

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 U.S. 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 Agreement) at the World Trade Organization (WTO), trade policy has been used to promote enforcement of IPR abroad. The United States and several trading partners have been negotiating the Anti-Counterfeiting Trade Agreement (ACTA), which 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, the May 10, 2007 bipartisan trade agreement led to a scale-back of some of the IPR requirements in the Peru, Panama and Colombia FTAs, in an effort 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 or suspending preferential duty-free entry to certain products from the country.

IPR protection and enforcement has been a focal point of legislative activity in recent sessions of Congress. In the 110th Congress, legislation was enacted to establish a new entity to coordinate intellectual property activities within the federal government (P.L. 110-403). In the 111th Congress, legislation was introduced calling for greater U.S. international IPR enforcement efforts and increased prioritization of resources devoted to such activities (H.R. 496 and related bill S. 1466; H.R. 2410 and H.R. 2475).

Given the role of IPR in the U.S. economy and its contribution to U.S. employment and trade, IPR issues related to international trade policy may figure prominently in the 112th congressional agenda. Congress may choose to consider whether or not FTAs are an appropriate vehicle for boosting intellectual property protection and enforcement. Congress also may balance IPR protection and enforcement with other public policy goals such as access to medicine in poor or developing countries. In addition, Congress may examine the effectiveness of the current U.S. coordinating structure for promoting international IPR support.

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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 domestic 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. In light of the recent international financial crisis and global economic downturn, congressional interest has grown in the role of IPR in advancing U.S. industrial competitiveness and contributing to U.S. economic recovery following the recent international crisis. Members of Congress also have expressed concern about the potential health and safety consequences of counterfeit pharmaceutical drugs and other products, as well as the possible link between terrorist groups and traffic in counterfeit and pirated goods.

This report discusses the different kinds of IPR and 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.

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 IPR

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 (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 also may 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 patent holder recoups these up-front costs through a temporary monopoly over sale of the invention. In return for this economic rent, the patent holder 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 for 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.

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

[1] Uniform Trade Secret Act, §1(4).

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 IPR

IPR infringement is the misappropriation or violation of the IPR. 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 reproducing, performing, making sound or visual recordings of, or broadcasting a copyrighted work without the consent of the copyright owner.

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.

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

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 are major challenges for trademarked products. The counterfeited product can be sold for a premium because of its association with 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

The total number of patent filing applications received under the Patent Cooperation Treaty (PCT), an international patent filing system administered by the World Intellectual Property Organization (WIPO), has grown in recent years. After peaking in 2008, international patent filings under the PCT fell by 4.5% in 2009, reflecting the international financial crisis. The contraction of the global economy has been associated with a decline in investment and spending on research and development.[4] In 2010, international patent filings grew by 4.8% to 162,900—nearly 2008 levels (see **Table 1**).[5]

Intellectual property holdings that are protected by international agreements are highly concentrated in certain countries. The United States continues to be the source of the world's largest number of patent filing applications under the PCT, accounting for nearly one-third of such filings in 2010. However, the U.S. growth rate of patent filings has been negative in recent years. The United States, along with Germany and Japan, accounted for about 60% of all patent applications filed in 2010 under the PCT. China ranked as the fourth largest source of international patent filings under the PCT in 2010, representing about 8% of global filings. China had the highest growth rate in such filings, at about 56% in that year.

Table 1. Global Intellectual Property Filings Through the PCT, 2006-2009

Country	2008	2009	2010		
	Filings	Filings	Filings	Percent of	Growth from

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

[4] 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.

[5] WIPO, "International Patent Filings Recover in 2010," press release, February 9, 2011, http://www.wipo.int/pressroom/en/articles/2011/article_0004.html.

Country	2008	2009	2010		
				Total	Previous Years
United States	51,637	45,618	44,855	27.5%	-1.7%
Japan	28,760	29,802	32,156	19.7%	7.9%
Germany	18,855	16,797	17,171	10.5%	2.2%
China	6,120	7,900	12,337	7.6%	56.2%
South Korea	7,899	8,035	9,686	5.9%	20.5%
France	7,072	7,237	7,193	4.4%	-0.6%
United Kingdom	5,466	5,044	4,857	3.0%	-3.7%
Netherlands	4,363	4,462	4,097	2.5%	-8.2%
Switzerland	3,799	3,671	3,611	2.2%	-1.6%
Sweden	4,137	3,567	3,152	1.9%	-11.6%
Canada	2,976	2,527	2,707	1.7%	7.1%
Italy	2,883	2,652	2,632	1.6%	-0.8%
Finland	2,214	2,123	2,076	1.3%	-2.2%
Australia	1,938	1,740	1,736	1.1%	-0.2%
Spain	1,390	1,564	1,725	1.1%	10.3%
All Others	13,725	12,659	12,909	7.9%	2.0%
Total	**163,234**	**155,398**	**162,900**		

Source: World Intellectual Property Organization.

Contribution of Intellectual Property to U.S. Economy

Intellectual property is an important source of comparative advantage for the United States. Nearly every industry depends on IPR for its businesses. Among the industries that are dependent on patent protection are the aerospace, automotive, computer, consumer electronics, pharmaceutical, and semiconductor industries. Copyright-based industries include the software, data processing, motion picture, 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]

The role of IPR in the U.S. economy has been longstanding. Some evidence suggests that factors linked to innovation account for about three-fourths of the United States' post-World War II growth rate.[7] In recent years, the role of IPR in the U.S. economy has grown. Various studies

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

[7] Arti Rai, Stuart Graham, and Mark Doms, *Patent Reform: Unleashing Innovation, Promoting Economic Growth & Producing High-Paying Jobs*, Department of Commerce, A White Paper from the U.S. Department of Commerce, (continued...)

suggest that IP-related industries are one of the largest source of jobs in the United States. One study using data from 2000-2007 found that, among tradable industries, IP-intensive industries surpass non-IP-intensive industries on a range of economic measures, including job creation, wages, output and sales per employee, and exports. During this time period, according to the study, IP-intensive industries paid both their low- and highly skilled employees close to 60% more than non-IP-intensive industries. The report also found that IP-intensive industries represented nearly 60% of total U.S. exports during 2000-2007.[8] More broadly, IPR-intensive industries may contribute positively to the U.S. economy through productivity gains and other spillover effects.

Industry-specific figures may further demonstrate the importance of IP to the U.S. economy. For example, in 2007, the business and entertainment software, motion picture, recording, and publishing industries, which rely on copyright protection, were estimated to contribute about $889 billion to the U.S. economy ("value-added" to current GDP), or about 6.44% of the U.S. economy. This was an increase from 2006, during which the value-added of these copyright industries to the U.S. GDP totaled $837 billion, or 6.35% of the U.S. economy. These copyright industries also accounted for nearly 23% of real U.S. annual economic growth in 2007, up from about 13% in 2006. In terms of U.S. employment, the copyright industries represented 4% of U.S. workers (5.6 million workers) in 2007, similar to the prior year. Foreign sales and exports from these industries amounted to $126 billion in 2007, up from $116 billion in 2006.[9]

The pharmaceutical industry, which is patent-intensive, provides another illustration of intellectual property contributions to the U.S. economy. In 2009, domestic sales by research-based pharmaceutical companies that are members of Pharmaceutical Researchers and Manufacturers of America (PhRMA) reached an estimated $183 billion, while sales abroad by PhRMA member companies totaled about $103 billion.[10]

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.[11] In 2009, U.S. receipts from cross-border trade in royalties and license fees (relating to patent, trademark, copyright, and other intangible rights) totaled $89.8 billion, down from $93.9 billion in the previous year. Also in 2009, U.S. payments of royalties and license fees to foreign countries amounted to $25.2 billion, down from $25.8 billion in the year before. Industrial processes, computer software, and trademarks accounted for the bulk of U.S. international trade in intangible assets.[12]

(...continued)

April 13, 2010.

[8] Nam D. Pham, *The Impact of Innovation and the Role of Intellectual Property Rights on U.S. Productivity, Competitiveness, Jobs, Wages, and Exports*, NDP Consulting Group, April 2010.

[9] Stephen E. Siwek, *Copyright Industries in the U.S. Economy: The 2003-2007 Report*, prepared for the International Intellectual Property Alliance (IIPA), http://www.iipa.com, pp. 3-7.

[10] PhRMA, *Pharmaceutical Industry Profile 2010*, Washington, D.C., March 2010, http://www.phrma.org, p. 50.

[11] 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.

[12] Jennifer Koncz and Anne Flatness, "U.S. International Services," *Survey of Current Business*, U.S. Bureau of Economic Analysis (BEA), October 2010. This measure of cross-border trade in royalties and license fees by U.S. companies include transactions with both affiliated and unaffiliated foreign companies.

Some advocates of civil liberties assert that empirical analysis on the role of IPR in the U.S. economy may not be fully evaluating the economic and commercial benefits of lawful exceptions and limitations to exclusive rights. For example, by one estimate, businesses that rely on "fair use" exceptions to U.S. copyright law contribute $2.2 trillion to the U.S. economy. The "fair use" doctrine permits limitations and exceptions to the exclusive right afforded by copyright law. It permits limited use of copyrighted works without requiring permission from the right holder in certain cases, examples of which may include news reporting, research, teaching, and library use.[13]

Prevalence and Economic Consequences of IPR Infringement

Advances in information and technology and declining costs of transportation and communication, spurred by globalization, have fundamentally changed information and trade flows. Such changes have created new markets for U.S. exporters, but at the same time, have been associated with the proliferation of counterfeiting and piracy on a global scale.

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. According to PhRMA, it takes a pharmaceutical company about 10 to 15 years of research and development to create a new drug. PhRMA member companies collectively spent an estimated $46 billion for research and development (domestic and abroad) in 2009.[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 that can be easily duplicated, such as recorded or digital media, also has led to an increase in counterfeiting and piracy. Increasing Internet usage 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, customs data on seizures of counterfeit and pirated goods may offer some idea of the magnitudes involved. One study by the Organization for Economic Cooperation and Development (OECD) indirectly extrapolated available customs data on seizures to conclude that world trade in counterfeit and pirated goods may have amounted to about $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

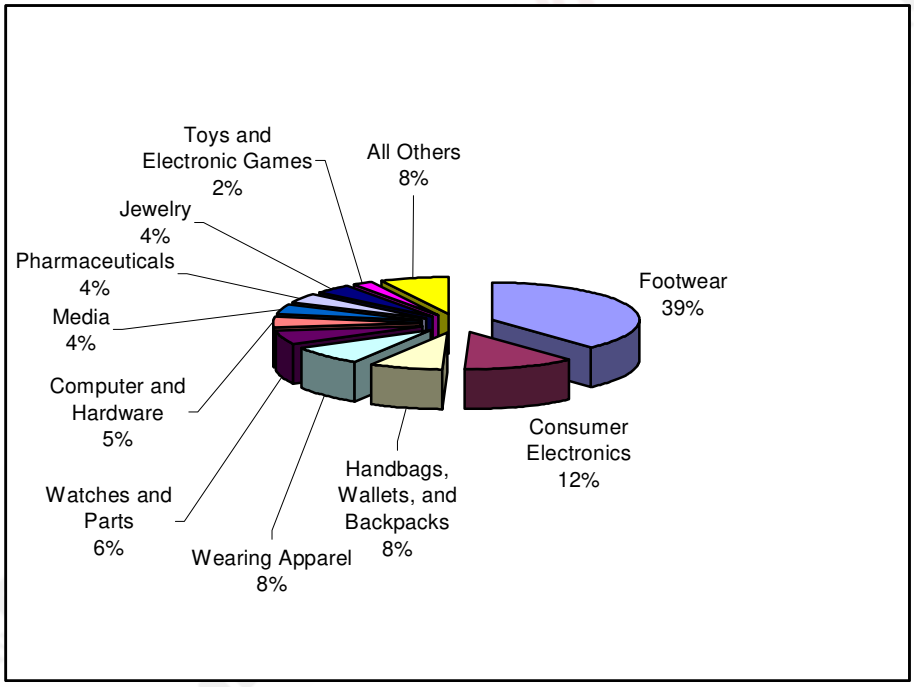
[13] Thomas Rogers and Andrew Zamosszegi, *Fair Use in the U.S. Economy:Economic Contribution of Industries Relying on Fair Use*, Prepared for the Computer & Communications Industry Association (CCIA), 2010. CCIA, "Fair Use Doctrine Vital for All of Us," press release, November 18, 2009, http://www.ccianet.org/index.asp?sid=5&artid=125&evtflg=False. See also CRS Report RL33631, *Copyright Licensing in Music Distribution, Reproduction, and Public Performance*, by Brian T. Yeh.

[14] Ibid., p. 2.

goods produced and consumed within a country and does not include infringing goods distributed over the Internet. If these figures were included, the trade estimate likely would be higher.[15] Updated estimates from the OECD suggest that trade in IPR-infringing goods may have totaled up to $250 billion in 2007. During that same time period, the share of counterfeiting and pirated goods in world trade also is estimated to have increased—from 1.85% in 2000 to 1.95% in 2007.[16]

Data on pirated and counterfeit seizures of imports at the U.S. border shed light of the magnitude of the issue in the U.S. context (see **Figure 1**). In FY2009, the Customs and Border Protection (CBP) and Immigration and Customs Enforcement (ICE) agencies of the Department of Homeland Security (DHS) made 14,841 IPR-related seizures, more than double the FY2005 level of 8,022. Between FY2005-FY2008, the domestic value of IPR-related seizures grew by more than 25% each year. The domestic value of seizures peaked at $272 million in FY2008 and then dropped by 4% to about $261 million in FY2009.[17]

Figure 1. Border Seizures of Counterfeit and Pirated Goods: FY2009



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

Of all U.S. trading partners, China continues to account for the majority of counterfeits intercepted at the U.S. border. In FY2009, seizures of goods originating from China represented

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

[16] Organization for Economic Cooperation and Development (OECD), *The Economic Impact of Counterfeiting and Piracy*, 2007. OECD, *Magnitude of Counterfeiting and Piracy of Tangible Products: An Update*, November 2009.

[17] U.S CBP and U.S. ICE, *Intellectual Property Rights Seizure Statistics: FY2009*, October 2010.

79% of all seizures and $205 million in value. Other top trading partners from which IPR-infringing goods were seized include Hong Kong, India, Taiwan, and Korea. [18]

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. The total value of IPR-related seizures of commodities that represent potential safety and security risks was $32 million in FY2009. Pharmaceutical goods were the top commodity posing safe and security risks, accounting for 34% ($11 million in domestic value) of such commodities intercepted at U.S. borders. Imports from China represented 62% of IPR-related goods that were intercepted at U.S. borders and identified as presenting safety and security risks, followed by such imports from India at 9%.[19]

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 addition, beyond the direct losses faced by U.S. intellectual property-based firms, the U.S. economy may face additional "downstream" losses from IPR infringement. According to this view, counterfeiting and piracy losses to U.S. firms, for example, also result in the loss of jobs that would have been created if the infringement did not occur, which translates into lost earnings by U.S. workers. This, in turn, translates into lost tax revenues for federal, state, and local governments from lost personal income, corporate income, and production taxes.[20]

Attempts have been made in some economic sectors to quantify the IPR infringement levels and related losses to legitimate U.S. businesses. 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 1,900 U.S. copyright-based companies, provides annual estimates of U.S. trade loss associated with copyright infringements in selected countries.[21] For 2009, IIPA estimated that copyright piracy in 43 countries resulted in $14.3 billion in U.S. business software losses and $1.4 billion in U.S. records and music losses. China was the leading culprit in terms of trade losses due to copyright piracy, contributing to $3.4 billion in business software losses and $466 million in records and music losses to U.S. businesses.[22]

[18] Ibid.

[19] Ibid.

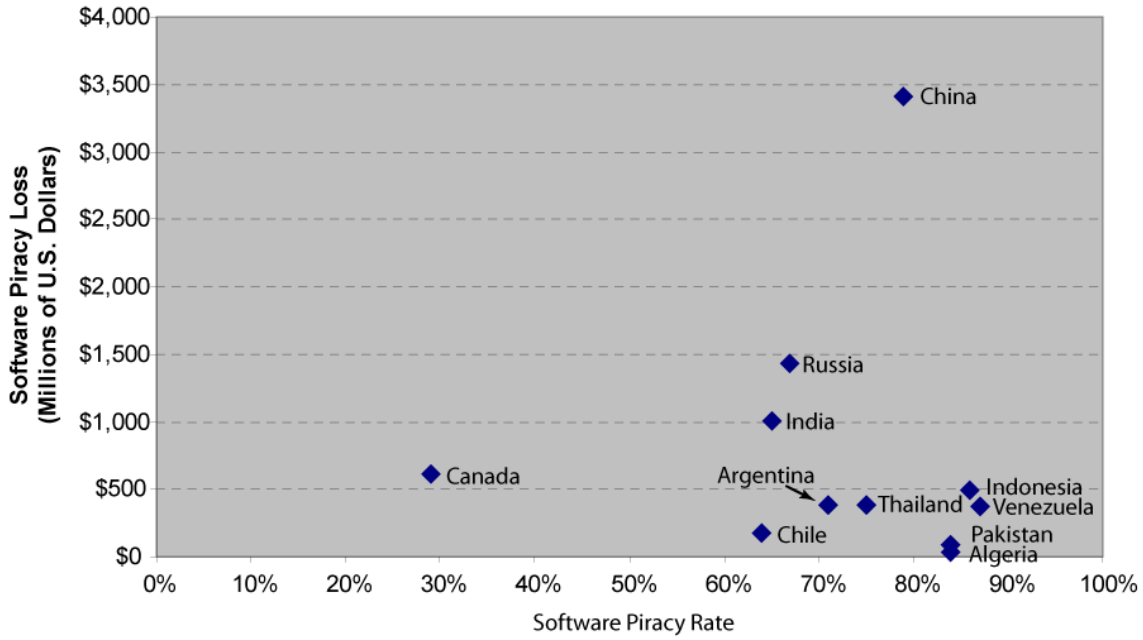
[20] There may be limitations on data estimating the impact of counterfeiting and piracy on the U.S. economy. Some critics point out that many of the estimates for losses associated with IPR infringement are generated by industry groups that may have self-interested motivations and hence, the negative effects may be exaggerated.

[21] The IIPA member associations are: Association of American Publishers (AAP), Business Software Alliance (BSA), Entertainment Software Alliance (ESA), Independent Film & Television Alliance (I.F.T.A.), Motion Picture Association of America (MPAA), National Music Publishers' Association (NMPA), and Recording Industry Association of America (RIAA).

[22] IIPA, *IIPA 2009 "Special 301" USTR Decisions*, issued June 30, 2009.

There is not always a direct relationship between IPR infringement rates and the costs to U.S. firms (see **Figure 2**). 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. Thus, estimated losses from IPR infringement may be lower in a country with high piracy rates but a small market for the United States, compared to a country with lower piracy rates but a bigger market for United States.

Figure 2. Estimated Software Piracy Rates in Selected Countries and Estimated Related Software Piracy Losses to U.S. Businesses



Source: Business Software Alliance.

Notes: The countries listed were identified as Priority Watch List countries in the 2010 "Special 301" report released by the Office of the U.S. Trade Representative.

Pharmaceutical Industry

In previous years, PhRMA has provided annual estimates of U.S. pharmaceutical industry losses from foreign violations of data exclusivity and patent protection.[23] In its 2007 Special 301 submission to the USTR, 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 2**).[24] Damages reported in the 2007 submission were nearly double those reported in the prior year's submission. While the total loss associated with IPR infringement grew, damages

[23] 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.

[24] 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.

as a percentage of sales declined from the 2006 submission to the 2007 submission.[25] At the time of reporting for submissions for subsequent years, PhRMA was not able to provide estimates of damages resulting from trade barriers associated with intellectual property protection and market access.[26]

Table 2. Estimated Damages for PhRMA Member Companies From Data Exclusivity and Patent Protection Violations

	2006 Submission (Oct. 2004 - Sept. 2005)	2007 Submission (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.

Limitations on Data Estimating IPR Infringement Costs

There may be limitations to data estimating the impact of counterfeiting and piracy on the U.S. economy. According to a study conducted by the U.S. Government Accountability Office (GAO), the U.S. government does not systematically collect data or analyze the impacts of counterfeiting and piracy on the U.S. economy. In many cases, the federal government relies on estimates conducted by industry groups. However, industry associations may not always release their proprietary data sources and methods, complicating efforts to verify such estimates.[27] Some critics point out that many of the estimates for losses associated with IPR infringement are generated by industry groups that may have self-interested motivations.[28]

There is a possibility that such IPR infringement loss estimates may overestimate the extent to which sales of pirated and counterfeit goods displace legitimate sales. Methods for calculating data on counterfeiting and piracy often involve certain assumptions. Estimates of losses from IPR infringement can be highly sensitive to how these assumptions are derived and weighted. Some analysts question the proposition that sales of pirated goods translate directly into revenue losses for legitimate firms. 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.[29] For consumers in poor developing countries, especially, this assumption may not be tenable. Others also question the statistical techniques used to develop these estimates. [30]

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

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

[27] U.S. Government Accountability Office, *Intellectual Property: Observations on Efforts to Quantify the Economic Effects of Counterfeit and Pirated Goods*, GAO-10-423, April 2010.

[28] Monika Ermert, "Speculation Persists on ACTA as First Official Meeting Concludes," *Intellectual Property Watch*, June 5, 2008. Robin Gross, *IP Justice White Paper on the Proposed Anti-Counterfeiting Trade Agreement (ACTA)*, IP Justice, March 25, 2008, p. 6.

[29] Robert G. Picard, "A Note on Economic Losses Due to Theft, Infringement, and Piracy of Protected Works," *Journal*

(continued...)

At the same time, there is a possibility that some IPR infringement loss estimates may underestimate the losses to U.S. businesses. For example, U.S. trade losses due to copyright infringement may be higher than reported because estimates oftentimes do not account for all forms of piracy, such as Internet piracy, which is an increasingly significant contributor to copyright piracy.[31] One study estimates that nearly 24% of global internet traffic infringes upon copyright.[32]

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 multilateral, 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 Agreement), which 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 2**), 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

(...continued)

of Media Economics, 17(3), 207-217, 2004.

[30] U.S. Government Accountability Office, *Intellectual Property: Observations on Efforts to Quantify the Economic Effects of Counterfeit and Pirated Goods*, GAO-10-423, April 2010.

[31] IIPA, "IIPA's 2009 Special 301 Report on Copyright Protection and Enforcement," submitted to the U.S. Trade Representative by IIPA on February 17, 2009, http://www.iipa.com.

[32] Envisional, *Technical Report: An Estimate of Infringing Use of the Internet*, January 2011.

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 re-imposition of tariffs) for non-compliance, sets this agreement apart from previous IPR treaties that did not have effective dispute settlement mechanisms.

U.S. WTO Cases Against China on IPR

In April 2007, the United States filed two WTO dispute settlement cases against China, alleging inadequacies in China's enforcement of IPR laws and its barriers to market access for U.S. copyright businesses.[33]

- In January 2009, the DSU issued its final ruling on the case centering on IPR enforcement issues. The WTO panel ruled in the United States' favor that China's denial of copyright protection to works without censorship approval is inconsistent with the TRIPS Agreement. The 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. 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. China agreed to implement the WTO ruling.[34]
- In August 2009, a WTO panel ruled that a number of China's restrictions on trading rights and distribution of IPR-related products were inconsistent with WTO rules. However, the WTO panel did not address whether China's censorship policies or import limitations on foreign films violate WTO rules. China agreed to implement the WTO ruling.[35]

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."[36] 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

[33] 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.

[34] 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.

[35] For more information on U.S-China IPR and other trade issues, see CRS Report RL33536, *China-U.S. Trade Issues*, by Wayne M. Morrison.

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

> 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 was set at 10 years (January 1, 2006), and for pharmaceuticals, the compliance period was later extended to 2016.[37]

Declaration on TRIPS Agreement and Public Health [38]

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.[39] 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

[37] "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.

[38] See CRS Report R40607, *Intellectual Property Rights and Access to Medicines: International Trade Issues*, by Shayerah Ilias.

[39] 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.

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[40] 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 153 WTO member states. The deadline for ratification has been extended to December 30, 2011. Until then, the 2003 waiver continues in force. To date, the following WTO members have ratified the amendment: the United States, Switzerland, El Salvador, South Korea, Norway, India, the Philippines, Israel, Japan, Australia, Singapore, Hong Kong, China, the 27 countries of the European Union, Mauritius, Egypt, Mexico, Jordan, Brazil, Morocco, Albania, Macau, Canada, Bahrain, Colombia, Zambia, Nicaragua, Pakistan, the Former Yugoslav Republic of Macedonia, Uganda, Mongolia, Croatia, and Senegal.[41]

The system 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.[42]

[40] "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.

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

[42] "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.

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.[43] 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.[44] 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.[45]

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.

World Intellectual Property Organization (WIPO)

In addition to the WTO, the other main multilateral venue for addressing IPR issues is the World Intellectual Property Organization (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 3**). 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.[46] Recent WIPO efforts have focused on patent law. In June 2000, WIPO

[43] 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.

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

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

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

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. Government leaders participating in the Group of 8 (G8) meeting in July 2008 called for "accelerated discussions" of the SPLT.[47]

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.[48] 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.[49]

Table 3. Summary of WIPO-Administered IPR Treaties

Treaty	Date Concluded	Provisions
Intellectual Property Protection Treaties		
Paris Convention for the Protection of Industrial 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 Protection 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	1971	Protects producers of phonograms against

[47] Monika Ermert, "G8 Governments Want ACTA Finalised This Year, SPLT Talks Accelerated ," *Intellectual Property Watch*, July 9, 2008.

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

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

Treaty	Date Concluded	Provisions
Phonograms Against Unauthorized Duplication of their Phonograms (Phonograms Convention)		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)
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

Treaty	Date Concluded	Provisions
		(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 and Negotiating Objectives

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 for FTAs were first enacted in trade promotion 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 the North American Free Trade Agreement (NAFTA). In the intervening period since the 1988 Act, the TRIPS agreement came into force and the IPR provisions of NAFTA became the template for future bilateral or regional FTAs. Thus, the focus of IPR negotiating objectives shifted from creating to strengthening the IPR trade regime.

More recent FTA negotiations have been conducted under the Trade Promotion Authority Act of 2002 (P.L. 107-210), which included two broad IPR negotiating objectives. 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 of the Trade Promotion Authority Act of 2002 was to negotiate trade agreements in terms of IPR that "reflect a standard of protection similar to that found in U.S. law."[50] 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.

In May 2007, the Bush Administration and Congress concluded a bipartisan agreement on trade policy that addressed some Members' concerns about the implications of enhanced IPR on developing countries' ability to meet public health needs.[51] 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 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.

Current IPR-Related U.S. FTA Activity

In 2011, the Obama Administration may ask Congress to approve a free trade agreement (FTA) with South Korea, as well as FTAs with Colombia and Panama. These three FTAs were negotiated by the Bush Administration, but have not been implemented.

Meanwhile, the Obama Administration has entered into negotiations with participants in the Trans-Pacific Partnership (TPP) Agreement—Australia, Brunei, Chile, New Zealand, Peru, Malaysia, Singapore, and Vietnam. The objective is to build on U.S. trade ties in the region

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

[51] The May 10, 2007 bipartisan trade agreement is available online at: http://www.ustr.gov/assets/Document_Library/Fact_Sheets/2007/asset_upload_file127_11319.pdf.

already established in FTAs with Australia, Chile, and Singapore and to provide a high-standard framework for expanded free trade in the region.[20] IPR, particularly in the area of pharmaceuticals, may prove to be a contentious issue in the negotiation of the TPP.

In addition, the Obama Administration has been conducting negotiations on the Anti-Counterfeiting Trade Agreement (ACTA), a proposed agreement being negotiated by Australia, Canada, the 27 member states of the European Union, Japan, South Korea, Mexico, Morocco, New Zealand, Singapore, Switzerland, and the United States. Negotiations on the ACTA Agreement began under the Bush Administration. The ACTA would build on the minimum standards for IPR protection and enforcement set forth by the TRIPS Agreement. It is being crafted independent of any existing international organization or agreement. The eleventh and final round of negotiations concluded on October 2, 2010, and the ACTA participants released to the public a draft text of the agreement. ACTA participants are working to resolve outstanding issues in the agreement.[52]

Central IPR Standards in U.S. FTAs

What follows is a discussion of some of the central patent and copyright standards sought in FTAs that are currently in force or have been signed by the United States (see **Table 4**).[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

[52] For more information, see CRS Report R41107, *The Proposed Anti-Counterfeiting Trade Agreement: Background and Key Issues*, by Shayerah Ilias.

[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.

Peru, Colombia, and Panama state that patent term restorations for pharmaceutical products are optional.

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 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.

[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.

Parallel Importation: 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 IPR, 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.

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

[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.

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 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.

Table 4. 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*	National regulatory authorities cannot provide marketing approval for a generic version of a patented drug without	Eliminates mandate that regulatory authorities cannot approve a generic drug for marketing if patent for drug

[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.

Intellectual Property Forms	TRIPS Provisions	General TRIPS-Plus Provisions in FTAs	Scale-down of TRIPS-Plus Standards
	owner must be notified if another entity is seeking marketing approval for generic version of patented product, Article 4.23.b)	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)*	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)*
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),*	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*

Intellectual Property Forms	TRIPS Provisions	General TRIPS-Plus Provisions in FTAs	Scale-down of TRIPS-Plus Standards
	Bahrain (Article 14.8.(1-2)), Oman (Article 15.8.2, plants not discussed),		*(Article 16.9.2), Panama (Article 15.9.2), Colombia (Article 16.9.2)*
	Jordan, (no mention), Singapore (no mention), Australia (no mention), Korea (no mention)		
Copyrights			
Rights-management information	Not discussed	Outlaws removal or alternation of information	
	NAFTA (no mention), Jordan (no mention)	*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)	No less than 70 years from death of author or authorized publication	
	NAFTA (Article 1705.4), Jordan (no mention)	*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	Signatories must agree to prohibit circumvention	
	NAFTA (no mention)	*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	ISPs are provided with limited liability in certain situations of copyright infringement on their servers if they comply with regulations	
	NAFTA (no mention), Jordan (no mention)	*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" 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 (OCRs) on countries to monitor their progress on intellectual property issues. OCRs 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.

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

Special 301 Report for 2010

For the *2010 Special 301 Report*, the USTR reviewed the IPR policies and practices of 77 countries.[61]

- Despite some improvements, China and Russia remain top concerns for the Administration due to their inadequate IPR regimes.
- The USTR placed eleven countries on the Priority Watch List: Algeria, Argentina, Canada, Chile, China, India, Indonesia, Pakistan, Russia, Thailand, and Venezuela.
- The USTR placed another 29 countries were placed on the Watch List.
- No countries were designated as Priority Foreign Countries. Paraguay was identified for Section 306 monitoring.
- The USTR announced that it would conduct OCRs for the Philippines and Thailand to monitor these nations' progress on IPR and to evaluate their Special 301 status.
- Israel's status in the Special 301 Report is pending, following the conclusion of an OCR and an understanding reached by the United States and Israel on several issues in Israel's IPR regime for pharmaceutical products.[62]
- The USTR removed the Czech Republic, Hungary, and Poland from the Special 301Watch List for significant improvement in their protection and enforcement of IPR. Following an OCR on Saudi Arabia, the USTR decided to remove Saudi Arabia from the Watch List on the basis of improvements in IPR enforcement, prosecution, and transparency issues.

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 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.

[61] The USTR *Special 301 Report 2010* is available on the USTR website, http://www.ustr.gov.

[62] Letter from Ambassador Ron Kirk, U.S. Trade Representative, to The Honorable Benyamin Ben-Eliezer, Ministry of Industry, Trade and Labor, February 18, 2010.

[63] Conversation with USTR official, July 2006.

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 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]

[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.

[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.

During FY2009, the ITC reported a total of 85 active section 337 investigations and ancillary proceedings, comparable to the FY2008 level. Of the 85 active investigations in FY2009, 29 constituted of new section 337 investigations and 7 were new ancillary proceedings stemming from previously concluded section 337 investigations. The section 337 investigations frequently involved advanced technology areas, such as integrated circuit, computer, telecommunications, and other electronic technologies. Over 60% of the new section 337 investigations that were active in FY2009 involved cases of alleged patent infringement. In FY2009, the ITC issued three general exclusion orders, eight limited exclusion orders, and 23 cease-and-desist orders.[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 December 31, 2010.[69]

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.[70]

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. For 2009, the USTR continued to evaluate IPR protection in Lebanon, Russia, and Uzbekistan on the basis of IIPA petitions for ongoing GSP reviews.[71]

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.

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[68] U.S. International Trade Commission, *Year in Review: Fiscal Year 2009*, USITC Publication 4167, p. 14.

[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] 91 USC 2462(b)(2)

[71] USTR, *GSP: 2009 Annual Review*, http://www.ustr.gov.

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. What follows is a discussion of the various IPR functions of U.S. agencies.

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.[72]

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.[73] 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).[74] The PTO is fully funded through fees generated from patent and trademark applications. The Consolidated Appropriations Act, 2010 (P.L. 111-117) provided $1.89 billion in budgetary authority to the PTO for FY2010, down from $2.01 billion provided for FY2009 (P.L. 111-8).

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.[75] For FY2010, the Consolidated Appropriations Act, 2010 (P.L. 111-117) provided the ITA with $456.20 million (including both direct appropriation and anticipated receipts from fees), up from $429.9 million provided in FY2009 (P.L. 111-8).

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

[73] NIPLECC, *Report to the President and Congress on Coordination of Intellectual Property Enforcement and Protection*, January 2008, p. 21.

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

[75] NIPLECC, *Report to the President and Congress on Coordination of Intellectual Property Enforcement and Protection*, January 2008, p. 21.

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.[76] 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 Consolidated Appropriations Act, 2010 (P.L. 111-117) provided $7.66 billion to the FBI for FY2010, up from the FY2009 level of $7.07 billion (P.L. 111-8).

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 Intellectual Property Rights Coordination Center that coordinates U.S. Government domestic and international law enforcement activities.[77]

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.[78] 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.[79] For FY2010, the Consolidated Appropriations Act, 2010 provided $8.07 billion in budget authority to CBP, up from $7.60 billion in FY2009.

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

[76] 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.

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

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

[79] NIPLECC, *Report to the President and Congress on Coordination of Intellectual Property Enforcement and Protection*, January 2008, pp. 15-16. Additional information about CBP is available at http://www.cbp.gov.

obtained from ICE activities that is relevant to identifying and apprehending counterfeit shipments is provided to CBP.[80] For FY2010, the Consolidated Appropriations Act, 2010 provided $5.34 billion in budget authority to ICE, up from $4.93 billion in FY2009.

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.[81] The enacted FY2010 Agricultural appropriation, P.L. 111-80, contained $2.36 billion in budget authority for the FDA, up from $2.05 billion for FY2009.

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.[82] The enacted FY2010 Legislative appropriation, P.L. 111-68, contained $20.9 million in new budget authority (not including authority to spend $33.3 million in receipts) for the Copyright Office, up from $18.3 million in new budget authority in FY2009 (not including authority to spend $33.3 million receipts).

Copyright Office appropriations also specify funding for IPR-related activities in developing countries. As in previous years, the FY2010 appropriations act provided $100,000 to 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

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

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

[82] NIPLECC, *Report to the President and Congress on Coordination of Intellectual Property Enforcement and Protection*, January 2008, p. 18. Also see Copyright Office website, http://www.copyright.gov.

standards to fight global piracy and counterfeiting.[83] As in previous years, the Consolidated Appropriations Act, 2010 (P.L. 111-117) provided $5 million from the INCLE Account for combating copyright piracy (Section 688).

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.[84]

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.[85] The FY2010 funding level for USTR was $47.83 million, under the Consolidated Appropriations Act, 2010 (P.L. 111-117), up from the FY2009 funding level of $47.3 million. Explanatory language in H.Rept. 111-149, accompanying P.L. 111-117, encouraged the USTR to continue prioritizing IPR issues with China, Russia, and Canada in bilateral and multilateral trade negotiations.

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.[86] For FY2010, the Consolidated Appropriations Act, 2010 (P.L. 111-117) provided the ITC with $81.86 million in budget authority, up from the FY2009 level of $75.1 million.

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[83] NIPLECC, *Report to the President and Congress on Coordination of Intellectual Property Enforcement and Protection*, January 2008, pp. 17-18. Additional information about the State Department is available at http://www.state.gov.

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

[85] NIPLECC, *Report to the President and Congress on Coordination of Intellectual Property Enforcement and Protection*, January 2008, p. 25. Also see USTR website, http://www.ustr.gov.

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

Intellectual Property Enforcement Coordinator (IPEC)

In October 2008, Congress created an Intellectual Property Enforcement Coordinator (IPEC), through the Prioritizing Resources and Organization for Intellectual Property Act of 2008 (P.L. 110-403). The IPEC, located in the Executive Office of the President – specifically in the Office of Management and Budget – 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.[87]

Under P.L. 110-403, the IPEC is to chair a 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.

The IPEC, assisted by its Advisory Committee, also is charged with developing a "Joint Strategic Plan" for combating counterfeiting and piracy. Legislation requires the Joint Strategic Plan to include in its objectives: reducing counterfeiting and infringing goods in the domestic and international supply chain, identifying and addressing barriers to effective enforcement domestically, ensuring that information is shared among the relevant departments and agencies, eliminating domestic and international counterfeiting and infringement networks, strengthening the capacity of foreign countries to protect and enforce IPR, and cooperating with other countries to establish international standards and policies to enforce IPR.

In 2009, President Obama nominated and the Senate confirmed Victoria A. Espinel as the IPEC. In June 2010, IPEC Espinel released the *2010 Joint Strategic Plan on Intellectual Property Enforcement*. The plan identifies 33 "enforcement strategy action items," categorized under six major areas of focus: (1) leading by example; (2) increasing transparency; (3) ensuring efficiency and coordination; (4) enforcing U.S. rights internationally; (5) securing the supply chain; and (6) building a data-driven government.[88]

The House Conference Report (H.Rept. 111-366 to H.R. 3288) provided for a transfer of $176,000 from the White House to the OMB, to reflect the Administration's decision to locate the new IPEC in the OMB rather than the White House.

Issues for Congress

The role of Congress in addressing IPR and trade-related issues stems from the U.S. Constitution, which provides Congress with the power "To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective

[87] In creating the IPEC, P.L. 110-403 repealed the authorities creating the National Intellectual Property Law Enforcement Coordination Council (NIPLECC). Established by Congress in 1999, NIPLECC coordinated U.S. activities to protect and enforce IPR domestically and abroad, drawing together the major federal agencies the help to enforce IPR. The Copyright Office participated in the Council in an advisory role. The U.S. Coordinator for International Intellectual Property Enforcement headed NIPLECC's interagency coordination efforts. NIPLECC, *Report to the President and Congress on Coordination of Intellectual Property Enforcement and Protection*, January 2008, pp. 3-4.

[88] Executive Office of the President, *2010 Joint Strategic Plan on Intellectual Property Enforcement*, June 2010, http://www.whitehouse.gov/sites/default/files/omb/assets/intellectualproperty/intellectualproperty_strategic_plan.pdf.

Writings and Discoveries" and "To regulate Commerce with foreign Nations."[89] While the U.S. Constitution provides Congress with the power to regulate international trade, the authority to negotiate trade agreements has been delegated periodically to the President. However, congressional action is needed to bring the trade agreements into force.

From a policy perspective, congressional consideration of IPR may take place in the context of the National Export Initiative (NEI), an Obama Administration plan introduced in early 2010 to double U.S. exports in five years to create two million U.S. jobs.[90] A report submitted by the President's Export Promotion Cabinet on implementing the NEI discussed the relationship between strengthening IPR regimes internationally and promoting U.S. exports.[91] In December 2010, the President's Export Council sent a letter to President Obama highlighting the importance of addressing inadequate protection and enforcement of IPR as a means for "boosting exports and foreign sales, and promoting the sustained growth of well compensated U.S. jobs." The President's Export Council expressed support for making "efforts to combat weak and ineffective intellectual property regimes abroad an integral and essential part of the National Export Initiative." [92]

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. Some question the appropriateness of using regional and bilateral FTAs for this pursuing stronger IPR, 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 Trade Promotion Authority (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 leaders and the Bush 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

[89] *U.S. Constitution*, Article 1, Section 8.

[90] "National Export Initiative," Executive Order 13534 of March 11, 2010, 75 *Federal Registrar* 12433, March 16, 2010.

[91] Export Promotion Cabinet, *Report to the President on the National Export Initiative: The Export Promotion Cabinet's Plan for Doubling U.S. Exports in Five Years*, Washington, D.C., September 2010. The President's Export Promotion Cabinet is a high-level body comprised of the Secretaries or Directors of key federal agencies involved in U.S. export promotion efforts.

[92] Letter from Jim McNerney, The President's Export Council, to President Obama, December 9, 2010, http://trade.gov/pec/docs/PEC_IPR_Letter_120910.pdf. The President's Export Council is a private sector national advisory committee on international trade.

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. Congress also may choose to consider whether or not to follow the template provided by the Peru, Panama, and Colombia FTAs in future trade negotiations, such as negotiations on the Trans-Pacific Partnership Agreement.

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.

Prior to the establishment of the Intellectual Property Enforcement Coordinator (IPEC), the U.S. IPR organizational structure was coordinated by the National Intellectual Property Law Enforcement Coordinating Council (NIPLECC). Some Members of Congress were critical of NIPLECC's organizational response to international IPR protection and enforcement. Recent GAO testimony pointed out some of the problems associated with NIPLECC, including an absence of mission, dearth of activities, and poor image among businesses.[94] 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) was signed by President Bush on October 13, 2008. The act, among other provisions, replaced NIPLECC with an IPEC. Elevating the IPEC's profile by placing it in the EOP, some lawmakers hope, will promote more effective coordination of the organizational structure's response to international IPR protection and enforcement issues. Others argue that the effectiveness of the IPEC will depend on what resources are allocated for its activities.

While protection and enforcement of IPR is a stated trade policy priority for the United States, it is difficult to get a sense of the magnitude of funding and resources devoted toward IPR support. Some agencies do not have a separate budgetary line item for IPR-related activities, and Congress does not always designate specific funds for IPR activities in its appropriations for agencies.[95] 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 may complicate the ability of lawmakers to

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

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

weigh the threat of IPR infringement against the federal resources available for IPR and other government priorities.

Legislation was introduced in the 111th Congress to advance U.S. IPR protection and enforcement efforts as part of U.S. trade policy. The Trade Enforcement Act of 2009 (H.R. 496, S. 1466) would have created new IPR coordinator positions in the Department of the Treasury and the Department of Homeland Security's Customs and Border Protection (CBP) and Immigration and Customs Enforcement (ICE) agencies; increased IPR resources, staff, funding, and training for CBP and ICE; required the development of a strategy for IPR enforcement; and created a Advisory Committee on Import Safety and Intellectual Property Rights Enforcement, among other provisions.

Some lawmakers also support increasing the priority that IPR is given as part of U.S. foreign policy. Foreign relations appropriations legislation for FY2010 (H.R. 2410, H.R. 2475) would have required the Secretary of State to appoint ten intellectual property attachés to serve in U.S. missions overseas and would have directed the Secretary of State to consider assigning such attachés to missions in countries which have been identified under Section 182 of the Trade Act of 1974.

Some may support efforts to promote IPR as a part of U.S. trade, foreign, or other forms of policy. Others may raise concerns about how the promotion of IPR may affect U.S. efforts to advance other policy goals. In addition, while some support efforts to increase resources dedicated to IPR protection and enforcement, others question what implications such increased resources might have for U.S. coordination of IPR protection and enforcement activities.

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