violations, PhRMA used a ten-year patent protection period and considered any sales not made by the patent holder within that period to be damages. For some countries, PhRMA did not report damages because data was not available at the time.

[34] Economic losses in PhRMA's annual Special 301 submission are not reported on calendar-year basis because fourth quarter economic data is not available at the time the report is issued.

[35] PhRMA, *Special 301 Submission for 2007.* See Appendix: Damage Estimate Methodology, p. v.

[36] PhRMA, *Special 301 Submission 2008*.

The Organization Structure of IPR Protection

Given the importance of intellectual property to the U.S. economy and the economic losses associated with counterfeiting and piracy, the United States is a leading advocate of strong global IPR standards and enforcement. Increasingly, the United States has integrated IPR policy in its international trade policy activities, pursuing enhanced IPR laws and enforcement through the WTO, regional and bilateral trade agreements, and national trade laws.

Multilateral IPR System

World Trade Organization (WTO)

At the center of the present multilateral trading system is the World Trade Organization (WTO), an international organization established in 1995 as the successor to the General Agreements on Tariffs and Trade (GATT). The WTO was established as the result of the Uruguay Round of trade negotiations (1986-1994), which resulted in numerous agreements on trade in goods, services, investment and other non-tariff barriers to trade. One of the Uruguay Round agreements was the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). The TRIPS Agreement sets minimum standards on intellectual property rights protection and enforcement with which all WTO member states must comply. The United States, the European countries, and the IPR business community were instrumental in including IPR on the Uruguay Round agenda. Many developing countries were wary of including IPR in trade negotiations, preferring to discuss them under the World Intellectual Property Organization (WIPO) (see below) instead. However, developing countries acceded, after being granted delayed compliance periods, and after achieving negotiating goals on other issues such as textiles and clothing, and savoring the prospect of operating under a rules-based trading system.

While previous international agreements on intellectual property rights continue to exist (see **Table 4**), the TRIPS Agreement was the first time that intellectual property rules were incorporated into the multilateral trading system. Two basic tenets of the TRIPS Agreement are national treatment (signatories must treat parties of other WTO members no less favorably in terms of IPR protection than the party's own nationals) and most-favored-nation treatment (any advantage in IPR protection granted to the party of another WTO member shall be granted to nationals of all other WTO member states).

Much of the TRIPS Agreement sets out the extent of the agreement's coverage of the various types of intellectual property: copyrights, trademarks, geographical indications, industrial designs, patents, layout of circuitry design, trade secrets, and test data. The TRIPS Agreement provisions build on several existing IPR treaties administered by the WIPO (discussed below). Another part provides standards of enforcement for IPR covered by the agreement. It enumerates standards for civil and administrative procedures and remedies, the application of border measures, and criminal procedures. A Council for the TRIPS Agreement was established to monitor the implementation of the agreement and transition arrangements were devised for developing countries. Finally, the agreement provides for the resolution of disputes under the Uruguay Round Agreement's Dispute Settlement Understanding (DSU). The binding nature of the DSU, with the possibility of the withdrawal of trade concessions (usually the reimposition of tariffs) for non-compliance, sets this agreement apart from previous IPR treaties that did not have effective dispute settlement mechanisms. In April 2007, the United States filed two WTO dispute

settlement cases against China, alleging inadequacies in China's IPR laws and its barriers to market access for U.S. copyright businesses.[37] In January 2009, the DSU publicly issued its final ruling on the copyright case. The WTO panel ruled in the United States' favor that China's denial of copyright protection to works that do not have censorship approval is inconsistent with the TRIPS Agreement. The WTO panel also agreed with the United States that it is impermissible for China to publicly auction IPR-infringing goods seized at the border, with the only requirement being that fake brands and trademarks be removed from the goods. However, the WTO panel ruled that more evidence was needed before deciding whether or not China's threshold values for prosecuting counterfeiting and piracy permit commercial scale IPR infringement.[38]

The TRIPS Agreement also seeks a balance of rights and obligations between the private right, enumerated above, and the obligation "to secure social and cultural development that benefits all."[39] Article 7 declares that:

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

This paragraph attempts to link the protection of IPR with greater technology transfer, including technology covered by IPR protection, to the developing world. The language itself has been interpreted in various ways. Developed countries have tended to consider this language exhortatory, but developing countries have tried, without much success, to make technology transfer a meaningful obligation within the TRIPS Agreement system. Article 66.2 of the agreement requires developed country members to provide incentives to their enterprises and institutions to promote technology transfer to least-developed countries to assist them in establishing a viable technology base. Developed countries report annually on their efforts to encourage technology transfer (LDCs).

Complying with international IPR standards may impose greater burdens on developing countries than developed countries. Developing countries generally have to engage in greater efforts to bring their laws, judicial processes, and enforcement mechanism into compliance with the TRIPS Agreement. Consequently, developing countries were given an extended period of time in which to bring their laws and enforcement mechanisms into compliance with the TRIPS Agreement. Developing countries and post-Soviet states were given an additional four years from the entry into force of the agreement (January 1, 1995). For products that were not covered by a country's patent system (such as pharmaceuticals in many cases), an additional five years was granted to bring such products under coverage. For developing countries, all provisions of the TRIPS agreement should now be in force. For the least developed countries (LDCs), the phase-in period

[37] USTR, "United States Files WTO Cases Against China Over Deficiencies in China's Intellectual Property Rights Laws and Market Access Barriers to Copyright-Based Industries," press release, April 9, 2007, http://www.ustr.gov. See also CRS Report RL33536, *China-U.S. Trade Issues*, by Wayne M. Morrison.

[38] WTO, "WTO issues panel report on U.S.-China dispute over intellectual property rights," press release, January 26, 2009. USTR, "United States Wins WTO Dispute Over Deficiencies in China's Intellectual Property Rights Law," press release, January 26, 2009. Daniel Pruzin, "WTO Publishes Final Ruling in U.S. Complaint Against Chinese IPR Enforcement Measures," *International Trade Daily*, January 27, 2009.

[39] Pascal Lamy, "Trade-Related Aspects of Intellectual Property Rights - Ten Years Later," *Journal of World Trade,* October 2004, p. 925.

was set at 10 years (January 1, 2006), and for pharmaceuticals, the compliance period was later extended to 2016.[40]

Declaration on TRIPS Agreement and Public Health [41]

In agreeing to launch the Doha Round of WTO trade negotiations, trade ministers adopted a "Declaration on the TRIPS Agreement and Public Health" on November 14, 2001.[42] The Declaration sought to alleviate developing country dissatisfaction with aspects of the TRIPS regime. It delayed the implementation of patent system provisions for pharmaceutical products for least developed countries (LDCs) until 2016. The declaration committed member states to interpret and implement the agreement to support public health and to promote access to medicines for all. The Declaration recognized certain "flexibilities" in the TRIPS agreement to allow each member to grant compulsory licenses for pharmaceuticals and to determine what constitutes a national emergency, expressly including public health emergencies such as HIV/AIDS, malaria, and tuberculosis or other epidemics.

Paragraph 6 of the Declaration directed the WTO members to formulate a solution to a corollary concern, the use of compulsory licensing by countries with insufficient or inadequate manufacturing capability. 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. They are authorized by Article 31 of TRIPS, which places certain limitations on their use, scope, duration. A provision that predominantly restricted production authorized by compulsory license to the domestic market became the focal point of the negotiations because it, in effect, conveys the right of compulsory licensing only to countries with the capability to manufacture a given product. Countries without a domestic manufacturing capability were essentially precluded from using this flexibility of the TRIPS agreement.

On the eve of the Cancun Ministerial in August 2003, WTO members agreed on a Decision[43] 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 least developed countries (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 152 WTO member states. Until then, the 2003 waiver continues in force. To date, 45 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, and Brazil) have ratified the amendment.[44] The system

[40] "Extension of the Transition Period under Article 66.1 of the TRIPS Agreement for Least-Developed Country Members for Certain Obligations with Respect to Pharmaceutical Products," WTO Document IP/C/25, July 1, 2002.

[41] See also CRS Report RL33750, *The WTO, Intellectual Property Rights, and the Access to Medicines Controversy*, by Ian F. Fergusson.

[42] Declaration on the TRIPS Agreement and Public Health, (WT/MIN(01)/DEC/2), November 14, 2001, available at http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm.

[43] "Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health," IP/C/W/405, August 30, 2003, and accompanying Chairman's statement, available at http://www.wto.org/english/news_e/pres03_e/pr350_e.htm.

[44] "Members accepting amendment of the TRIPS Agreement," http://www.wto.org/english/tratop_e/trips_e/amendment_e.htm.

established by the WTO allows LDC and countries without sufficient manufacturing capacity to issue a compulsory license to a company in a country that can produce such a product. After a matching compulsory license is issued by the producer country, the drug can be manufacturing and exported subject to various notification requirements, quantity and safeguard restrictions. While several exporting countries have established laws and procedures for implementing this system, only Rwanda has availed itself to use the system to import HIV/AIDS medicines from a generic manufacturer in Canada.[45]

Intellectual Property Protection and Development

The controversy over the relationship between IPR and development was engaged by the advent of the TRIPS Agreement, which for the first time placed IPR obligations on developing countries. Some hold that expansion of IPR is an obstacle to growth and development in less advanced countries, while others, with a diametrically opposing view, maintain that IPR are beneficial to both developed and developing countries.

Some IPR critics believe that a strong IPR regime may reduce developing countries' access to technology from advanced countries by imposing higher fees for technology licenses and production right, limiting their innovation and economic growth and development. For instance, Japan, Singapore, Taiwan, and South Korea enhanced their technological abilities and developed their economies through "reverse engineering" of foreign technologies.

Others claim that IPR promote technology transfer through increased trade, foreign investment, and licensing in the long-run by making a country more attractive to foreign partners. A 2002 OECD study concluded that stronger IPR laws, particularly enhanced patent standards, may be associated with increased foreign direct investment (FDI) and trade for developing countries over time, with variation by industries and level of development.[46] For instance, India experienced an increase in foreign investment and technology transfer once it expanded its patent protection. China offers a counterexample of a country with a weak IPR regime but high FDI and trade levels.

There is also evidence that IPR's impact on developing countries may vary by the level of development. One study suggests that IPR protection may offer more benefits for the more industrialized developing countries, such as Brazil and India, compared to other developing countries. Such industrializing economies could experience economic growth of as much as 0.5% annually through increased trade, FDI, and licensing.[47] Another study finds that rapid economic growth is associated with weak intellectual property regimes, but that developing countries with higher levels of per capita income may benefit economically from stronger IPR regimes.[48]

There is also concern that strengthened patent protection may drive up prices for medicines or delay the entry of generic drugs into the market, reducing access to HIV/AIDS treatments and other drugs. IPR supporters argue that strong IPR is critical to creating incentives for pharmaceutical innovations and suggest that reduced prices are no guarantee that needed goods will make it into the hands of individuals in developing countries due to political corruption, poverty, and poor social infrastructure.

[45] "Canada Issues Compulsory License For HIV/AIDS Drug Export To Rwanda, In First Test Of WTO Procedure," *Bridges Weekly Trade News Digest*, September 26, 2007, http://www.ictsd.org/weekly/07-09-26/story2.htm.

[46] OECD, *The Impact of Trade-Related Intellectual Property Rights on Trade and Foreign Direct Investment in Developing Countries*, May 28, 2003, p. 21, http://www.oecd.org.

[47] Keith E. Maskus, *Intellectual Property Rights in the Global Economy*, Institute for International Economics (IIE), Washington, D.C., August 2000.

[48] Commission on Intellectual Property Rights (CIPR), *Integrating Intellectual Property Rights and Development Policy*, September 2002.

World Intellectual Property Organization (WIPO)

In addition to the WTO, the other main multilateral venue for addressing IPR issues is WIPO, a United Nations agency. Established in 1967, WIPO is charged with fostering the effective use and protection of intellectual property globally. WIPO's mandate focuses exclusively on intellectual property, in contrast to the WTO's broader international trade mandate. WIPO's antecedents are the 1883 Paris Convention for the Protection of Industry Property and the 1886 Berne Convention for the Protection of Literary and Artistic Work. Most of the substantive provisions of these two treaties are incorporated in the WTO's TRIPS Agreement. WIPO's primary function is to administer a group of IPR treaties which put forth minimum standards for member states (shown in **Table 5**). All international IPR treaties, save TRIPS, are administered by WIPO.

In order to address digital technology issues not dealt with in the TRIPS Agreement, WIPO established the WIPO Copyright Treaty (WCT) and WIPO Performance and Phonograms Treaty (WPPT) in 1996.[49] Recent WIPO efforts have focused on patent law. In June 2000, WIPO signatories adopted the Patent Law Treaty (PLT), which called for harmonization of patent procedures. This agreement went into force on April 28, 2005. Discussions began in May 2001 for the Substantive Patent Law Treaty (SPLT), which targets issues specifically related to patent grants, but stalled in 2006.

WIPO's other functions include assisting member states through training programs, legislative information, intellectual property institutional development, automation and office modernization efforts, and public awareness activities. WIPO's enforcement activities are more limited than those of the WTO. Through its Advisory Committee on Enforcement (ACE), WIPO cooperates with member states to promote international coordination on enforcement activities.

With the emergence of the TRIPS Agreement, some observers question the relevance of WIPO. However, others contend that the TRIPS Agreement has given WIPO a new and stronger role. Through a 1996 agreement between the WTO and WIPO, the two organizations have agreed to work closely together to ensure the implementation of the TRIPS Agreement by member states through legal and technical assistance and technical cooperation.[50] In 1998, WIPO and WTO began a joint initiative based on the 1996 agreement to enhance their coordination of technical cooperation activities in order to assist developing countries, in particular, to fulfill their TRIPS commitments.[51]

[49] These WCT and WPPT frequently are referred to as the WIPO Internet Treaties.

[50] "Agreement between the World Intellectual Property Organization and the World Trade Organization," http://www.wto.org/english/tratop_e/trips_e/wtowip_e.htm.

[51] WIPO, *Intellectual Property Handbook*, http://www.wipo.org, p. 359.

Table 5. Summary of WIPO-Administered IPR Treaties

Treaty	Date Concluded	Provisions
Intellectual Property Protection Treaties		
Paris Convention for the Protection of Industry Property (Paris Convention)	1883 (entered into force 1884)	Protects industrial property (includes patents, marks, industrial designs, utility models, trade names, and geographic indications)
Berne Convention for the Protection of Literary and Artistic Works (Berne Convention)	1886 (entered into force 1886)	Protects literary and artistic works, providing right to control and receive payments for use
Madrid Agreement for the Repression of False and Deceptive Indications of Source on Goods (Madrid Agreement - Indications of Source)	1891	Requires States to seize imported goods with false/deceptive indications of source or to prohibit importation of such goods; open to States party to Paris Convention (1883)
Rome Convention for the Protecting of Performers, Producers of Phonograms and Broadcasting Organizations (Rome Convention)	1961	Protects rights of performers against certain acts to which they have not agreed; protects rights of producers of phonograms, and broadcasting organizations to authorize/prohibit certain acts; open to States party to Berne Convention (1886)
Convention for the Protection of Producers of Phonograms Against Unauthorized Duplication of their Phonograms (Phonograms Convention)	1971	Protects producers of phonograms against unauthorized reproduction of their phonograms or importation of duplications for public distribution
Brussels Convention Relating to the Distribution of Programme-Carrying Signals Transmitted by Satellite (Brussels Convention)	1974	Protects against the unauthorized distribution of program-carrying signals transmitted by satellite
Nairobi Treaty on the Protection of the Olympic Symbol (Nairobi Treaty)	1981	Protects Olympic symbol against unauthorized commercial uses
Treaty on the International Registration of Audiovisual Works (Film Register Treaty)	1989	Establishes International Register for Audiovisual Works
Treaty on Intellectual Property in Respect to Integrated Circuits (Washington Treaty)	1989	Protects layout designs which display electrical components of an integrated circuit
Trademark Law Treaty (TLT)	1994	Streamlines national and regional trademark registration processes
WIPO Copyright Treaty (WCT)	1996 (entered into force 2002)	Special agreement under Berne Convention; grants exclusive rights to owners of copyright in computer programs and compilations of data/other material
WIPO Performances and Phonograms Treaty (WPPT)	1996 (entered into force 2002)	Grants exclusive rights to performers and phonogram producers
Patent Law Treaty (PLT)	2000 (entered into 2005)	Aims to harmonize and streamline national and regional patent application procedures and patents
Singapore Treaty on the Law of the Trademarks	2006 (not yet in force)	Builds on TLT (1994); aims to harmonize trademark registration procedures; has wider scope (includes communication technology developments)

Treaty	Date Concluded	Provisions
Global Protection System Treaties		
Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure (Budapest Treaty)	1977 (entered into force 1980)	Special agreement under Paris Convention (1883); requires States to recognize the deposit of a microorganism with any "international depositary authority"
Madrid Agreement Concerning the International Registration of Marks (Madrid Agreement - Marks)	1891	Requires seizure of imported goods with false/deceptive indication of source or prohibition of importation of such goods; open to States party to Paris Convention (1883)
Hague Agreement Concerning the International Registration of Industrial Designs (Hague Agreement)	1925 (entered into force 1928)	Allows protection of industrial designs in all member states on basis of single application with WIPO; three acts currently in force: 1934, 1960, and 1999 Acts
Lisbon Agreement for the Protection of Appellations of Origin and their International Registration (Lisbon Agreement)	1958	Provides international protection for geographical indications
Patent Cooperation Treaty (PCT)	1970 (entered into force 1978)	Establishes an international patent filing system; allows a single international patent application to have legal standing in all countries signatory to PCT; open to States party to Paris Convention (1883)
Protocol Relating to the Madrid Agreement (Madrid Protocol)	1989 (entered into force 1995)	Relates to Madrid Agreement (1891); seeks to make Madrid system more amenable to domestic laws of certain who are not yet signatories to Madrid Agreement; open to States party to Paris Convention (1883)
Classification Treaties		
Nice Agreement Concerning the International Classification of Goods and Services of the Purposes of the Registration of Marks (Nice Agreement)	1957 (entered into force 1961)	Establishes a classification of goods and services in order to register trademarks and service marks; open to States party to Paris Convention (1883)
Locarno Agreement Establishing an International Classification for Industrial Designs	1968 (entered into force 1971)	Establishes a classification for industrial designs; open to States party to Paris Convention (1883)
Strasbourg Agreement Concerning the Industrial Patent Classification (Strasbourg Agreement)	1971 (entered into force 1975)	Establishes the International Patent Classification (IPC); open to States party to Paris Convention (1883)
Vienna Agreement Establishing Classification of the Figurative Elements of Marks (Vienna Agreement)	1973 (entered into force 1985)	Establishes a classification for marks which consist/contain figurative components; open to States party to Paris Convention (1883)

Source: WIPO.

Free Trade Agreements

In recent years, the United States increasingly has focused on free trade agreements (FTAs) as an instrument to promote stronger IPR regimes by foreign trading partners. In general, the United States has viewed the TRIPS Agreement and WIPO-administered treaties as a minimum standard and has pursued higher IPR protection and enforcement levels through regional and bilateral agreements.

Trade Promotion Authority

Under Trade Promotion Authority (TPA), Congress delegates its constitutional authority to regulate foreign commerce to the President to negotiate and enter into certain free trade agreements (FTAs), and to have their implementing bills considered under expedited legislative procedures (no amendment, up-or-down vote), provided the President follows the guidelines, objectives, reporting, and consultation requirements mandated by Congress. IPR have become important negotiating objectives in grants of trade promotion authority; the most recent extension of that authority expired on July 1, 2007.

IPR negotiating objectives were first enacted in trade negotiating authority (then known as fast-track authority) by the Omnibus Trade and Competitiveness Act of 1988 (*P.L. 100-418*). The act sought enactment and enforcement of adequate IPR protection from negotiating partners. It also sought to strengthen international rules, dispute settlement, and enforcement procedures through the GATT and other existing intellectual property conventions. This negotiating mandate led to the establishment of the TRIPS Agreement during the Uruguay Round and the IPR provisions in North American Free Trade Agreement (NAFTA).

FTA negotiations in this century have been conducted under the Trade Promotion Authority Act of 2002 (*P.L. 107-210*). In the intervening period since the 1988 Act, the TRIPS agreement came into force and the IPR provisions of NAFTA became the template for further bilateral or regional FTAs. Thus the focus of IPR negotiating objectives shifted from creating to strengthening the IPR trade regime. One broad objective was to apply the existing IPR protection to digital media. The negotiating objectives contained provisions to extend IPR protection to new and emerging technologies and to methods of transmission and dissemination. The language called for standards of enforcement to keep pace with technological change and to allow rights-holders the legal and technological protections for their works over the Internet and other new media.

A second broad objective was to negotiate trade agreements in terms of IPR that "reflect a standard of protection similar to that found in U.S. law."[52] This phrase opened the door to the negotiation of provisions that go beyond the level of protection provided in the TRIPS agreement. Often referred to as "TRIPS-plus" provisions, these obligations include expanding coverage to new sectors; establishing more extensive standards of protection; and reducing the flexibility options available in TRIPS. Some of the new measures also address technological innovations that have come about since the TRIPS Agreement.

[52] P.L. 107-210, Sec. 2102(b)(4).

With the change of control in the 110th Congress, Democrats called for changes in the administration's trade negotiating strategy in return for support of future trade agreements. In May 2007, the Administration and Congressional leadership concluded a bipartisan agreement on trade policy that addressed Democratic concerns about the implications of enhanced IPR on developing countries' ability to meet public health needs. In particular, Congressional leadership sought to ensure that pending FTAs allowed trading partners to have enough flexibility to meet their IPR obligations and to be able to promote access to life-saving medicines, while otherwise meeting their international IPR protection and enforcement obligations. IPR language previously negotiated in the FTAs with the developing countries of Peru, Panama, and Colombia (discussed below) subsequently were modified to reflect the agreement. Because Korea is an industrialized country, the United States did not significantly scale-down the patent protection obligations in the U.S.-Korea FTA. What follows is a discussion of some of the central patent and copyright standards sought in FTAs that are currently in force or were modified by the White House and Congress (see **Table 6**).[53]

Patents

Patent protection is arguably the most contentious area of U.S. FTA negotiations on IPR issues. While the United States and other developed countries advocate for strong patent protections in order to promote innovation, there is concern that such stringent protections may delay developing countries' access to generic drugs and increase prices. Many of the FTAs in force include TRIPS-plus patent provisions, the most prominent of which are patent term length extensions, linkages between regulatory authority and patent status, data protection, compulsory licensing and parallel importation. The FTAs with Peru, Panama, and Colombia respond to the concerns of some Members of Congress over provisions that could restrict access to medicines in these countries and contain less ambitious standards for pharmaceutical patents, compared to previously negotiated FTAs. Pharmaceutical industry advocates express concern that this scale-down in patent protection in these FTAs may set a precedent for future FTA negotiations.[54]

Patent Term Extensions

Many FTAs include provisions for mandatory patent term length extensions beyond the TRIPS Agreement obligation of patent protection terms of twenty years from the filing date. These FTAs allow for extensions in cases of "unreasonable" delays in the issuance of patents due to the regulatory review or administrative process. Patent holders contend that such measures enhance the ability of rights-holders to recoup the costs of research and development of new products. However, there is concern that patent terms extensions may delay the entry of generic drugs into a market. In a scale-down from TRIPS-plus obligations, FTAs with Peru, Colombia, and Panama state that patent term restorations for pharmaceutical products are optional.

[53] For a more detailed discussion of the differences between the TRIPS Agreement and regional FTAs that are in force, see CRS Report RL33205, *Intellectual Property and the Free Trade Agreements: Innovation Policy Issues*, by John R. Thomas.

[54] "Brand-Name Industry Alarmed at IPR Precedent of FTA Template," *Inside US Trade*, May 18, 2007.

Patent Linkages

In general, the term "patent linkage" refers to the attachment of regulatory approval for the marketing of a drug with the status of a patent. If a patent exists, the FDA and its counterparts in other countries may not grant marketing approval for a generic version of a drug that is patented in the country without the permission of the patent holder. Patent linkage is a common provision in the trade agreements obtained by the United States. This presents a departure from TRIPS, under which generic drug manufacturers are able to apply for marketing approval without the patent owner's permission and prior to the expiration of the patent; this may reduce the time it takes for generic drugs to enter a market once the patent expires.[55] In light of developing country concerns about delays in access to generic versions of drugs, FTAs signed with Peru, Panama, and Colombia do not tie marketing approval for a generic drug with the patent status of its brand name drug.

Data Protection

In cases where the patent holders must submit undisclosed data regarding the safety or effectiveness of new pharmaceutical or agricultural products in order to market them, the TRIPS Agreement requires members to take measures to protect such data from disclosure and unfair commercial use. The TRIPS agreement does not prescribe any time period for this protection. Recent U.S. FTAs take these standards a step further, generally requiring a five-year period of marketing exclusivity for the patent holder, which typically begins from the date the product is approved in the country. Under this TRIPS-plus provision, generic drug manufacturers who want to market and distribute a generic version of a drug while the data exclusivity period is in effect must conduct their own clinical trials and submit their own findings to the national drug regulatory authority; they cannot rely on the findings submitted by the patent holder. Some critics contend that such provisions may raise the cost of manufacturing generic versions of patented drugs, as well as delay access to generic forms of drugs. The FTAs with Peru, Panama, and Colombia now include provisions that may reduce data exclusivity terms of five years by a minimum of six months in practice.[56]

Compulsory Licensing

A compulsory license is an authorization by a government for third parties (such as a company or the government itself) for the manufacture or use of a product under patent without the permission of the rights- holder. The TRIPS Agreement permits signatories to issue compulsory licenses for patented devices and provide compensation to the owner of the patent and does not limit the situations in which such licenses may be issued. The third party must have attempted to obtain permission from the patent holder, although this requirement is waived in times of national emergency or other extenuating circumstances. U.S. FTAs with Australia and Singapore limit attaining compulsory licenses only for domestic use and to situations of remedying antitrust violations or in situations of public non-commercial use, national emergency, or other cases of

[55] While TRIPS does not directly speak to the rights of generic drug manufacturers in obtaining marketing approval for a generic drug before the expiration of the patented drug, Article 30 of TRIPS permits exceptions of patent rights for activities such as "research, prior user rights, and pre-expiration testing."

[56] For example, under the Peru FTA, if a company files to market a new drug in Peru after making an initial filing in another country, such as the United States, and Peru approves the drug within six months of the filing, the data exclusivity period begins at the time the drug was approved in the country of the initial filing, not Peru.

extreme need. Also under these FTAs, the patent holder is under no obligation to provide test data, technical know-how or other undisclosed information for the patent subject to compulsory license. The compulsory license provisions have not been included in FTAs with developing countries.

Parallel Importing

Parallel imports, also known as grey-market goods, refer to goods imported into a country without permission of the rights-holder after those goods were legitimately sold elsewhere. Parallel importation relates to the concept of territorial exhaustion of IPRs, which governs the extent of IPR after the first sale. Under a national system of exhaustion practiced in the United States, IPR are exhausted domestically after the first sale, but not abroad, thus prohibiting trade in those goods without permission of the rights-holder. Under an international system, IPR are exhausted at the first sale for any destination, and such goods can be exported freely. Article 6 of the TRIPS specifically excludes issues arising from exhaustion of IPR from WTO dispute settlement, allowing each member to adopt different exhaustion regimes. Thus, TRIPS does not address the issue of parallel imports. Some developing countries contend that parallel importation is an alternative method for governments to increase access to medicines in the absence of a compulsory license.[57] Pharmaceutical companies have voiced concerns that this practice threatens their ability to engage in price differentiation between different markets. U.S. FTAs negotiated with Australia, Singapore, and Morocco disallow parallel importing of patented products. Subsequent U.S. negotiated FTAs have not included this provision, due to language included in the Science, State, Justice, and Commerce, and Related Agencies, Appropriations Act of 2006 (P.L. 109-108), which prohibited the use of such provisions.

[57] U.S. Government Accountability Office, *U.S. Trade Policy Guidance on WTO Declaration on Access to Medicines May Need Clarification*, GAO-97-1198, September 2007, p. 19.

Biodiversity and Traditional Knowledge

International trade negotiations increasingly have focused on the protection of plant and animal inventions, new plant varieties, traditional knowledge, and folklore. Some indigenous communities in developing countries and international non-governmental organizations have expressed concern about the use of patents to provide private rights for traditional knowledge and genetic material; the commercial use of such resources by entities other than the indigenous communities or countries from which such resources are derived; and the distribution of benefits from commercial use. The United States, other advanced countries, and business groups favor treating traditional knowledge and genetic material as intellectual property and protecting these resources through an IPR framework.

Article 27.3(b) of the TRIPS Agreement permits Member states to exempt "plants and animals other than micro-organisms, and essentially biological processes" from patentability. TRIPS requires Members to protect plant varieties through patent protection, some other system ("sui generis"), or a combination of the two. Paragraph 19 of the Doha Declaration added another dimension to the issue by requiring the TRIPS Council to probe the relationship between the TRIPS Agreement, the UN Convention on Biological Diversity (CBD), and traditional knowledge and folklore. These issues also are being discussed in WIPO's Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge, and Folklore (IGC).

India, Brazil, and Peru, among other countries, contend that patent applicants should be required to disclose the source of genetic materials, including plant life and traditional knowledge, before obtaining patents. The United States and the European Union have advocated for national systems in which companies are granted permission to research genetic materials and are obligated to share benefits from patents derived from those genetic products.

Some earlier U.S. FTAs have required signatories to provide protection for plants, animals, and plant varieties. The recent FTAs with Peru, Panama, and Colombia do not mandate patentability for plants and animals, but state that the countries should take efforts to expand patent coverage to these areas and to maintain this protection once it is offered. Side-letters in the three FTAs state the signatories' recognition of the importance of biodiversity and traditional knowledge and pledge the countries to work together to address these issues through the IGC.

Copyright

In the area of copyright protection, the United States has pursued certain TRIPS-plus measures in FTAs, such as extending copyright terms; including anti-circumvention provisions; and protecting rights-management information in its FTAs. The TRIPS Agreement does not mention any obligations regarding rights-management information, which is "electronic information that identifies a protected work, its author, and terms and conditions of use,"[58] perhaps due to the fact these technologies were not available at the time. In contrast, U.S.-negotiated trade agreements prohibit the removal or alteration of such information.

While patent protection has experienced policy shifts in the FTAs with Peru, Panama, and Colombia, copyright protection provisions have remained fairly consistent through the FTAs. In general, FTA signatories are obligated to provide an additional twenty years of copyright protection. This brings the minimum copyright term to seventy years from the death of the author or authorized publication, compared to fifty under the TRIPS Agreement. Responding to technological innovations not discussed in the TRIPS Agreement, many of the FTAs require trading partners to outlaw circumvention of copyrighted works. These provisions build on the U.S. Digital Millennium Copyright Act (DMCA) of 1998.[59] Also based on the DMCA, many

[58] CRS Report RL33205, *Intellectual Property and the Free Trade Agreements: Innovation Policy Issues*, by John R. Thomas.

[59] The DMCA (P.L. 105-304) prohibits disabling technological protection measures designed to protect copyright works through activities such as descrambling or decrypting copyrighted workers.

FTAs contain provisions that regulate the liability of Internet service providers (ISPs) for copyright infringement that occurs within their networks. Under the FTAs, ISPs are provided limited immunity from copyright liability in certain kinds of infringing activities if they comply with regulations. For instance, ISPs must block access to or remove infringing materials as soon as they are aware of the infringement. Copyright holders argue that it is necessary for ISPs to assist in enforcing copyright for copyright laws to be effective. However, critics claim that these provisions impose excessive burdens on ISPs, reduce the rights of internet users, and limit the policy flexibility of FTA signatories in determining their own IPR regimes.

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Table 6. Patent and Copyright Provisions in the TRIPS Agreement and U.S. FTAs

Intellectual Property Forms	TRIPS Provisions	General TRIPS-Plus Provisions in FTAs	Scale-down of TRIPS-Plus Standards
Patents			
Patent term extensions	No provisions	Mandatory extensions in cases of unreasonable delays in patent grants/regulatory approval *Jordan (Article 4.23.a),* *Chile (Article 17.9.6; 17.9.2a), Singapore (Article 16.7.7; 18.8.4a), Australia (Article 17.9.8; 17.10.4), Morocco (Article 15.9.7; 15.10.3), CAFTA-DR (Article 15.9.6; 15.10.2), Bahrain (Article 14.8.6),Oman (Article 15.8.6), Korea (Article 18.8.6)*	Optional extensions in cases of unreasonable delays in patent grants/regulatory approval *NAFTA (Article 1709.12)* *Peru (Article 16.9.6), Panama (Article 16.9.6), Colombia (Article 16.9.6)*
Market approval linked to patent status	No provisions *NAFTA (no mention),* *Jordan (no linkage, but patent owner must be notified if another entity is seeking marketing approval for generic version of patented product, Article 4.23.b)*	National regulatory authorities cannot provide marketing approval for a generic version of a patented drug without permission from rights-holder; also requires notification of rights-holder if marketing permitted *Chile (Article 17.10.2b), Singapore (16.8.4c),Australia (Article 17.10.4), Morocco (Article 15.10.4), CAFTA-DR (Article 15.10.2), Bahrain (Article 14.9.4), Oman (15.9.4), Korea (Article 18.9.5)*	Eliminates mandate that regulatory authorities cannot approve a generic drug for marketing if patent for drug in place *Peru (Article 16.10.4), Panama (Article 15.10.4), Colombia (Article 16.10.4)*
Protection for undisclosed test or other data	Members must protect data from unfair commercial use (Article 39.3) *Jordan (Article 4.22)*	Provides for at least five years of data exclusivity from date of approval in country for pharmaceuticals that contain new chemical products *NAFTA (Article 1711.6), Bahrain (Article 14.9.1), Oman (Article 15.9(1-2), CAFTA-DR (Article 15.10.1), Singapore (Article 16.8(1-3)), Australia (Article 17.10.1), Morocco (Article 15.10.1), Chile (Article 17.10.1), Korea (Article 18.9(1-2))*	Provides for at least five years of marketing exclusivity from date of approval in country of first filing if new drug is granted marketing approval within six months in country of second filing *Peru (Article 16.10.2), Panama (Article 15.10.4), Colombia (Article 16.10.2)*
Issuance of compulsory licenses	Some restrictions in issuance of compulsory licenses; circumstances under which licenses can be issued not limited (Article 13) *NAFTA (Article 1709.10),*	Limits issuance of compulsory license to specific cases: Correcting anti-competitive practices, public non-commercial contexts, national emergencies, and other extremely urgent situations *Jordan (Article 4.20), Singapore (Article 16.7.6), Australia (Article 17.9.7)*	Not discussed *Chile (no mention), Morocco (no mention), CAFTA-DR (no mention), Bahrain (no mention), Oman (no mention)* *Peru (no mention), Panama (no mention), Colombia (no mention), (no mention)*

Intellectual Property Forms	TRIPS Provisions	General TRIPS-Plus Provisions in FTAs	Scale-down of TRIPS-Plus Standards
Parallel importing of patented products	TRIPS will not be used to discuss IPR exhaustion (Article 6) *Jordan (no mention), Chile (no mention), CAFTA-DR (no mention), Bahrain (no mention), Oman (no mention)*	Parallel importation can be restricted or prohibited *NAFTA (Article 1709.5, 1709.9), Singapore (Article 16.7.2), Morocco (Article 15.9.4), Australia (Article 17.9.4)*	Not discussed *Peru (no mention), Panama (no mention), Colombia (no mention), Korea (no mention)*
Biodiversity and traditional knowledge	Members may exclude plants and animals from patentability (micro-organisms and non-biological and micro-biological processes must be eligible for patents); must provide protection of plant varieties (Article 27.3(b)) *NAFTA (Article 1709.3), Bahrain (Article 14.8.(1-2)), Oman (Article 15.8.2, plants not discussed),* *Jordan, (no mention), Singapore (no mention), Australia (no mention), Korea (no mention)*	Countries shall make patents available for plants and animals *Morocco (Article 15.9.2, plants and animals mentioned, plant varieties are not mentioned)*	Members may exclude plants and animals from patentability, but shall take reasonable effort to provide patent protection for plants or animals and maintain protection once offered *Chile (Article 17.9.2, mentions plants but not animals), CAFTA-DR (Article 15.9.2), Peru (Article 16.9.2), Panama (Article 15.9.2), Colombia (Article 16.9.2)*
Copyrights			
Rights-management information	Not discussed *NAFTA (no mention), Jordan (no mention)*	Outlaws removal or alternation of information *Chile (Article 17.5.6), Australia (Article 17.4.8), Singapore (Article 16.4.8), Morocco (Article 15.5.9), CAFTA-DR (Article 15.5.8), Bahrain (Article 14.4.8), Oman (Article 15.4.8), Peru (Article 16.7.5), Panama (Article 15.5.8), Colombia (Article 16.7.5), Korea (Article 18.4.8)*	
Term of protection	No less than 50 years from authorized publication (Article 12) *NAFTA (Article 1705.4), Jordan (no mention)*	No less than 70 years from death of author or authorized publication *Chile (Article 17.5.4), Singapore (Article 16.4.4), Australia (Article 17.4.4), Morocco (Article 15.5.5), CAFTA-DR (Article 15.5.4), Bahrain (Article 14.4.4), Oman (Article 15.4.4), Peru (Article 16.5.5), Panama (Article 15.5.4), Colombia (Article 16.5.5), Korea (Article 18.4.4)*	
Circumvention of copyrighted work	Not discussed *NAFTA (no mention)*	Signatories must agree to prohibit circumvention *Jordan (Article 4.6), Chile (Article 17.5.5), Singapore (Article 16.4.7), Australia (Article 17.4.7), Morocco (Article 15.5.8), CAFTA-DR (Article 15.5.7), Bahrain (Article 14.4.7), Oman (Article 15.4.7), Peru (Article 16.7.4), Panama (Article 15.5.7), Colombia (Article 16.7.4), Korea (Article 18.4.7)*	
ISP Liability	Not discussed *NAFTA (no mention), Jordan (no mention)*	ISPs are provided with limited liability in certain situations of copyright infringement on their servers if they comply with regulations *Chile (Article 17.11.23), Singapore (Article 16.9.22), Australia (Article 17.11.29), Morocco, CAFTA-DR (Article 15.11.27), Bahrain, Oman (Article 15.10.29), Peru (Article 16.11.29), Panama (Article 15.11.27), Colombia (Article 16.11.29), Korea (Article 18.10.30)*	

Note: When there is no mention of an issue in an FTA, the TRIPS standard generally holds.

U.S. Trade Law

Special 301

Section 301 of the Trade Act of 1974 (P.L. 93-618), as amended, is the principle U.S. statute for identifying foreign trade barriers due to inadequate intellectual property protection. The 1988 Omnibus Trade and Competitiveness Act (P.L. 100-418) strengthened Section 301 by creating "Special 301" provisions, which require the USTR to conduct an annual review of foreign countries' intellectual property policies and practices. By April 30th of each year, the USTR must identify countries that do not offer "adequate and effective" protection of IPR or "fair and equitable market access to United States person that rely upon intellectual property rights." According to an amendment to the Special 301 provisions by the Uruguay Round Agreements Act (P.L. 103-465), the USTR can identify a country as denying sufficient intellectual property protection even if the country is complying with its TRIPS commitments. These findings are submitted in the USTR's annual "Special 301" report.

Special 301 Country Lists

Within 30 days of submitting the annual National Trade Estimates of Foreign Trade Barriers report, the USTR must determine which of the identified countries are "Priority Foreign Countries." Countries that "have the most onerous or egregious acts, policies or practices that deny intellectual property protection and limit market access to U.S. persons or firms depending on intellectual property rights protection" and "have the greatest adverse impact (actual or potential) on the relevant United States products" may be identified as "Priority Foreign Countries." These countries may be investigated under section 301 provisions of the Trade Act of 1974. The USTR cannot identify countries as Priority Foreign Countries if they have entered into good faith negotiations or have made significant progress in improving their intellectual property protection record.[60]

If a country is named as a "Priority Foreign Country," the USTR must launch an investigation into that country's IPR practices. This investigation is conducted in a manner similar to a "Section 301" investigation; the USTR must determine a course of action within six months (9 months if a determination of complex circumstances is made). The USTR may suspend trade concessions and impose import restrictions or duties, or enter into a binding agreement with the priority country that would eliminate the act, policy, or practice that is the subject of the action to be taken. Since the advent of the WTO and its recourse to dispute settlement, the use of the first option may lead to the initiation of dispute settlement proceedings at the WTO for member countries, rather than unilateral retaliation. For countries outside the WTO, the possibility of trade sanctions remain.

The USTR also has created several administrative categories for country identification in the Special 301 Report. "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. The USTR may place a country on the Priority Watch List when the country lacks proper intellectual property protection and has a market of significant U.S. interest. "Watch List"

[60] For the Special 301 provisions, see 19 U.S.C. §2242; Trade Act of 1974, as amended, (P.L. 93-618), §182.

countries have intellectual property protection inadequacies that are less severe than those on the Priority Watch List, but still attract U.S. attention. Just being on one of the Special 301 lists may induce countries to improve their IPR protection. Finally, countries identified for "Section 306" are monitored for compliance with bilateral intellectual property agreements used to resolve investigations under Section 301. Additionally, the USTR launches out-of-cycle reviews on countries to monitor their progress on intellectual property issues. Out-of-cycle reviews are conducted on countries that USTR considers to require further review and may result in status changes for the following year's Special 301 report.

Special 301 Report for 2008

For its 2008 Special 301 Report, the USTR reviewed the IPR policies and practices of 78 countries. The report states that, despite some improvements, China and Russia remain top concerns for the Administration due to their inadequate IPR protection and enforcement.

China and Russia, along with seven other countries (Argentina, Chile, India, Israel, Pakistan, Thailand, and Venezuela) were placed on the Priority Watch List for 2008. The USTR placed another 36 countries on its Watch List. No countries were designated as Priority Foreign Countries. The 2008 Special 301 Report also noted progress made by trading partners. Egypt, Lebanon, Turkey, and Ukraine were downgraded from the Priority Watch List to the Watch List, while Belize and Lithuania were removed from the Special 301 listings completely for 2008. In 2007, the USTR downgraded Brazil from the Priority Watch List to the Watch List, where it remains, and removed the Bahamas, Bulgaria, Croatia, the European Union, and Latvia from the Special 301 listings altogether.

China and Paraguay both continue to be subject to section 306 monitoring. In addition, in the 2008 report, the USTR announced out-of-cycle reviews for Taiwan and Israel. In the 2007 report, the USTR declared out-of-cycle reviews for Russia, Brazil, the Czech Republic, and Pakistan. [61]

On January 16, 2009, the USTR removed Taiwan from the Special 301 Watch List, following the out-of-cycle review, due to IPR improvements, including the creation of a specialized IPR court in July 2008, progress in combating Internet and university piracy, and legislation that provides liability limitations to Internet Service Providers that specify actions for addressing infringing activities. USTR will continue to monitor Taiwan's progress in improving its IPR protection and enforcement..[62]

Country Identification Factors

Identification of countries for the "Special 301" lists is a lengthy process of information gathering and analysis based on the USTR's annual trade barriers report and consultations with a wide variety of sources, including government agencies, industry groups, other private sector representatives, Congressional leaders, and foreign governments. The Special 301 statute is the overall guideline for identifying countries for the various lists. However, placements are country-specific and, according to a USTR official, take into consideration a host of factors, several of which are mentioned in the Special 301 report.[63] These include the level and scope of the country's IPR infringement and their impact on the U.S. economy. Other considerations include the strength of the country's IPR laws and enforcement of IPR laws. The USTR also evaluates progress made by the country in improving IPR protection and enforcement in the past year. However, even significant progress oftentimes does not change the position or inclusion of a country on the lists. For instance, the USTR may decide not to upgrade a country from the Priority Watch List to the Watch List so that it can continue monitoring the country's intellectual property practices. Also, the USTR may note significant progress made by a country but not

[61] The USTR *Special 301 Report 2008* is available on the USTR website, http://www.ustr.gov.

[62] Amy Tsui, "Bush Administration Removes Taiwan From Watch List of Nations Failing in IPR," *International Trade Daily*, January 21, 2009.

[63] Conversation with USTR official, July 2006.

remove the country from the Special 301 list in order to continue highlighting concerns about the country's practices and limit backsliding. Another consideration for the USTR is the sincerity of the country's commitment to multilateral and bilateral trade agreements. There is no weighting criteria for the factors or a formula to determine the placement of a country on the watch list. Furthermore, no particular threshold exists for determining when a country should be upgraded or downgraded on the list.

Some observers speculate that the Special 301 rankings are subject to external influences. The lack of a specific framework for placing countries, aside from the general directives from the Special 301 statute, has raised concerns that foreign policy considerations affect the process. For example, an IIPA representative suggested that USTR placement of countries is influenced by geopolitical reasons.[64] This source cites Russia as an example of a country with high IPR infringement that could be named as a Priority Foreign Country but is not due to unrelated foreign policy considerations. Other observers of U.S. trade policy suggest that pharmaceutical companies have a stronghold on policy direction. Oxfam International, a confederation of poverty-alleviation organizations, contends that the U.S. government's policy on patents "is still largely influenced by the narrow commercial interests of the giant pharmaceutical companies."[65] A USTR official stated that the interests of pharmaceutical companies do not override concerns by other interest groups in evaluating country placement for the Special 301 report. The official emphasized that all industry group submissions are given fair and due consideration.[66]

Section 337

Section 337 of the Tariff Act of 1930 (19 U.S.C. 1337), as amended, prohibits unfair methods of competition or other unfair acts in the importation of products into the United States. It also prohibits the importation of articles that infringe valid U.S. patents, copyrights, processes, trademarks, semiconductor products produced by infringing a protected mask work, or protected design rights. While the statute has been utilized to counter imports of products judged to be produced by unfair competition, monopolistic, or anti-competitive practices, it has become increasingly used for its IPR enforcement functions in recent years. Under the statute, the import or sale of an infringing product is illegal only if a U.S. industry is producing an article covered by the relevant IPR exists or is in the process of being established. However, unlike other trade remedies such as antidumping or countervailing duty actions, no showing of injury due to the import is required.

The U.S. International Trade Commission (ITC) administers section 337 proceedings. USITC must investigate complaints either brought to it or ones commenced under its own initiative. An administrative law judge (ALJ) provides an initial determination (ID) to the ITC which can accept the ID or order a further review of it in whole or in part. If the ITC finds a violation, it may issue two types of remedies: exclusion orders or cease and desist orders. The ITC may issue either a limited or general exclusion order enforced by U.S. Customs. A general exclusion order directs U.S. Customs to keep out all infringing articles regardless of the source. More commonly, a limited exclusion order is employed to exclude infringing articles from the firm subject to the ITC's investigation. Alternatively, the ITC may enforce a cease and desist order to stop the sale of

[64] Telephone conversation with PhRMA representative, July 2006.

[65] Oxfam International, *US bullying on drug patents: One year after Doha*, Briefing Paper 33.

[66] Telephone conversation with USTR official, July 2006.

the infringing product in the United States. However, the ITC may consider several public interest criteria and decline to issue a remedy. Also, the President may disapprove a remedial order during a 60 day period for "policy reasons," which has been interpreted to mean national security reasons.[67]

During FY2007, the ITC reported a total of 77 active section 337 investigations and ancillary proceedings, of which 39 were instituted in 2007. All of the new section 337 investigations involved patent infringement. The ITC completed a total of 34 investigations and ancillary proceedings in 2007, which resulted in 8 exclusion orders and 26 cease-and-desist orders. According to the ITC, section 337 cases increasingly involve advanced technologies in the computer, telecommunications, automotive, and pharmaceutical sectors. [68]

Generalized System of Preferences

The Generalized System of Preferences (GSP) is a program that provides preferential duty-free entry to certain products from designated developing countries. The purpose of the program is to foster economic growth in developing countries by increasing their export markets. The Trade Act of 1974 authorized the GSP for a ten-year time frame, and the program has been renewed from time to time. Most recently, in 2006, Congress extended GSP through 2008.[69] The GSP program currently offers preferential access for about 5,000 products from 132 countries and territories.[70]

Although the GSP is non-reciprocal, it can be used to promote stronger intellectual property protection and enforcement abroad. Under the GSP statute, the President must consider a set of mandatory criteria that a country must fulfill in order to be designated as a GSP beneficiary. Additionally, the President may evaluate a country on the basis of certain discretionary criteria, including the country's provision of IPR protection.[71]

The GSP program undergoes an annual review by the GSP Subcommittee of the Trade Policy Staff Committee (TPSC), which is headed by the USTR. As part of its evaluation, the TPSC addresses concerns about specific country practices (such as intellectual property protection) and makes recommendations to the President. The USTR currently is reviewing a petition by the IIPA to remove Brazil from GSP benefits because of its alleged insufficient IPR protection. In 2006, the USTR concluded a review of Pakistan's IPR policies and practices in response to a petition also by IIPA for copyright evaluations. The review found that Pakistan has taken steps to reduce IPR optical disc piracy. Consequently, Pakistan remains a GSP beneficiary.[72] For 2008, the USTR is scheduled to continue evaluating IPR protection in Russia, Lebanon, and Uzbekistan on the basis of IIPA petitions for ongoing GSP reviews.[73]

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[67] For more information on the Section 337 investigation and enforcement process, see CRS Report RS22880, *Intellectual Property Rights Protection and Enforcement: Section 337 of the Tariff Act of 1930*, by Shayerah Ilias.

[68] U.S. International Trade Commission, *The Year in Trade 2007*, USITC Publication 4026, Washington, D.C., July 2008, http://hotdocs.usitc.gov/docs/pubs/332/pub4026.pdf.

[69] For a more thorough discussion of GSP, see CRS Report RL33663, *Generalized System of Preferences: Background and Renewal Debate*, by Vivian C. Jones.

[70] USTR, *U.S. Generalized System of Preferences Guidebook*, February 2007.

[71] 91 USC 2462(b)(2)

[72] USTR, "USTR Ends Review of Pakistan's Protection of Intellectual Property Rights," press release, January 24, 2006.

[73] USTR, *GSP: 2007 Annual Review*, http://www.ustr.gov.

U.S. Agency Functions and Funding for IPR

The United States has a complex apparatus for supporting intellectual property rights, with responsibilities cutting across many different federal government agencies. Protection activities include developing IPR policy, informing and advising Congress about IPR-related issues, participating in international trade negotiations to promote IPR, and providing IPR training and technical assistance in other countries. Enforcement activities involve the conduct of criminal investigations in the United States and abroad, interdiction of pirated and counterfeit goods, and monitoring of compliance with trade agreements. Enforcement also involves capacity-building activities to foster stronger IPR law enforcement in other countries.

It is difficult to obtain a complete picture of the magnitude of federal budget devoted to intellectual property laws. Some of these agencies perform their IPR related activities within existing budget parameters, and do not differentiate specific sums devoted to IPR-related activities. Based on a review of agency funding by Congress, it appears that the U.S. government provided at least $1.92 billion for IPR protection and enforcement for FY2008, a slight increase from at least $1.81 billion for FY2007 (see **Table 7**). The total is likely to be higher since the amount of funding devoted toward IPR activities was not determined for all agencies. What follows is a discussion of the various IPR functions of U.S. agencies. The Consolidated Security, Disaster Assistance, and Continuing Appropriations Act, 2009 (P.L. 110-329) continues agency funding at FY2008 levels through March 6, 2009.

Department of Commerce (Commerce)

Two agencies within the Department of Commerce, the Patent and Trademark Office (PTO) and the International Trade Administration (ITA) address IPR issues. Additionally, the National Intellectual Property Law Enforcement Coordinating Council (NIPLECC), an interagency coordinating body, is housed within Commerce.[74]

United States Patent and Trademark Office (PTO)

The PTO administers the U.S. laws pertaining to patents and trademarks. The agency processes patent and trademark applications, issues patents and registers trademarks, and circulates patent and trademark information. The PTO develops IPR protection and enforcement policy and collaborates with other agencies to develop intellectual property provisions in FTAs and other international agreements. Additionally, the PTO offers training, technical assistance, and trade capacity building programs to assist in promoting strong IPR regimes in foreign countries.[75] The PTO does not have jurisdiction over determining patent and trademark infringements; such determinations and remedies are made at the U.S. federal district court level or through the U.S. International Trade Commission's Section 337 proceedings (discussed above).[76] The PTO is fully funded through fees generated from patent and trademark applications. For FY2007, the Revised Continuing Appropriations Resolution (P.L. 110-5) provided the PTO with budgetary authority to spend $1.8 billion. The Consolidated Appropriations Act for FY2008 (P.L. 110-161) provided the

[74] General information about the Department of Commerce is available at http://www.doc.gov.

[75] NIPLECC, *Report to the President and Congress on Coordination of Intellectual Property Enforcement and Protection*, September 2006, pp. 47-49.

[76] Conversation with PTO official, November 26, 2007.

PTO with budgetary authority to spend $1.9 billion. According to the PTO Congressional Liaison, funding for efforts such as the Strategy Targeting Organized Piracy (STOP), NIPLECC activities, and IPR technical and training programs comes from this account.

International Trade Administration (ITA)

The ITA administers many of the international trade programs of the Department of Commerce, include aspects involving IPR. The ITA monitors foreign countries' progress in implementing intellectual property agreements; reviews Generalized System of Preferences (GSP) petitions submitted by industry and coordinates the Commerce Department's response to these petitions; represents the Commerce Department at the WTO TRIPS Council; meets with trading partners to advance U.S. intellectual property interests abroad; and works with U.S. businesses and industry groups to make sure that IPR-related trade concerns are addressed.[77] Based on the Revised Continuing Appropriations Resolution for 2007 (P.L. 110-5), ITA funding was enacted at $395.6 million, identical to the agency's 2006 budget. IPR funding is not distinguished in the budget, but an ITA official estimated that FY2007 spending on IPR specifically was $9.6 million.[78] For FY2008, P.L. 110-161 provides ITA with $413.2 million in enacted funds (including both direct appropriation and anticipated receipts from fees).

Department of Justice (DOJ)

The DOJ enforces criminal laws that protect IPR in the United States and internationally through the prosecution of intellectual property cases. The Civil Division's Office of Consumer Litigation specializes in intellectual property cases involving public health and safety. The Federal Bureau of Investigation (FBI) has an intellectual property enforcement program focusing on those intellectual property crimes that have the most bearing on national and economic security, such as trade secret theft, Internet piracy, and counterfeit good trafficking.[79] In addition to enforcement activities, the DOJ also works with Congress to develop laws that increase protection of IPR and provides training and technical assistance programs on IPR enforcement through its Criminal Division. The FY2007 SSJC Conference Report (H.Rept. 109-520) provided DOJ with $2.2 million for intellectual property investigations and prosecution. The FY2008 Senate CJS Conference Report (S.Rept. 110-124) substantially increased IPR funding, providing $13.1 million for domestic and international intellectual property investigations and prosecution, as well as the creation of a FBI operational unit dedicated wholly to working with the DOJ's Computer Crime and Intellectual Property Section on criminal intellectual property cases.

Department of Homeland Security (DHS)

The DHS, through its Customs and Border Protection (CPB) unit and Immigration and Customs Enforcement (ICE) unit, conducts intellectual property rights enforcement activities. Neither DHS unit has a line item for IPR enforcement. The ICE and the FBI jointly run the National

[77] NIPLECC, *Report to the President and Congress on Coordination of Intellectual Property Enforcement and Protection*, September 2006, pp. 67-69.

[78] Conversation with ITA official, October 17, 2007.

[79] DOJ, *Progress Report of the Department of Justice's Task Force on Intellectual Property*, June 2006, http://www.usdoj.gov/opa/documents/ipreport61906.pdf, pp. 17-24.

Intellectual Property Rights Coordination Center that coordinates U.S. Government domestic and international law enforcement activities.[80]

Customs and Border Protection (CBP)

Taking the lead in day-to-day IPR enforcement activities at the U.S. border, the CBP is responsible for detecting and seizing counterfeit and pirated goods entering the United States and determining penalties for infringement.[81] CBP has the authority to determine whether or not imports infringe federally registered trademarks and copyrights and to detain or seize such infringing goods. Owners of copyrights and trademarks are able to record information about their rights in the CBP's electronic IPR database. As noted earlier, in contrast to trademarks and copyrights, CBP does not have the jurisdiction to make determinations about patent infringements. However, it is able to block imports determined by the ITC to infringe a U.S. patent by a Section 337 investigation (see above).[82] H.Rept. 109-476 noted the gravity of the IPR infringement problem and requested CBP to provide information on the resources devoted to preventing IPR infringement for 2004-2007 (projected).

Immigration and Customs Enforcement (ICE)

ICE is charged with investigating violations of U.S. law that are connected with U.S. borders. ICE "identifies, investigates, apprehends, and removes" international criminal groups and other criminals. ICE conducts inquiries into the importation and distribution of counterfeit goods. ICE activities are closely linked with those of CBP. For instance, when CBP identifies and seizes counterfeit goods, the issue is referred to ICE for criminal investigation. Likewise, information obtained from ICE activities that is relevant to identifying and apprehending counterfeit shipments is provided to CBP.[83]

Food and Drug Administration (FDA)

The FDA, which is an agency of the Department of Health and Human Services (DHHS), is responsible for protecting public health by ensuring the safety and effectiveness of medicines, food, and other products. As part of its activities, the FDA works to protect consumers against counterfeit medicines. To combat the entry of foreign counterfeit drugs into the U.S. drug supply, the FDA works in conjunction with the CBP to conduct border inspections of FDA-regulated products. The FDA also engages in foreign inspections to ensure that foreign manufacturers meet FDA quality and labeling requirements. Funding for preventing counterfeits from entering the United States is part of overall FDA import safety efforts.[84]

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[80] Information about the DHS is available at http://www.dhs.gov.

[81] Certain customs-related IPR policy-making resides within in the Treasury.

[82] NIPLECC, *Report to the President and Congress on Coordination of Intellectual Property Enforcement and Protection*, September 2006, pp. 143-145. Additional information about CBP is available at http://www.cbp.gov.

[83] Ibid. Also refer to the ICE website, http://www.ice.gov.

[84] Conversation with FDA official, November 26, 2007. Additional information is available on the FDA website, http://www.fda.gov.

Copyright Office

The Copyright Office of the Library of Congress administers U.S. copyright law by registering claims to copyright and related documents, including "assignments or transfers of rights" and maintains information on registrations, recordings, compulsory licenses, and other copyright-related actions. Additionally, the Copyright Office provides legal and technical expertise on national and international copyright issues to the U.S. government. The Copyright Office also works with other federal agencies to provide assistance and advice in negotiations for international intellectual property agreements, as well as technical assistance to foreign countries crafting their own copyright laws.[85] For FY2007, the Copyright Office was provided $22.7 million (not including authority to spend receipts) (P.L. 110-5). The FY2008 Consolidated Appropriations Act provides the Copyright Office with $5.3 million in new budgetary authority (not including authority to spend $44.2 million in receipts).

Copyright Office appropriations also specify funding for IPR-related activities in developing countries. The FY2007 Legislative Branch Appropriations Act (H.R. 5521) provided that not more than $100,000 be available for the International Copyright Institute in the Copyright Office of the Library of Congress to train nationals of developing countries in intellectual property laws and policies. For FY2008, the Consolidated Appropriations Act (P.L. 110-161) also provided $100,000 for the International Copyright Institute for such activities.

Department of State (State)

State represents U.S. views in both bilateral and multilateral arenas. State works to build international consensus for intellectual property rights enforcement. Information from State's foreign postings informs the USTR Special 301 review. In particular, the Bureau of International Narcotics Control and Law Enforcement (INCLE) works to combat intellectual property piracy, while the Bureau of Energy, Economics and Business Affairs supports stronger international IPR standards to fight global piracy and counterfeiting.[86] While the FY2007 SSJC Conference Report (H.Rept. 109-520) did not dedicate any funding for IPR enforcement, it called for embassies in major U.S. markets, such as China, Russia, and Brazil, to develop surveys to measure levels of piracy and counterfeiting and to increase dialogue with officials in Chinese provinces to encourage implementation of China's IPR obligations. The FY2007 Foreign Operations Conference Report (H.Rept. 109-486) recommended $5 million for programs to fight intellectual property piracy under the INCLE Account. The Consolidated Appropriations Act for 2008 (P.L. 110-161) provides $5 million from the INCLE Account for combating piracy (Section 688). The act notes that the funds should be used in countries that are not members of the Organization for Economic Cooperation and Development (OECD) and specifies some of the activities for which the funds may be used, including providing equipment and training for law enforcement; training judges and prosecutors; and providing assistance in complying with international IPR treaties and agreements.

[85] NIPLECC, *Report to the President and Congress on Coordination of Intellectual Property Enforcement and Protection*, September 2006, pp. 97-98. Also see Copyright Office website, http://www.copyright.gov.

[86] NIPLECC, *Report to the President and Congress on Coordination of Intellectual Property Enforcement and Protection*, September 2006, pp. 81-84. Additional information about the State Department is available at http://www.state.gov.

U.S. Agency for International Development (AID)

AID funds training and technical assistance to improve the compliance with the TRIPS Agreement and bilateral trade agreements with the United States. Funding for these projects generally have been undertaken by regional or country missions; there is no separate budgetary line item for IPR enforcement and training. According to the AID Trade Capacity Building (TCB) database, AID projects for TCB for compliance with the TRIPS Agreement totaled $2.1 million in 2006 and $2.9 million in 2007, down from a peak of $6.9 million in 2003.[87]

United States Trade Representative (USTR)

The USTR is the lead trade agency of the United States government. Through its annual Special 301 report, USTR is charged with monitoring the adequacy and effectiveness of IPR protection of our trading partners as well as their compliance with bilateral and multilateral trade agreements, to identify countries not in compliance with such agreements, and to negotiate with those countries better compliance. USTR also advances greater protection and enforcement of IPR in its negotiations of U.S. free trade agreements. Additionally, USTR works to implement the Administration's STOP! Initiative, which draws together the major federal government agencies, private sector groups, and trading partners to take targeted action in fighting piracy and counterfeiting.[88]

The FY2007 funding level for USTR was $44.2 million, provided under the Revised Continuing Appropriations Resolution (P.L. 110-5). The FY2008 funding level for USTR was $44.1 million, under the Consolidated Appropriations Act (P.L. 110-161). In the House SSJC Committee Report (H.Rept. 110-240), the USTR was provided with $48.4 million for FY2008, $4 million more than requested, to reflect increased USTR focus on international IPR protection and enforcement, among other activities. USTR does not differentiate sums for its various negotiating activities, and Congress has not designated specific funds to IPR activities within USTR.

United States International Trade Commission (ITC)

The ITC is a quasi-judicial federal government agency responsible for investigating and arbitrating complaints of unfair trade practices. The ITC adjudicates allegations of imported products that infringe U.S. patents, trademarks, and copyrights through its Section 337 proceedings (see above). The primary remedy employed by the ITC is to order the CBP to stop imports from entering the border. Additionally, the ITC may issue "cease and desist" orders against individuals determined to be IPR violators. Damages for IPR infringement cannot be received through ITC court proceedings; rights-holders seeking damages must file action with the U.S. federal district court.[89] For FY2008, ITC was provided with $68.4 million in P.L. 110-161.

[87] Trade Capacity Database and general AID information is accessible at http://www.usaid.gov.

[88] NIPLECC, *Report to the President and Congress on Coordination of Intellectual Property Enforcement and Protection*, September 2006, pp. 91-96. Also see USTR website, http://www.ustr.gov.

[89] U.S. ITC website, http://www.usitc.gov.

National Intellectual Property Law Enforcement Coordinating Council (NIPLECC)

Created by Congress in 1999, NIPLECC coordinates U.S. activities to protect and enforce IPR domestically and abroad. NIPLECC draws together major federal agencies that help to enforce IPR. Members include USTR Commerce, DHS, DOJ, and State, as well as and their subagencies. The Copyright Office participates in the Council in an advisory role. The U.S. Coordinator for International Intellectual Property Enforcement heads NIPLECC's interagency coordination efforts.[90] In the SSJC Conference Report (H.Rept. 109-520) for FY2007, NIPLECC is provided with $900,000 in dedicated funding under the Department of Commerce heading. For FY2008, P.L. 110-161 allows for $1 million to be transferred from the PTO for activities associated with NIPLECC. In addition, the House SSJC Committee Report (H.Rept. 110-240) called for the FBI to increase the number of agents dedicated to IPR infringement investigations in NIPLECC. In October 2008, the authorities creating NIPLECC were repealed by the "Prioritizing Resources and Organization for Intellectual Property Act of 2008" (P.L. 110-403), which created an Intellectual Property Enforcement Coordinator located in the Executive Office of the President (see section "Effectiveness of the U.S. IPR Organizational Structure," below).

Strategy Targeting Organized Piracy (STOP!)

In 2006, NIPLECC adopted the Administration's STOP! as its plan of action for protecting intellectual property rights abroad. The Administration established STOP! in 2004 to crack down on criminal networks in pirated and counterfeit goods trafficking. This initiative expresses the Administration's commitment to intellectual property protection and enforcement. STOP! is similar to NIPLECC in that it is a coordinating structure to enhance U.S. IPR protection and enforcement and works with many of the same agencies as NIPLECC, such as Commerce, DOJ, DHS, State, and USTR. The FDA is not a part of NIPLECC, but is a participant in STOP!.[91] The budget for STOP! comes from Department of Commerce funding.[92] The FY2007 SSJC Conference Report (H.Rept. 109-520) expressed support for the STOP! initiative, but did not specify any funding for initiative.

[90] NIPLECC, *Report to the President and Congress on Coordination of Intellectual Property Enforcement and Protection*, September 2006, pp. 12-15

[91] Office of the U.S. IPR Coordinator, *Strategy for Targeting Organized Piracy: Accomplishments and Achievements*, September 2007.

[92] U.S. Government Accountability Office, *Intellectual Property: National Enforcement Strategy Needs Stronger Leadership and More Accountability*, GAO-07-710T, p. 6.

Table 7. FY2007-FY2008 IPR Protection and Enforcement Dedicated Funding for U.S. Government Agencies

Government Agency	FY2008 Dedicated Funding	FY2008 Activities	FY2007 Dedicated Funding
PTO	$1.9 billion	Administering patent and trademark applications; policy guidance; training and technical assistance	$1.8 billion
NIPLECC	$1 million	Interagency IPR enforcement coordination	$900,000
Department of Justice	$13.1 million	Intellectual property investigations and prosecutions; NIPLECC support	$2.2 million
Copyright Office	$100,000	International Copyright Institute activities	$100,000
Department of State	$5 million	Combat intellectual property piracy under International Narcotics Control and Law Enforcement Account	$5 million
USAID	$2.9 million (for 2007)	Trade capacity building for TRIPS and IPR compliance	$2.1 million (for 2006)
Total	**$1.92 billion**	**U.S. government IPR activities**	**$1.81 billion**

Note: While all of PTO's activities are dedicated toward IPR support, it is difficult to determine exactly how much is directed toward international IPR promotion efforts.

Issues for Congress

U.S. Efforts to Promote IPR Through Trade Policy

Since the inclusion of IPR provisions in the TRIPS Agreement, there has been an ongoing debate about the appropriateness of including IPR as a component of U.S. trade policy. Some argue that IPR, which grant legal temporary monopolies to rights-holders for their creations, are actually barriers to trade and have no place in trade liberalization negotiations. Others contend that IPR promote trade through innovation, economic growth, and technology transfer from advanced to developing countries.

In addition to this broader discussion about the role of IPR in trade policy, concerns have been voiced about the trade policy channels used by the United States to promote international IPR protection and enforcement. The Bush Administration has pursued strengthened international IPR through multilateral, regional, and bilateral venues. However, some question the appropriateness of using regional and bilateral FTAs for this purpose, contending that such actions take away from the effectiveness of multilateral IPR promotion efforts. Periodically, members of Congress have expressed concern over U.S attempts to expand the IPR obligations of foreign countries through trade agreements. In 2002, the TPA legislation was amended to state that the United States recognized the Doha Declaration on the TRIPS Agreement and Public Health in the context of negotiating FTAs. In the 110th Congress, Congressional Democrats and the Administration agreed to modifications of the patent provisions in the Peru FTA as a result of the May 2007 bipartisan trade agreement. Still, a Government Accountability Office (GAO) report suggests that USTR should offer clearer policy guidance to align FTA negotiating activities with the WTO

Doha Declaration.[93] Additionally, there is concern by some that the ratchet of IPR commitments pursued through regional and bilateral FTAs may be too stringent for developing countries and may limit innovation and creativity by stifling the exchange of ideas.

Further expansion of IPR provisions may be affected by the language of any future TPA. In discussions about renewal of TPA, Congress may choose to consider possible reiteration or expansion on its IPR goals related to global health from the 2002 TPA. At issue for Congress is whether or not to follow the template provided by the Peru, Panama, and Colombia FTAs in future trade negotiations.

Without renewal of the TPA, the Administration may be prompted to seek stronger IPR through plurilateral venues. In October 2007, the United States and several key foreign trading partners (Australia, Canada, member states of the European Union, Japan, Mexico, Morocco, New Zealand, Singapore, South Korea, Switzerland) announced their intention to begin negotiating an Anti-Counterfeiting Trade Agreement (ACTA). The countries have pledged to go beyond the TRIPS Agreement by promoting international cooperation, developing "best practices" for enforcement, and establishing a strong legal framework for enforcement.[94] ACTA would provide IPR enforcement tools where the TRIPS Agreement and other international treaties fall short.[95] Copyright-based businesses and anti-piracy advocates voice strong support for the ACTA. However, some observers have been concerned with the extent to which U.S. 'fair use' practices would be maintained under an agreement. Other parties have expressed concern with what they consider the secrecy with which ACTA is being negotiated. On September 17, 2008, numerous consumer groups led by the Electronic Frontier Foundation sued USTR under the Freedom Of Information Act to obtain the negotiating text of the agreement. USTR has responded that negotiations are still at the conceptual phase, and that 'understandings of confidentiality' are routine in negotiating trade agreements.[96] Nonetheless, certain issues have been discussed as potential components of an agreement, including:

- the role of internet service providers (ISP) in enforcing IPR laws online and the potential liability of ISPs for infringements over their networks.
- the ability of customs officials to enforce IPR laws at the border through seizure of infringing products without being prompted by the rights-holder.
- the scope of criminal penalties for 'willful' violations of 'commercial scale' trademark and copyright infringement, including mandatory imprisonment, monetary fines, and the seizure and destruction of infringing goods.[97]

In the latest ACTA meeting, held in mid-December 2008, participants affirmed the importance of transparency and on engaging in future discussions about sharing additional information regarding the ACTA negotiations with the public.[98]

[93] 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.

[94] USTR, "Anti-Counterfeiting Trade Agreement," fact sheet, August 4, 2008.

[95] Liza Porteus Viana, "USTR Plans Another Year of Elevating IP Protection With Trading Partners," *Intellectual Property Watch*, April 4, 2008.

[96] "USTR Official Cites Confidentiality 'Understandings' in ACTA Negotiations," *International Trade Reporter,* September 25, 2008.

[97] "U.S. Seeks Police Powers, Stiffer IPR Penalties at ACTA Meeting in Tokyo," *Inside U.S. Trade*, October 17, 2008.

[98] Amy Tsui, "ACTA Negotiating Members Meet in Paris For Fourth Time Dec. 15-18 With EU Hosting," (continued...)

Effectiveness of the U.S. IPR Organizational Structure

There are concerns on the part of some lawmakers about whether or not the present U.S. IPR organizational structure is doing enough to enforce foreign countries' IPR obligations, as well as concerns about whether or not the structure is capable of doing more.

Some members of Congress have criticized the U.S. organizational response to international IPR protection and enforcement, particularly that of the National Intellectual Property Law Enforcement Coordinating Council (NIPLECC). Recent GAO testimony points out some of the problems associated with NIPLECC, including an absence of mission, dearth of activities, and poor image among businesses.[99] The FY2007 CJS Committee Report (S.Rept. 109-280) expressed concern about the lack of information on NIPLECC's progress and evidence of success.

In the 110th Congress, several bills were introduced to repeal and replace NIPLECC. The *Prioritizing Resources and Organization for Intellectual Property Act of 2008* (P.L. 110-403) (S. 3325, Leahy) was signed by President Bush on October 13, 2008. The act, among other provisions, replaces NIPLECC with an Intellectual Property Enforcement Coordinator (IPEC). The IPEC, located in the Executive Office of the President and subject to Senate confirmation, is charged with coordinating U.S. government agency IPR enforcement actions and with providing assistance to the USTR in conducting trade negotiations relating to IPR enforcement abroad. The IPEC will also oversee an intellectual property enforcement advisory committee composed of representatives from the Office of Management and Budget, the Departments of Justice, Commerce, State, Homeland Security, Agriculture, the Food and Drug Administration, the Agency for International Development, and the Register of Copyrights. This committee will assist the IPEC in the development of a joint strategic plan to combat counterfeiting and infringement.

In contrast to NIPLECC, GAO interviews with agency officials suggest that STOP! is viewed positively for its role in enhancing IPR enforcement as a priority among federal agencies, the private sector, and internationally. As a presidential initiative, STOP! does not derive from statutory authority. According to the GAO, STOP! does not fully meet the characteristics associated with being an "effective national strategy." GAO has expressed concern that STOP! does not discuss risk management or the costs, investments, and processes needed to balance the threats associated with counterfeit products with the resources that are available.[100] In testimony before the Senate Banking, Housing, and Urban Affairs Committee, foreign policy observer Moises Naim stated that governments must be selective in setting their priorities, adding, "It is unrealistic to expect governments to combat every aspect of counterfeiting... This approach will further burden already over-stretched governments and greatly reduce their effectiveness."[101] One

(...continued)

International Trade Daily, December 22, 2008.

[99] U.S. Government Accountability Office, *National Enforcement Strategy Needs Stronger Leadership and More Accountability*, GAO-07-710T, April 12, 2007, pp. 8-10.

[100] Ibid., p. 11.

[101] U.S. Congress, Senate Committee on Banking, Housing, and Urban Affairs, Subcommittee on Security and International Trade and Finance, *Pirating the American Dream: Intellectual Property Theft's Impact on America's Place in the Global Economy and Strategies for Improving Enforcement*, prepared by Moises Naim, 110th Cong., 2nd sess., April 12, 2007.

question inferred from the foregoing is whether the United States can or should devote equal resources to prevent the importation of fake Gucci bags and counterfeit medicines.

While protection and enforcement of IPR is a stated priority for the United States, it is difficult to get a sense of the magnitude of funding and resources devoted toward IPR support, as there is no one line item in the federal budget for IPR protection. Our analysis suggests that the United States spent at least $1.9 billion to support IPR in FY2008. The proposed budget for FY2009 by the President suggests that intellectual property enforcement is a top priority. The President's funding requests for FY2008 for IPR-related agencies were greater than for FY2008.[102] Additionally, there is limited information on the economic and other impacts of piracy and counterfeiting on the United States. For example, in its Special 301 Report, USTR uses industry figures that are not independently confirmed. This complicates the ability of lawmakers to weigh the threat of IPR infringement against the federal resources available for IPR and other government priorities.

IPR and Import Safety

There also has been increasing focus on the relationship between trade in counterfeit and pirated goods and the health and safety of U.S. imports. While the effects of IPR infringement on the U.S. economy and trade are well noted, there is limited quantitative evidence of the extent to which fake imports may affect the health and safety of U.S. consumers. Anecdotal evidence suggests that the health and safety repercussions may be serious.[103]

Many foreign countries do not have adequate frameworks to regulate product safety, increasing the possibility of trade in counterfeit and pirated goods, which may be substandard or hazardous. Imports from China, in particular, have been an ongoing focus area. For instance, among the various Food and Drug Administration recalls of imports from China in 2007, certain toothpaste products with poisonous chemicals were found to be counterfeit goods.[104] In addition, active pharmaceutical ingredients (APIs) found in many drugs are imported from China. With high IPR-infringement rates in China, there is concern about the health and safety risks of fake APIs entering into the U.S. supply and distribution chain.

During the 110th Congress, a number of bills were proposed and hearings were held that focused on boosting the import safety of food and products such as pharmaceutical drugs, toothpaste, and toys. On August 14, 2008, the President signed into law the *Consumer Product Safety Improvement Act of 2008* (P.L. 110-314). While many support increased scrutiny of imports from sending countries and at the U.S. border, others express concern that the scope of the proposals may impede trade flows.

[102] Liza Porteus Viana, "US Fiscal 2009 Proposed Budget Shows IP Enforcement a Priority," *Intellectual Property Watch*, February 6, 2008.

[103] Michele Forzley, *Counterfeit Goods and the Public's Health and Safety*, International Intellectual Property Institute, July 2003.

[104] For more information, see CRS Report RS22713, *Health and Safety Concerns Over U.S. Imports of Chinese Products: An Overview*, by Wayne M. Morrison

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