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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. They may take forms such as patents, trade secrets, copyrights, trademarks, or geographical indications. Congress has constitutional responsibility for legislating and overseeing IPR and international trade policy. Responsibility for developing IPR policy, engaging in IPR-related international negotiations, and enforcing IPR laws cuts across multiple U.S. government agencies.

The protection and enforcement of IPR is an important and longstanding component of U.S. international trade policy and U.S. trade negotiating objectives. U.S. trade policy also seeks to address new and evolving issues in the IPR landscape related to the growing role of emerging markets in the global market place and the increased level of digital trade.

Since the North American Free Trade Agreement (NAFTA) and the 1995 World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) at the, trade policy has been used to advance IPR rules internationally. The TRIPS Agreement set minimum standards for IPR protection and enforcement. The United States engages in efforts with other trading partners to build on the TRIPS Agreement, particularly through the negotiation of regional and bilateral free trade agreements (FTAs). To date, the United States has entered into 14 FTAs with 20 countries, which generally include IPR commitments exceeding obligations under the TRIPS Agreement ("TRIPS-plus"). IPR issues are prominent in the ongoing U.S. FTA negotiations of the proposed Trans-Pacific Partnership (TPP) and Transatlantic Trade and Investment Partnership (T-TIP). On June 29, 2015, President Obama signed the Bipartisan Trade Promotion and Accountability Act (P.L. 114-26), known as Trade Promotion Authority (TPA), setting forth negotiating objectives on IPR. Many of these objectives are to seek to negotiate TRIPS-plus provisions in U.S. FTAs.

Other trade policy tools also are available to advance U.S. international IPR objectives. 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 that infringe on U.S. IPR. 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 issues related to international trade policy may figure prominently in the 114th congressional agenda. Congress may:

- examine the role of IPR in U.S. trade policy, including the implications of IPR trade negotiating objectives in Trade Promotion Authority (TPA);
- conduct oversight of implementation of the IPR commitments in existing trade agreements, as well as in the current U.S. trade negotiations on TPP and T-TIP;
- conduct oversight of the role of IPR in U.S. economic growth and innovation, and how the protection and enforcement of IPR relates to other public policy goals, such as access to medicines in poor or developing countries and the free flow of data;

- consider the possibility of additional policy options to address IPR concerns in emerging economies that are not a part of existing U.S. FTAs or included in current U.S. FTA negotiations, as well as new and evolving IPR issues, such as with respect to indigenous innovation, "forced" localization barriers to trade, and trade secret theft through cybercrime; and
- examine the effectiveness of the current U.S. coordinating structure and the adequacy of current federal resources for promoting international IPR support.

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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, IPR protection and enforcement have come to the forefront as a key international trade issue for the United States—largely due to the role of intellectual property in an innovative U.S. economy and competitive advantage—and figure prominently in the multilateral trade policy arena and in regional and bilateral U.S. free trade agreements (FTAs).

Congress has legislative, oversight, and appropriations responsibilities related to IPR and trade policy. This role of Congress 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 Writings and Discoveries" and to "regulate Commerce with foreign Nations."[1] Since 1988, Congress has included IPR as a principal U.S. trade negotiating objective, and has passed laws, such as "Special 301" to advance protection and enforcement of U.S. IPR in global markets. The context for congressional interest may include policy concerns such as: the role of IPR in the U.S. economy; the impact of IPR infringement on U.S. commercial, health, safety, and security interests; and the balance between protecting IPR to stimulate innovation and advancing other public policy goals.

This report discusses the different types of IPR and IPR infringement; the role of IPR in the U.S. economy; estimated losses associated with IPR infringement; the organizational structure of IPR protection and U.S. trade policy; and issues for Congress regarding IPR and international trade.

IPR Definitions

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 forms such as 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 Agreement) 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, WTO members are obliged to abide by WTO rules, and their IPR enforcement practices can be challenged by other WTO members through the WTO dispute settlement process.

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 and "non-obvious" (involving an inventive step), and have a potential industrial or commercial application. The patent provides the holder with the exclusive right to exclude others from making, using, selling, or importing into the United States the patented

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

invention for a period of 20 years.[2] 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 (R&D). The patent holder recoups these up-front costs through a temporary monopoly over 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 U.S. 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.[3] Examples of trade secrets include blueprints, customer lists, pricing information, and source code. While protection of patents and copyright is an exclusive matter of federal law, trade secret protection is found not only in federal law, but also in state law. Most states have adopted the Uniform Trade Secret Act (UTSA), a model law drafted by the National Conference of Commissioners on Uniform State Laws.

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 protection 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 right 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, fixed in physical and/or digital forms. 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 provides copyright protection for life of the author plus 70 years for personal works, or 120 years from creation (or 95 years from publication) for corporate works. Copyrights may be registered by the U.S. Copyright Office of the Library of Congress, although protection arises immediately upon fixation in a tangible medium of expression.

[2] In some cases, the effective duration of patent protection can be shorter, for example, because of regulatory delays in the approval of the patent or delays in obtaining marketing approval for the patented invention.

[3] Uniform Trade Secret Act, §1(4).

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, symbol, or sound 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 product originating from a particular 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. In general, however, the United States protects geographic indications through trademark law.

Theft of Intellectual Property

Infringement

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 invention. As relates to international trade, the greatest challenge to the patent right is infringement in foreign countries, or non-observance by WTO member states of the minimal standards of the TRIPS Agreement. Copyright infringement occurs when a third party engages in reproducing, performing, or distributing a copyrighted work without the consent of the copyright owner. In addition to the term infringement, other terms are used to describe certain violations of IPR.

Piracy

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

Counterfeiting

An imitation of a product is referred to as a "counterfeit" or a "fake." Counterfeit products are manufactured, marketed, and distributed with the appearance of being the genuine good and

originating from the genuine manufacturer.[4] 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. Consumer experience with a counterfeited good of inferior quality can damage the reputation of the trademark product. Additionally, counterfeited goods of inferior quality may be potentially harmful. Popular examples of counterfeit products include fake fashionwear (e.g., counterfeits of brand-name bags and watches) or fake pharmaceutical products (e.g., counterfeits of 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.

Trade Secret Theft

Theft of trade secrets generally takes one of two forms as a federal crime. **Industrial espionage** refers to the stealing of trade secret information that relates to a product in interstate or foreign commerce, to the economic benefit of third parties and to the injury of the trade secret owner (18 U.S.C. 1832). **Economic espionage** refers to the stealing of a trade secret when the intent to benefit a foreign power (18 U.S.C. 1831).[5] Trade secret theft can occur through cyber means (see below).[6]

Cybertheft

Criminal activity, including IP theft, increasingly occurs in **cyberspace**—which can be thought of as a "virtual environment of information and interactions between people."[7] Internet-related crimes are often referred to as **cybercrime**, though no one definition appears to exist for it within the U.S. government.[8] One of type of cybercrime is **cybertheft**, which broadly may be defined as crimes in which a computer is used to steal money or other things of value and can include "embezzlement, fraud, theft of intellectual property, and theft of personal and financial data."[9] Other terms that may encompass Internet-related IPR theft include **cyber intrusions** and **cyberattacks**.

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

[5] See CRS Report R42681, *Stealing Trade Secrets and Economic Espionage: An Overview of 18 U.S.C. 1831 and 1832*, by (name redacted). For more information, see CRS Report R43714, *Protection of Trade Secrets: Overview of Current Law and Legislation*, by (name redacted)

[6] USTR, *2015 Special 301 Report,* April 2015, p. 20.

[7] National Security Agency, *Statement for the Record, Lieutenant General Keith Alexander, Commander, Joint Functional Component Command for Network Warfare*, Before the House Armed Services Committee, Terrorism, Unconventional Threats, and Capabilities Subcommittee, May 5, 2009.

[8] CRS Report R42547, *Cybercrime: Conceptual Issues for Congress and U.S. Law Enforcement*, by (name redacted) and (name redacted) .

[9] Office of Justice Programs, Bureau of Justice Statistics, "Cybercrime."

Innovation Indicators

According to the Organization for Economic Co-operation and Development (OECD), innovation is the "implementation of a new or significantly improved product (good or service), or process, a new marketing method, or a new organizational method." Possible innovation-related indicators include activities concerning commercializing inventions and new technologies.[10] Trends in the total number of patent applications under the Patent Cooperation Treaty (PCT), an international patent filing system administered by the World Intellectual Property Organization (WIPO), may be illustrative (see **Table 1** and **Figure 1**).[11] The United States remains the source of the world's largest number of PCT filing applications and, along with Germany and Japan and China, accounted for over 60% of all 2014 PCT applications. China notably had double-digit growth in 2014. The top fields of technology in PCT filings were computer technology, digital communication, electrical machinery/apparatus/energy, medical technology, and measurement.[12]

Table 1. Patent Filings Through the PCT: Selected Countries

Country	2013	2014 (estimate)	2014 Global Share	2013-2014 Growth
World	205,272	214,500	100.0%	4.5%
United States	57,441	61,492	28.7%	7.1%
Japan	43,771	42,459	19.8%	-3.0%
China	21,514	25,539	11.9%	18.7%
Germany	17,913	18,008	8.4%	0.5%
Republic of Korea	12,381	13,151	6.1%	6.2%
France	7,905	8,319	3.9%	5.2%
United Kingdom	4,847	5,282	2.5%	9.0%
Netherlands	4,188	4,218	2.0%	0.7%
Switzerland	4,372	4,115	1.9%	-5.9%
Sweden	3,946	3,925	1.8%	-0.5%
Canada	2,845	3,089	1.4%	8.6%
Russia	1,191	890	0.6%	5.6%
India	1,320	1,394	0.3%	-11.6%
Brazil	657	581	0.1%	21.9%
Mexico	233	284	10.6%	3.2%
Rest of World	20,748	21,754	100.0%	4.5%

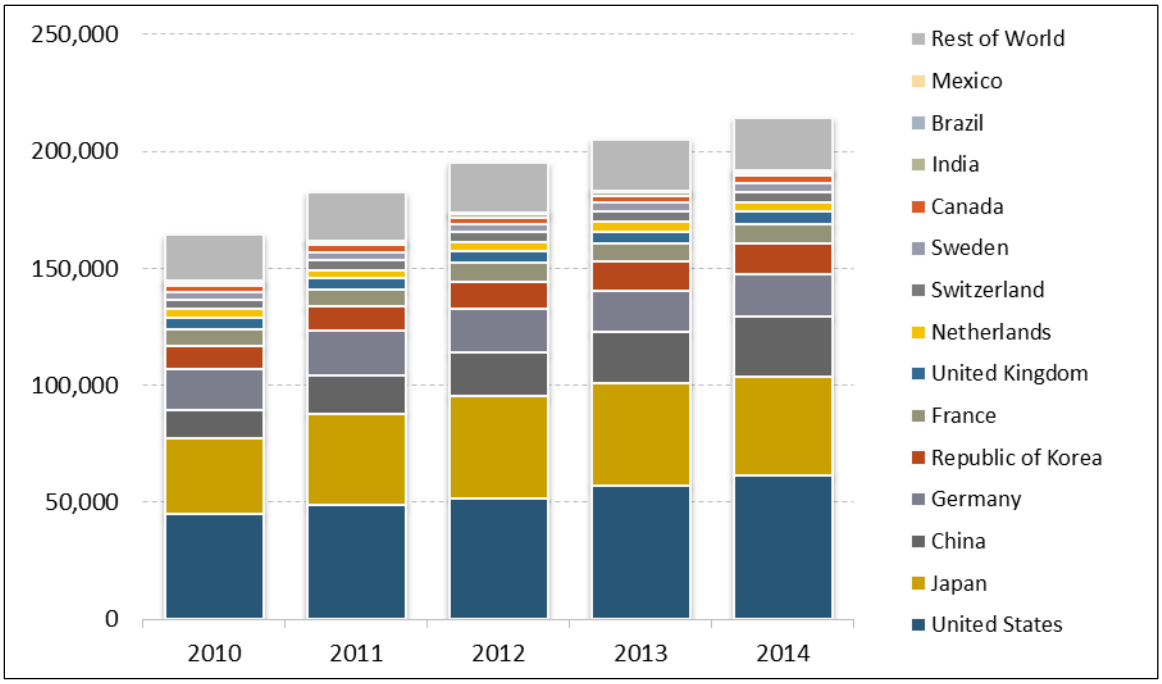
Source: World Intellectual Property Organization (WIPO), *Patent Cooperation Treaty Yearly Review: 2015*.

[10] National Science Board (NSB), *Science and Engineering Indicators 2015*, pp. 6-39 – 6-49.

[11] "Patenting is an intermediate step toward innovation, and patent data provide indirect and partial indicators of innovation. Not all inventions are patented, and the propensity to patent differs by industry and technology. Not all patents are of equal value, and not all foster innovation—patents may be obtained to block rivals, negotiate with competitors help in infringement lawsuits." W. Cohen, R. Nelson, and J. Walsh, "Protecting Their Intellectual Assets: Appropriability Conditions and Why U.S. Manufacturing Firms Patent (or Not)," National Bureau of Economic Research (NBER), Working Paper No. 7552, 2000; cited in NSB, *Science and Engineering Indicators 2015*, p. 6-40.

[12] WIPO, "Telecom Firms Lead WIPO International Patent Filings," press release, March 19, 2015.

Figure 1. Patent Filings through the PCT: Selected Countries, 2010-2014



Source: CRS, based on data from World Intellectual Property Organization (WIPO), *Patent Cooperation Treaty Yearly Review: 2015*.

Note: Data for 2014 are estimates.

Role of IP in U.S. Economy and Trade

Intellectual property generally is viewed as a longstanding strategic driver of U.S. productivity, economic growth, employment, higher wages, and exports. It also is considered a key source of U.S. comparative advantage, such as in innovation and high-technology products. Nearly every industry depends on it 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.[13]

Overall Role

IP-intensive industries are considered to play a major role in the U.S. economy and international trade. What follows are some findings from a 2012 study by the U.S. Department of Commerce.[14]

- **U.S. economic impact.** In 2010, a subset of the most intellectual property-intensive industries directly supported 27.1 million jobs in the United States, or

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

[14] Department of Commerce, *Intellectual Property and the U.S. Economy: Industries in Focus*, March 2012, http://www.uspto.gov/news/publications/IP_Report_March_2012.pdf.

about 19% of total U.S. employment. They also indirectly supported 12.9 million U.S. jobs via the supply chain in other industries. In 2010, the wages of employees working in IP-intensive industries tended to be about 42% higher on average than those working in non-IP-intensive industries. These industries accounted for about $5 trillion in value added to the U.S. economy, more than one-third of the U.S. gross domestic product (GDP).

- **U.S. trade in goods.** In 2010, IP-related merchandise exports amounted to $775 billion (two-thirds of total U.S. merchandise exports), while IP-related merchandise imports reached $1,336 billion (about 70% of total U.S. merchandise imports). Key sectors for IP-intensive merchandise trade include semiconductor and electric parts, basic chemicals, motor vehicles, pharmaceuticals and medicine, and computer and peripheral equipment.[15]
- **U.S. trade in services.** In 2007, exports of services by IP-intensive industries totaled about $90 billion (about 19% of total U.S. private services exports). Key sources of services exports included the software publishing, motion picture and video, financial services, science R&D, and management and technical consulting industries. The study did not provide information on imports of services by IP-intensive industries, though it should be noted that the United States runs an overall surplus in international trade in services.[16]

Royalty and Licensing Charges

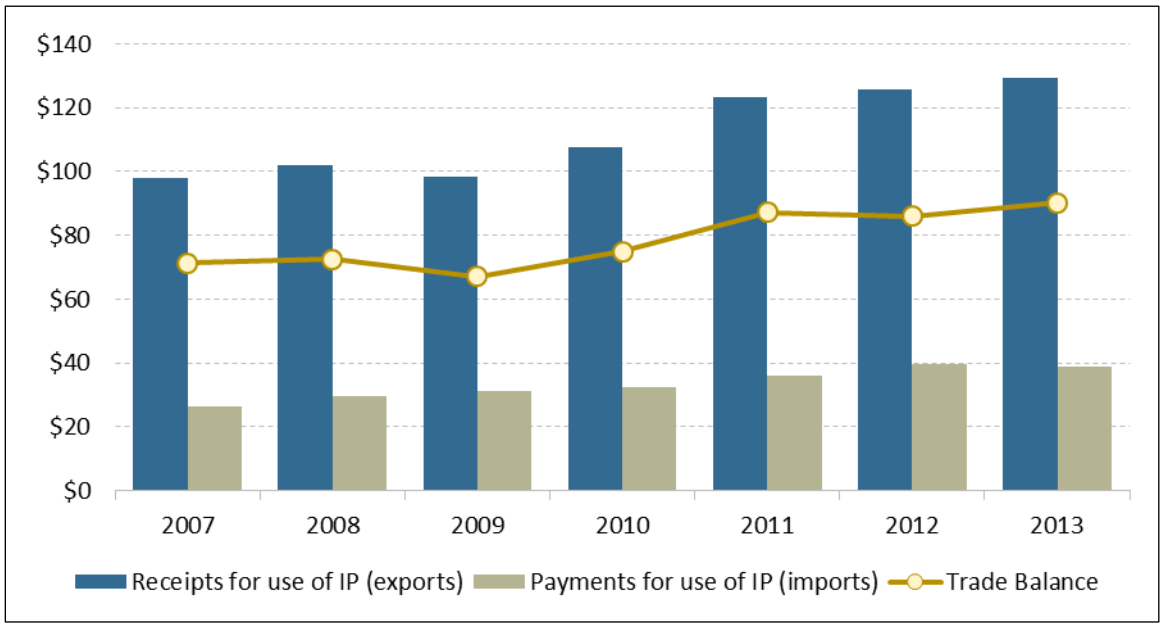
The role of IP-intensive industries in U.S. trade in services includes charges for U.S. IP, i.e., receipts (exports) and payments (imports) of royalties and licensing fees. Right holders may authorize the use of technologies, trademarks, and entertainment products that they own to entities in foreign countries, resulting in revenues through royalties and license fees. In 2013, U.S. receipts from cross-border trade in royalties and license fees (relating to patent, trademark, copyright, and other intangible rights) totaled $129 billion, while U.S. payments of royalties and license fees to foreign countries amounted to $39 billion, resulting in a trade surplus of $90 billion (see **Figure 2**).

[15] It is important to note that trade statistics may not capture the full importance of IP-intensive products to the U.S. economy, as many IP-intensive products are manufactured abroad as part of the global supply chain, and the full value added of these products is not accounted for in trade statistics. In addition, services statistics are limited.

[16] CRS Report R43291, *U.S. Trade in Services: Trends and Policy Issues*, by (name redacted)

Figure 2. U.S. Trade in Services: Royalties and License Fees from Intellectual Property Use, 2007-2013

(Billions of U.S. Dollars)



Source: BEA, U.S. International Services data.

Specific U.S. Industries

Industry-specific figures may further demonstrate the role of IP in the U.S. economy. For example:

- **Copyright industries.** According to a study commissioned by the International Intellectual Property Alliance (IIPA), in 2013, industries categorized as part of the "core" copyright industries (e.g., computer software, videogames, books, newspapers, periodicals and journals, motion pictures, recorded music, and radio and television broadcasting) contributed about $1.1 trillion to the U.S. economy ("value-added" to current GDP), representing about 6.7% of the U.S. economy. The study also estimated that the "core" copyright industries employed nearly 5.5 million workers in 2013, representing about 4% of the total U.S. workforce. In addition, the study estimated that foreign sales of certain U.S. copyright sectors totaled $156.3 billion in 2013.[17]
- **Pharmaceutical industry.** According to the Pharmaceutical Researchers and Manufacturers of America (PhRMA), American biopharmaceutical companies support more than 810,000 direct jobs and nearly 3.4 million jobs in total, when accounting for indirect jobs (vendors and suppliers) and induced jobs (additional

[17] Stephen E. Siwek, *Copyright Industries in the U.S. Economy: The 2014 Report*, Economists Incorporated, Prepared for the International Intellectual Property Alliance (IIPA).

private economic activity).[18] PhRMA says that the economic output associated with this work is nearly $800 billion every year.[19]

- **Manufacturing industry:** Based on data from a study by NDP Analytics, a private sector research firm, between 2000-2012, among U.S. manufacturing industries exceeded non-IP-intensive manufacturing industries on a number of economic measures per employee: R&D investment, wages, exports, value-added, and gross output.[20] For example, during 2000-2012, the study estimated that exports per employee for IP-intensive manufacturing industries averaged about $128 billion, compared to about $38 billion on average for non-IP-intensive manufacturing industries.[21]

"Fair Use" IPR Exceptions

Some advocates of civil liberties assert that empirical analysis on the role of IPR in the U.S. economy may not fully evaluate the economic and commercial benefits of lawful exceptions and limitations to exclusive rights—referred to broadly as "fair use." The "fair use" doctrine provides limitations and exceptions to the exclusive rights 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.[22] For example, by one estimate, in 2009, businesses that rely on "fair use" exceptions to U.S. copyright law generated total revenue of $4.5 trillion on average and $2.4 trillion on average of value-added (17% of total U.S. current dollar GDP).[23] Additionally, employment associated with "fair use" totaled around 17 million of U.S. employment in 2009, and U.S. exports associated with "fair use" totaled $266 billion in 2009.[24]

Quantifying 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 occurs with relatively low costs and risks and a high profit margin. According to PhRMA, it takes a pharmaceutical company over 10 years of R&D on average to create a new drug, with the average cost to develop a drug about $2.6

[18] PhRMA, *2015 Biopharmaceutical Research Industry Profile*, Washington, DC, April 2015.

[19] Ibid.

[20] Nam D. Pham, *IP-Intensive Manufacturing Industries: Driving U.S. Economic Growth*, NDP Analytics, March 2015, p. 8.

[21] Ibid.

[22] Thomas Rogers and Andrew Zamosszegi, *Fair Use in the U.S. Economy: Economic Contribution of Industries Relying on Fair Use: 2011*, Prepared for the Computer & Communications Industry Association (CCIA), 2011. See also CRS Report RL33631, *Copyright Licensing in Music Distribution, Reproduction, and Public Performance*, by (name redacted)

[23] Thomas Rogers and Andrew Zamosszegi, *Fair Use in the U.S. Economy: Economic Contribution of Industries Relying on Fair Use: 2011*, Prepared for CCIA, 2011, p. 6.

[24] Ibid., p. 7.

billion during the 2000s to early 2010s. In 2014, PhRMA member companies collectively spent an estimated $51 billion for research and development (domestic and abroad).[25] 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 considered to be relatively low.[26]

Limitations on Data Estimating IPR Infringement Costs

Quantification of the economic losses associated with IPR infringement has been a longstanding focus in the academic, policy, and industry literature. Many experts agree that it is difficult to quantify the magnitude of IPR theft with any precision. Reasons may include

- **Illicit nature of IPR infringement.** Because IPR infringement is illicit and secretive, tools that are used to measure legitimate business activity cannot necessarily be used to measure economic losses from IPR infringement. As such, it may be easier to quantify the positive contribution of copyright industries to the U.S. economy more precisely than to measure the losses to the U.S. economy from copyright piracy.
- **Quantifying specific components of economic impact.** The economic impact of IPR infringement depends on a range of factors, including the different types of infringing goods being sold, the rate at which consumers substitute buying infringing goods for legitimate goods, and IPR infringement's deterrence to R&D. It may be difficult to measure precisely these components of the economic impact of IPR infringement.[27]
- **Assumptions used to calculate economic impact.** 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. The basic economic model employed in some IPR loss estimates assumes that there is substitutability between pirated and legitimate goods. For example, under this model, sales of pirated goods may be equated to revenue losses of legitimate U.S. copyright businesses. Some analysts suggest that legitimate firms face a competition threat *only* if the individuals purchasing IPR-infringing products would be able and willing to purchase the legitimate product at the price offered when IPR infringement is not present.[28] For

[25] PhRMA, *2015 Biopharmaceutical Research Industry Profile*.

[26] For example, see Global Intellectual Property Center (GIPC), U.S. Chamber of Commerce, *Measuring Momentum: GIPC International IP Index*, First Edition, December 2012.

[27] National Intellectual Property Rights Coordination Center (IPR Center), *Intellectual Property Rights Violations: A Report on Threats to United States Interests at Home and Abroad*, November 2011.

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

consumers in poor developing countries, especially, this assumption may not be tenable.

- **IPR infringement in the digital environment.** While IPR infringement in the past primarily constituted counterfeiting and piracy of physical goods (such as optical media and books), there has been a growing amount of piracy taking place through digital mediums (such as illegal downloads of music and books over the Internet). It may be more complex to measure IPR infringement that takes place in the digital environment, and in turn, more difficult to measure the associated economic losses accurately. U.S. trade losses due to copyright infringement may be higher than reported because estimates often do not account for all forms of piracy, such as Internet piracy. One study estimates that nearly 24% of global Internet traffic infringes upon copyright.[29]
- **Sources of data.** Estimates on economic losses from IPR infringement come from a range of sources, including academic, policy, and industry sources. According to a U.S. Government Accountability Office (GAO) study, 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, companies may be reluctant to disclose their IPR losses because of possible reputational and commercial risks, and industry associations may not always release their proprietary data sources and methods, complicating efforts to verify such estimates.[30]

International Economic Effects

While assessments of the overall global economic costs of IPR infringement are limited, available evidence indicates that the adverse economic effects of global IPR infringement stand in the hundreds of billions of dollars, and are increasing.31 Customs data on seizures of counterfeit and pirated goods may offer some idea of the magnitudes involved in terms of impact on producers and exporters. A 2007 OECD study indirectly extrapolated available customs data on seizures to conclude that world trade in counterfeit and pirated goods may have amounted to $200 billion in 2005.[32] Updated OECD estimates 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.[33]

Building on the OECD's work is a study commissioned by the Business Action to Stop Counterfeiting and Piracy (BASCAP), a business initiative organized by the International Chamber of Commerce. According to the BASCAP study, for the G-20 economies, the total value

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

[30] U.S. Government Accountability Office (GAO), *Intellectual Property: Observations on Efforts to Quantify the Economic Effects of Counterfeit and Pirated Goods*, GAO-10-423, April 2010; and Commission on the Theft of American Intellectual Property, *The IP Commission Report*.

[31] IPR Center, *Intellectual Property Rights Violations: A Report on Threats to United States Interests at Home and Abroad*, November 2011.

[32] OECD, *The Economic Impact of Counterfeiting and Piracy*, June 2008.

[33] OECD, *Magnitude of Counterfeiting and Piracy of Tangible Products: An Update*, November 2009.

of counterfeit and pirated products was an estimated $455 billion to $650 billion in 2008, and is projected to reach $1.22 trillion to $1.77 trillion in 2015 (see **Table 2**).[34]

In terms of broader economy-wide effects, the BASCAP study estimated that G-20 economies lost over $125 billion every year from counterfeiting and piracy due to additional impacts on trade, foreign investment, employment, and other factors. In addition, the study estimated that G-20 economies lost about 2.5 million jobs from counterfeiting and piracy; i.e., up to 2.5 million legitimate jobs could have been created in the absence of counterfeiting and piracy.[35]

Table 2. Estimated International Economic Losses Due to Counterfeiting and Piracy, Selected Years

(Billions of U.S. Dollars)

Category	2008	2015
Internationally traded counterfeit and pirated products	285-360	770-960
Domestically produced and consumed counterfeit and pirated products	140-215	370-570
Digitally pirated products	30-75	80-240
Total	455-650	1,220-1,770

Source: Frontier Economics, *Estimating the Global Economic and Social Impacts of Counterfeiting and Piracy*, A Report Commissioned by Business Action to Stop Counterfeiting and Piracy (BASCAP), February 2011.

Notes: BASCAP economic loss estimates are restricted to the G-20 economies.

U.S. Economic Effects

While specific estimates vary, the available data suggest that U.S. economic losses from IPR infringement could be significant.

Customs Seizure Data

Data on pirated and counterfeit seizures of imports at U.S. borders by the Department of Homeland Security (DHS) shed light on the magnitude of the issue in the U.S. context. In FY2014, the number of IPR seizures at the U.S. border totaled 23,140 of commodities (shipped by express, mail, cargo, and other ways) valued at $1.2 billion (manufacturer's suggested retail price, MSRP).[36] China and Hong Kong ranked as the two largest source economies for seizures by value (see
Table 3). The commodities seized were diverse, with watches/jewelry and handbags/wallets being the top two types seized (see **Figure 3**). Goods in FY2014 included shipments of circumvention devices that violated the Digital Millennium Copyright Act. It is worth noting that customs data may be limited in that they do not reflect digital-based IPR infringement.

[34] Frontier Economics, *Estimating the Global Economic and Social Impacts of Counterfeiting and Piracy*, A Report Commissioned by Business Action to Stop Counterfeiting and Piracy (BASCAP), February 2011.

[35] Ibid.

[36] Manufacturer's suggested retail price (MSRP) is the price of goods had they been legal. U.S. Department of Homeland Security, *Intellectual Property Rights Seizure Statistics: Fiscal Year 2014*.

Table 3. IPR Seizures at U.S. Borders: Source Economies, FY2014

(Estimated MSRP, millions of U.S. dollars)

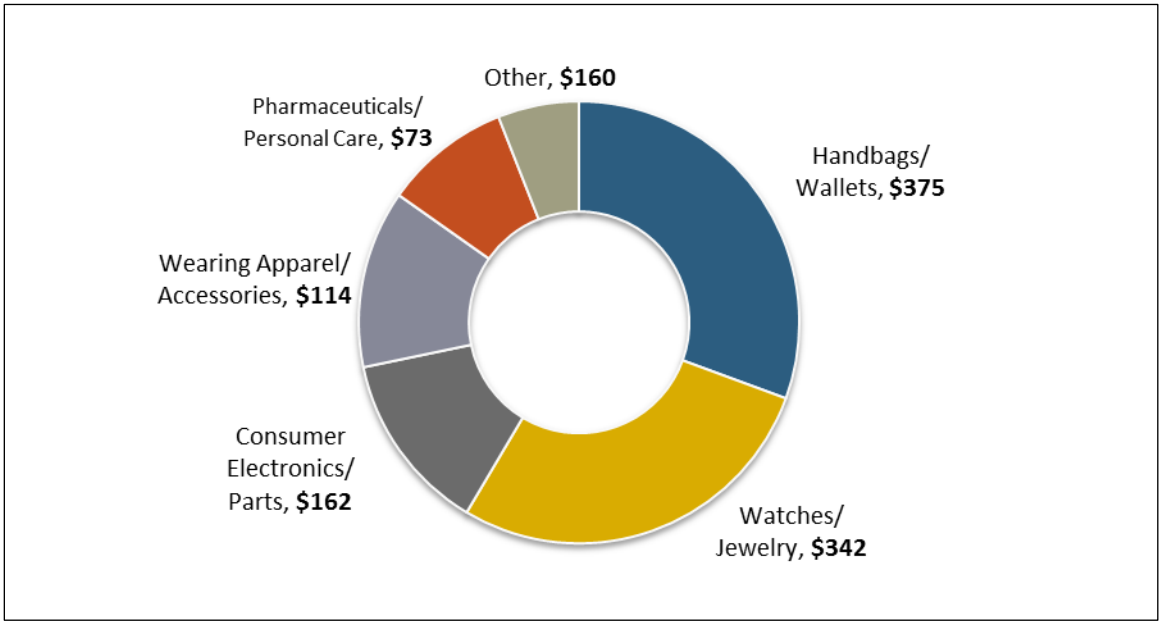
U.S. Trading Partner	Estimated MSRP	% of Total
Total	$1,226.3	100%
China	$772.6	63.0%
Hong Kong	$310.4	25.3%
Canada	$108.6	8.9%
India	$12.5	1.0%
United Arab Emirates	$5.5	0.5%
Taiwan	$3.8	0.3%
Singapore	$3.1	0.3%
Korea	$2.5	0.2%
Vietnam	$2.5	0.2%
Kenya	$2.4	0.2%
All Others	$2.3	0.2%

Source: CRS analysis of data from Department of Homeland Security, "Intellectual Property Rights Seizure Statistics Fiscal Year 2014."

Notes: Based on manufacturer's suggested retail price (MSRP) of goods had they been genuine.

Figure 3. IPR Seizures at U.S. Borders: Composition of Commodities, FY2014

(Estimated MSRP, millions of U.S. dollars)



Source: CRS analysis of data from Department of Homeland Security, "Intellectual Property Rights Seizure Statistics Fiscal Year 2014."

Notes: Based on manufacturer's suggested retail price (MSRP) of goods had they been genuine. "Other" includes footwear, computers/accessories, optical media, labels/tags, and toys.

Overall U.S. Estimates

U.S. industries that rely on IPR protection claim to lose billions of dollars in revenue annually due to piracy and counterfeiting. Beyond these direct losses, the United States may face additional "downstream" losses from counterfeiting and piracy. IPR infringement could result in the loss of jobs that would have been created if the infringement did not occur, which could translate into lost earnings by U.S. workers and, in turn, lost tax revenues for federal, state, and local governments.[37] Attempts have been made in specific economic sectors to quantify the IPR infringement levels and related losses to legitimate U.S. businesses.

A private Commission on the Theft of American Intellectual Property estimates the total level of U.S. economic losses to international theft of U.S. IP to be hundreds of billions dollars per year. The Commission says the level of losses is "at least in the range of total [U.S.] exports to Asia in 2012 (valued at $320 billion)."[38] Efforts also have been made to quantify U.S. economic losses from IPR infringement in terms of specific countries (see **text box**).

Estimate of Losses to U.S. Firms from IPR Infringement in China

The U.S. International Trade Commission (ITC) estimated losses to "firms in the U.S. IP-intensive economy that conducted business in China in 2009" to be about $48.2 billion in sales, royalties, or license fees due to IPR infringement in China. According to the ITC, this is a point estimate based on statistical analysis that falls within a broad range of $14.2 billion to $90.5 billion; the range reflects limitations of the underlying data as many firms were unable to calculate losses. In terms of specific sectors, the information/other services sector sustained the largest losses—at a point estimate of $26.7 billion with a range of $11.8 billion to $48.9 billion. In terms of specific types of IPR infringement, losses from copyright infringement were the largest—at a point estimate of $23.7 billion within a range of $10.2 billion to $37.3 billion. ITC also estimated that firms in the U.S. IP-intensive economy spent about $4.8 billion (within a range of $279.1 million to $9.4 billion) in 2009 to address possible Chinese IPR infringement.

Source: ITC, *China: Effects of Intellectual Property Infringement and Indigenous Innovation Policies on the U.S. Economy*, Investigation No. 332-519, USITC Publication 4226, May 2011.

Note: ITC results reflect responses to a ITC questionnaire to 5,051 U.S. firms in sectors considered to be IP-intensive. ITC used statistical sampling techniques to extrapolate results to the U.S. IP-intensive economy (16.3% of the U.S. economy). The statistical significance of the findings varied. See the report for more information.

In terms of losses from digital IP theft, a McAfee survey of over 1,000 senior IT executives from companies in Brazil, China, Japan, the Middle East, the United Kingdom, and the United States may provide some insight. According to the survey, the average company had about $12 million worth of sensitive information residing abroad, and companies lost on average $4.6 million worth of IP in 2008 from security breaches—possibly comparable or higher to such losses in subsequent years.[39]

[37] 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.

[38] U.S. Commission on the Theft of American Intellectual Property, *The IP Commission Report*, May 2013. This Commission describes itself as an "independent and bipartisan initiative of leading Americans from the private sector, public service in national security and foreign affairs, academe, and politics."

[39] McAfee, *Unsecured Economies: Protecting Vital Information*, 2009; cited in U.S. Chamber of Commerce, *The Case for Enhanced Protection of Trade Secrets in the Trans-Pacific Partnership Agreement*.

The Organizational 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 rules. Since the mid-1980s, 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).[40] The WTO was established as the result of the Uruguay Round of trade negotiations (1986-1994), which led to agreements to liberalize and establish or enhance rules on trade in goods, services, agriculture, 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 IPR 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 agreed, after being granted delayed compliance periods, and after achieving negotiating goals on other issues such as the end of quotas on textiles and clothing.

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

Much of the TRIPS Agreement sets out the extent of the agreement's coverage of the various types of intellectual property: patents, copyrights, trademarks, trade secrets, geographical indications, industrial designs, layout of circuitry design, 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 (see **text box**). The binding nature of the WTO dispute settlement mechanism, with the possibility of the withdrawal of trade concessions (usually the reimposition of tariffs) for non-compliance, sets this agreement apart from previous IPR treaties that did not have effective dispute settlement mechanisms.

[40] The GATT was originally established in 1947.

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.[41]

In January 2009, the WTO 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 the thresholds for prosecution of counterfeiting and piracy in China's criminal law permit commercial scale IPR infringement. China agreed to implement the WTO ruling.[42]

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.[43]

The United States has not filed any other WTO complaints concerning IPR since then. Nor has the United States brought any disputes under IPR provisions of U.S. FTAs.

The TRIPS Agreement also seeks a balance of rights and obligations between protecting private right holders and the obligation "to secure social and cultural development that benefits all."[44] Article 7 declares that

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

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

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 mechanisms 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

[41] 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 (name redacted) .

[42] 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.

[43] See CRS Report RL33536, *China-U.S. Trade Issues*, by (name redacted)

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

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 for IPR commitments was originally extended 10 years to January 1, 2006 (Article 66.1). In 2002, the WTO extended IPR obligations for least developed countries with respect to pharmaceuticals to January 1, 2016.[45] In addition, the WTO has extended the overall transitional period twice for LDCs—in 2005, an extension to July 1, 2013, and then in 2013, a further extension to July 1, 2021.[46] As such, LDCs are not required to apply TRIPS Agreement provisions—other than Articles 3, 4, and 5, until July 1, 2021, or until they cease to be LDC countries.[47] Article 66.1 acknowledges the:

> special needs and requirements of least-developed country Members, their economic, financial and administrative constraints, and their need for flexibility to create a viable technological base.

Doha Declaration on TRIPS Agreement and Public Health

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.[48] The Declaration sought to alleviate developing country dissatisfaction with aspects of the TRIPS regime (see **text box**). It delayed the implementation of patent system provisions for pharmaceutical products for least developed countries 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[49] 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.

[45] "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.

[46] WTO TRIPS Council, "Extension of the Transition Period Under Article 66.1 for Least Developed Country Members," June 12, 2013.

[47] TRIPS Article 3 provides for national treatment, and TRIPS Article 4 provides for most-favored-nation treatment. TRIPS Article 5 states that obligations under Article 3 and 4 do not apply to procedures provided under WIPO agreements related to the acquisition or maintenance of IPRs.

[48] 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.

[49] Compulsory licenses are issued by governments to authorize the use of or production of a patented item by a domestic party other than a patent holder.

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 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 relatively higher fees for technology licenses and production rights than would occur in the absence of IPR, 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.[50] For instance, India experienced an increase in foreign investment and technology transfer once it expanded its patent protection. However, in recent years, India has taken measures considered by the U.S. government and business leaders to be a "backsliding" on IPR commitments, raising concerns about the country's IPR and innovation environment. China offers a counterexample of a country that, despite some improvements, continues to have 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.[51] 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.[52]

Concern remains 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, lack of health care, and poor social infrastructure.

Paragraph 6 of the Doha Declaration directed the WTO members to formulate a solution to a corollary concern, the use of compulsory licensing by countries with insufficient or inadequate manufacturing capability. Compulsory licenses are issued by governments to authorize the use or production of a patented item by a domestic party other than a patent holder. They are authorized by Article 31 of TRIPS, which places certain limitations on their use, scope, and 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.

[50] 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.

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

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

On the eve of the Cancun Ministerial in August 2003, WTO members agreed on a Decision[53] 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 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 161 WTO member states. The deadline for ratification has been extended a number of times, most recently, until December 31, 2015.[54] Until then, the 2003 waiver continues in force. The United States was the first member to accept the amendment. To date, a total of 57 WTO members[55] have ratified the amendment.[56]

The system established by the WTO allows least developed countries 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 manufactured and exported subject to various notification requirements, as well as quantity and safeguard restrictions. While several exporting countries have established laws and procedures for implementing this system, only Rwanda has availed itself of the system to import HIV/AIDS medicines from a generic manufacturer in Canada.[57]

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 specialized agency affiliated with the United Nations with its own executive, legislative, and budgetary powers. Established in 1970, following the 1967 WIPO Convention's entry into force, 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 Industrial 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. 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, oftentimes collectively referred to as the "WIPO Internet Treaties."[58] Recent WIPO efforts have focused on patent law. In June 2000, WIPO signatories adopted the Patent Law Treaty (PLT), which called for harmonization of patent procedures. This agreement went

[53] "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.

[54] WTO, "Intellectual property meeting mulls Irish tobacco plan, drug tariffs, sport, non-violation, press release, October 10 and 11, 2013.

[55] The European Union (EU) signed an Instrument of Acceptance for EU members.

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

[57] WTO, "TRIPS and public health: dedicated webpage for notifications," https://www.wto.org/english/tratop_e/trips_e/public_health_e.htm.

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

into force on April 28, 2005. Discussions began in May 2001 for a Substantive Patent Law Treaty (SPLT), which would target harmonization issues specifically related to patent grants, but were put on hold in 2006. Different views reportedly emerged among developed and developing countries on what should be the objectives of substantive harmonization of patent laws, including whether it was an appropriate goal.[59] Government leaders participating in the Group of 8 (G-8) meeting in July 2008 called for "accelerated discussions" of the SPLT.[60] While discussions remain stalled, the main focus of the WIPO's work in this area has been on "building a technical and legal resource base from which to hold informed discussions in order to develop a work program" on various patent issues.[61] Presently, patent law harmonization efforts also are occurring in groupings outside of WIPO, including the Trilateral Cooperation, composed of the European Patent Office, Japan Patent Office, and U.S. Patent and Trademark Office (USPTO); and the IP5, composed of the members of the Trilateral Cooperation and also the Korean Intellectual Property Office and China's State Intellectual Property Office.[62]

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.

U.S. Trade Promotion Authority and Negotiating Objectives

On June 29, 2015, President Obama signed the Bipartisan Congressional Trade Priorities and Accountability Act of 2015, also known as Trade Promotion Authority (TPA). Previously "fast-track," TPA is the time-limited authority that Congress uses to set trade negotiating objectives, to establish notification and consultation requirements, and to have implementing bills for certain reciprocal trade agreements considered under expedited procedures, provided certain statutory requirements are met.[63] In recent grants of TPA, IPR issues have become important negotiating objectives.

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 General Agreement on Tariffs and Trade (GATT, the predecessor to the WTO) and other existing intellectual property conventions. This negotiating mandate led to the establishment of the TRIPS Agreement during the Uruguay Round of multilateral trade liberalization negotiations and the IPR provisions in the North American Free Trade Agreement (NAFTA). In the period since the 1988 Act, the IPR provisions of NAFTA and the TRIPS Agreement became the template for other bilateral or regional FTAs. The focus of IPR negotiating objectives shifted from creating to strengthening the IPR trade regime with the Trade Promotion Authority Act of

[59] David J. Kappos, "Patent Law Harmonization: The Time is Now," *Landslide*, vol. 3, no. 6 (July/August 2011).

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

[61] WIPO, "Standing Committee on the Law of Patents (SCP)," http://www.wipo.int/policy/en/scp/.

[62] U.S. Patent and Trademark Office, "Harmonization," http://www.uspto.gov/learning-and-resources/ip-policy/harmonization.

[63] See CRS Report RL33743, *Trade Promotion Authority (TPA) and the Role of Congress in Trade Policy*, by (name r edacted) .

2002 (P.L. 107-210), under which several FTA negotiations were concluded under the George W. Bush Administration.

2002 Trade Promotion Authority

The IPR negotiating objectives in the 2002 TPA were highly significant to the future contours of U.S. FTA negotiations. The objective to negotiate trade agreements in terms of IPR that "reflect a standard of protection similar to that found in U.S. law" led to the negotiation of provisions that go beyond the level of protection provided in the WTO TRIPS Agreement. Often referred to as "TRIPS-plus" provisions, they include expanding coverage to new sectors; establishing more extensive standards of protection; and reducing the flexibility options available in TRIPS, such as with respect to compulsory licensing. Some of the new measures also address technological innovations that have come about since the TRIPS Agreement.

The objective to apply existing IPR protections to digital media reflected the changing nature of global commerce. The language sought to extend provisions for IPR protection to new and emerging technologies and methods of transmission and dissemination. The language also called for standards of enforcement to keep pace with technological change and allow right holders legal and technological protections for their works over the Internet and other new media.

May 10, 2007, Bipartisan Trade Agreement

The May 10, 2007 Bipartisan Trade Agreement ("May 10th Agreement")—related to the then-pending FTAs with Colombia, Panama, Peru, and South Korea—established certain flexibilities for patent protections to promote further access to medicines in developing countries while maintaining a strong overall level of IPR protection.[64] After the transfer of control of the House following the 2006 elections, Members of the new Democratic majority sought certain changes in the aforementioned pending U.S. FTAs. With respect to IPR, the congressional leadership sought to ensure that pending FTAs allowed developing country trading partners enough flexibility both to meet their IPR obligations and to promote access to life-saving medicines. A Bipartisan Trade Agreement between the Bush Administration and the House leadership, building on the 2002 TPA negotiating objectives, was reached on May 10, 2007.[65] Following the May 10th Agreement, IPR language previously negotiated in the FTAs with Peru, Panama, and Colombia was modified to reflect its principles. The U.S.-South Korea FTA (KORUS) was not modified because South Korea is considered a developed country.

2015 Trade Promotion Authority

Congress passed the Bipartisan Comprehensive Trade Promotion and Accountability Act (P.L. 114-26) (TPA-2015) in June 2015, and President Obama signed the legislation on June 29. The IPR negotiating objectives include and expand upon the 2002 objectives. The 2015 objectives recognize the importance of digital trade to the economy and seek provisions to prohibit cybertheft and trade secret theft in the economy. The IPR objectives are considered principal negotiating objectives, meaning that a procedural disapproval resolution could be introduced to

[64] The May 10, 2007, Bipartisan Agreement on Trade Policy is available at https://ustr.gov/archive/assets/Document_Library/Fact_Sheets/2007/asset_upload_file127_11319.pdf.

[65] CRS Report RL33743, *Trade Promotion Authority (TPA) and the Role of Congress in Trade Policy*, by (name r edacted) ; and CRS Report R43491, *Trade Promotion Authority (TPA): Frequently Asked Questions*, by (name r edacted) and (name redacted) .

strip FTA implementing legislation of expedited legislation procedures if the legislation fails "to make progress on the policies, priorities, and objectives of the Act."[66] The objectives include

- Furthering adequate and effective protection of IPR through accelerated full implementation of the TRIPS Agreement and by ensuring FTAs negotiated by the United States "reflect a standard of protection similar to that found in U.S. law";
- Protecting IPR related to new technologies and new methods of transmission and distribution in a manner that "facilitates legitimate trade";
- Eliminating discriminatory treatment in the use and enforcement of IPR;
- Ensuring adequate rights holder protection through digital rights management practices;
- Providing strong enforcement of IPR;
- Negotiating the prevention and elimination of government involvement in violations of IPR such as cybertheft or piracy (a related protection of trade secrets and proprietary information collected by governments in the furtherance of regulations was contained in the negotiating objective on regulatory coherence); and
- Reaffirming the Doha Declaration on the TRIPS Agreement and Public Health, with additional language to "ensure that trade agreements foster innovation and access to medicine"—an objective that did not specifically refer to the patent protection provisions found in the May 10, 2007, Bipartisan Trade Agreement (discussed above), and where the added language seemingly could have been used to justify including or excluding those provisions in future FTAs.

Free Trade Agreement Negotiations

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 FTAs. To date, the United States has entered into 14 FTAs with 20 countries.

Trans-Pacific Partnership FTA

The Obama Administration is conducting negotiations with participants in the Trans-Pacific Partnership (TPP) Agreement—Australia, Brunei, Canada, Chile, Japan, Malaysia, Mexico, New Zealand, Peru, Singapore and Vietnam.[67] The objective is to build a comprehensive, high-standard reciprocal agreement to reduce and eliminate trade barriers and establish rules and disciplines to govern trade and investment in the region, and to expand and strengthen U.S. economic ties with other participating countries in the region. Through the TPP, the United States seeks to build on already established FTAs with Australia, Canada, Chile, Mexico, Peru, and Singapore.

The United States is negotiating extensive IPR provisions in the TPP consistent with the TPA mandate to "reflect a standard of protection similar to that found in U.S. law." On the debated

[66] Ibid.

[67] See CRS Report R42694, *The Trans-Pacific Partnership (TPP) Negotiations and Issues for Congress*, coordinated by (name redacted) .

issue of additional patent protection for pharmaceuticals (e.g., patent term extension, patent linkage, data protection), the United States reportedly has offered a plan perhaps at some variance to the May 10th provision: to require one standard, but to allow for phased implementation for developing countries, although final agreement on these provisions has yet to be reached.[68]

IPR reportedly has been one of the more controversial chapters in the TPP negotiating text. Significant disagreement reportedly continues to exist between and among the parties negotiating the TPP over a range of issues. However, data exclusivity for biologic medicines has become a particular source of contention. The United States is seeking a 12-year data exclusivity period for biologic drugs—large molecule medical preparations derived from living organisms, such as vaccines. This means that a producer of a follow-on—or bio-similar—biologic drug could not obtain the data used for marketing approval for 12 years after the brand-named biologic was originally marketed. Because few bio-similars are identical to the original biologic, drug manufacturers have sought extended periods of data exclusivity to recoup their investment in creating these drugs. However, some claim that these exclusivity periods serve to delay the introduction of generic drugs, making them unaffordable in developing countries and in countries trying to control health care costs. U.S. law calls for a 12-year period of data exclusivity, but other TPP countries either make no provision for exclusivity or provide shorter periods of protection (8 years in Japan and 5 in Australia).

Transatlantic Trade and Investment Partnership FTA

The Obama Administration also is conducting negotiations with the European Union (EU) on a comprehensive and high-standard FTA, referred to as the proposed Transatlantic Trade and Investment Partnership (T-TIP).[69] The United States and EU both maintain strong IPR standards and generally prioritize IPR protection and enforcement as a key trade negotiating objective. However, a final report by the U.S.-EU High Level Working Group on Jobs and Growth, which recommended the launch of the transatlantic FTA negotiations, suggested that it may be difficult to reconcile differences on the IPR obligations that each side typically includes in its FTAs.[70] For example, protection and enforcement of geographical indications could be controversial in the negotiations. The EU seeks strong GI protection because of their commercial value to EU producers (e.g., Parmesan cheese, Parma ham, Feta cheese, and Champagne). The United States tends to protect GIs through trademark law, and expresses concern that the EU approach to GIs is "over-broad" and negatively affects protection of trademark and market access for U.S. products that use generic names.[71]

Stakeholders on both sides could raise issues about how to balance IPR protection and enforcement with other public policy goals, such as access to medicines in poor or developing countries and the free flow of information. At the same time, T-TIP could lead to rules on trade

[68] "New TPP Leak Confirms Shift Toward Time-Based Transition on Drug IP," *Inside U.S. Trade*, August 7, 2015.

[69] See CRS Report R43387, *Transatlantic Trade and Investment Partnership (T-TIP) Negotiations*, by (name redacted) , (name redacted), and (name redacted) .

[70] U.S.-EU High Level Working Group on Jobs and Growth, *Final Report of the U.S.-EU High Level Working Group on Jobs and Growth*, February 11, 2013, http://www.ustr.gov/about-us/press-office/reports-and-publications/2013/final-report-us-eu-hlwg.

[71] USTR, *2012 National Trade Estimate Report on Foreign Trade Barriers*, March 2015, p. 136, https://ustr.gov/sites/default/files/2015%20NTE%20Combined.pdf.

secrets, an area of U.S. and EU concern in light of increased instances of trade secret theft internationally, including through cybercrime.[72]

Anti-Counterfeiting Trade Agreement

The Anti-Counterfeiting Trade Agreement (ACTA), which was negotiated outside of the WTO by the United States and nearly 40 other primarily developed countries, is intended to build on the TRIPS Agreement, such as by addressing new IPR issues in the digital environment. Concluded in 2010, the ACTA has not entered into force. The agreement's prospects are in question, following the European Parliament's rejection of it in 2012, amid widespread protests by advocates of Internet free speech. The ACTA needs instruments of ratification, acceptance, or approval from six signatories in order to enter into force. To date, Japan is the only party that has submitted a formal instrument of approval. IPR issues considered in the ACTA negotiations have reemerged in in the TPP and T-TIP negotiations, making the ACTA of continued congressional interest.

Core IPR Standards in U.S. FTAs

What follows is a discussion of some of the central patent and copyright commitments in U.S. FTAs and how they relate to the WTO TRIPS Agreement (see **Appendix A**).[73]

Patents

Patent protection is arguably one of the most contentious areas of U.S. FTA negotiations on IPR issues. In the context of pharmaceuticals, one view, espoused by the United States and other developed countries, is that patents provide incentives for innovation by enabling right holders to generate profits to recoup R&D and regulatory costs and invest in future innovations. Another view put forth by developing countries is that patents may raise the costs of drugs and delay the entry of generic competitors into the market, leading to concerns about impacts on affordable access to medicines.

Many 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 U.S. 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. With respect to these issues in the TPP, the overall stated position of the U.S. Trade Representative (USTR) is to seek:

> [p]harmaceutical IP provisions that promote innovation and the development of new, lifesaving medicines, create opportunities for robust generic drug competition, and ensure affordable access to medicines, taking into account levels of development among the TPP countries and their existing laws and international commitments[.][74]

[72] Executive Office of the President, *Administration's Strategy on Mitigating the Theft of U.S. Trade Secrets*, February 2013, http://www.whitehouse.gov//sites/default/files/omb/IPEC/admin_strategy_on_mitigating_the_theft_of_u.s._trade_secrets.pdf.

[73] For more 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 (name redacted).

[74] USTR, "The Trans-Pacific Partnership: Summary of U.S. Objectives."

Some key patent issues are discussed below.[75]

Patent Term Extensions

Patent term extensions beyond the 20-year protection for a patent may be provided in cases of "unreasonable delays" in issuing patents due to regulatory review or administrative process. Such extensions increase the length of time right holders have no generic competition, enhancing their ability to recoup R&D costs through the revenue that they generate from patented drugs and may make up time used in obtaining marketing approval. At the same time, this increased revenue also represents increased costs to consumers, such as by delaying the market entry of presumably lower-cost generic drugs.

TRIPS requires patent protection terms of 20 years from the filing date. It does not require patent term extensions in cases of "unreasonable" delays, but does obligate members to ensure procedures, subject to conditions, for granting or registering patent rights within a reasonable period of time.[76] Many FTAs include provisions for mandatory patent term length extensions beyond the TRIPS obligation of patent protection terms of twenty years from the filing date. These FTAs provide for extensions in cases of "unreasonable" delays in the issuance of patents due to regulatory review or administrative process, which lessen the effective 20-year term of patent protection. The U.S.-South Korea FTA(KORUS), for instance, defines "unreasonable delays" to " ... at least include a delay in the issuance of the patent of more than four years from the date of filing of the application in the territory of the Party, or three years after a request for examination of the application, whichever is later."[77] Reflecting the May 10th Agreement, U.S. FTAs with Colombia, Panama, and Peru state that patent term restorations in cases of "unreasonable delays" for pharmaceutical products are optional. At the same time, these FTAs require the countries to make "best efforts to process patent applications and marketing approval applications expeditiously with a view to avoiding unreasonable delays."[78]

Patent Linkages

Under patent linkage, if a patent currently is valid in a country, the regulatory body of that country (the counterpart of the U.S. Food and Drug Administration, FDA) may not grant marketing approval for a generic version of that drug without the permission of the patent holder. Patent linkage arguably strengthens patent protection, but lengthens the time it takes for generic drugs to enter a market once the patent expires.

TRIPS does not contain patent linkage obligations. Generic drug manufacturers are able to apply for marketing approval without the patent owner's permission and prior to the expiration of the patent. In contrast, patent linkage is a common requirement in many U.S. FTAs, including KORUS.[79] With patent linkage, national regulatory authorities cannot provide marketing approval for a generic version of a patented drug without permission from the right holder, as well as notification to the right holder if marketing is permitted. In contrast, the U.S. FTAs signed with

[75] For a discussion of pharmaceutical patent provisions in U.S. law, see for instance, CRS Report R41114, *The Hatch-Waxman Act: Over a Quarter Century Later*, by (name redacted) and (name redacted) ; and CRS Report R41483, *Follow-On Biologics: The Law and Intellectual Property Issues*, by (name redacted).

[76] TRIPS Agreement, Article 62.2.

[77] KORUS FTA, Article 18.8.6.

[78] Colombia FTA, Article 16.9.6; Panama FTA, Article 15.9.6; and Peru FTA, Article 16.9.6, with quoted language from Peru FTA.

[79] KORUS FTA, Article 18.9.5.

Peru, Panama, and Colombia do not tie marketing approval for a generic drug with the patent status of its brand name drug.

Data Protection

Data exclusivity provides a period of protection for test data[80] that prevents a generic company from relying on an innovator company's test data in order to gain marketing approval for a generic version of the brand name drug. During the data exclusivity period, the generic company would have to submit its own safety and efficacy data with new drug trials to get regulatory approval. Since clinical trials and other testing data submitted for marketing approval can be costly and take years to develop, test data protection provides an incentive for innovations. At the same time, such provisions may raise the cost of manufacturing generic versions of patented drugs, as well as delay access to generic forms of drugs.

In cases in which the patent holders must submit undisclosed data regarding the safety or efficacy of new pharmaceutical or agricultural products (such as data from clinical trials) in order to market them, TRIPS requires members to take measures to protect such data from disclosure and unfair commercial use, but does not prescribe any time period for this protection. Many U.S. FTAs take the test data protection standards beyond TRIPS. For new chemical products, these FTAs, including KORUS, generally provide a minimum *five-year* period of data exclusivity, which typically begins from the date of marketing approval in the country. In addition, for previously approved chemical products, KORUS requires a minimum *three-year* period of data exclusivity, which typically begins from the date of marketing approval in the country.[81]

The Colombia, Panama, and Peru FTAs maintain *five years* of data exclusivity for test data related to new chemical products. However, they also include other provisions that may reduce the data exclusivity term by a minimum of six months in practice. If the FTA country relies on marketing approval granted by the FDA and grants approval within six months of an application for marketing approval by a person that produced the data, then the five-year period begins in the FTA country when the drug was first approved in the United States (oftentimes called the "concurrent period"). As such, the data exclusivity period in the FTA country could run as long as the U.S. data exclusivity period, but no longer. The *three-year data* exclusivity period for previously approved chemical entities is optional.[82] Data exclusivity for biologics is an evolving area of debate in trade policy (see **text box**).

[80] Test data is information generated on the safety or effectiveness of new pharmaceutical products, for example, through clinical trials, by pharmaceutical companies that are submitted to regulatory authorities, such as the FDA.

[81] KORUS FTA, Article 18.9.1 and Article.18.9.2.

[82] Colombia FTA, Article 16.10.2; Panama FTA, Article 15.10.2; and Peru FTA, Article 16.10.2.

Data Protection for Biologics

Biological products ("biologics") are "large molecule" medical preparations derived from living organisms. Examples include vaccines, blood and blood components, and therapeutic proteins. Biologics are a relatively new area of pharmaceutical R&D;[83] by contrast, "small molecules" traditionally have been the active substances in most pharmaceutical drugs.

Data exclusivity has a special significance for biologics. Since biologics are based on unique cell lines or biological processes, they cannot be replicated as generics as easily and inexpensively by relying on the originator product's efficacy and safety test data, as is the case for traditional small molecules-based medicine. Rather, regulatory agencies require more costly clinical trials to approve "bio-similars."[84]

Data exclusivity protection of biologics has been an increasing area of focus in trade negotiations. In TPP, the USTR reportedly is seeking a 12-year period of data exclusivity for biologics. The USTR, in a blog post, stated, "[t]raditionally, the U.S. approach to trade negotiations has been to base proposals on existing U.S. law, where the current standard is 12 years."[85] The 2010 Patient Protection and Affordable Care Act provides a 12-year period of regulatory exclusivity for bio-similars.[86] However, the President's budget continues to call for a 7-year exclusivity period for bio-similar medicines.[87] Any FTA commitments that would require changes to U.S. law must be approved by Congress. Other TPP countries have shorter exclusivity or no separate provisions for biologics.

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. TRIPS 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. KORUS does not place any specific limitations on compulsory licensing. The compulsory license provisions have not been included in FTAs with developing countries.

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

[83] CRS Report R42890, *The Role of Patents and Regulatory Exclusivities in Pharmaceutical Innovation*, by (name re dacted) .

[84] World Health Organization (WHO), WTO, and WIPO, *Promoting Access to Medical Technologies and Innovation: Intersections Between Public Health, Intellectual Property, and Trade*, 2012, p. 52.

[85] USTR, "Stakeholder Input Sharpens, Focuses Work on Pharmaceutical IPR in the TPP," blog post, November 2013.

[86] Sec. 7002(a)(7) of P.L. 111-148 (42 U.S.C. §262(k)(7)).

[87] For example, see Office of Management and Budget, *The Budget for Fiscal Year 2016*, "Investing in America's Future," p. 63.

exhausted at the first sale for any destination, and such goods can be exported freely. 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.[88] Pharmaceutical companies have voiced concerns that this practice threatens their ability to engage in price differentiation between different markets.

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. 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.

Copyright

In the area of copyright protection, the United States has pursued certain TRIPS-plus measures in FTAs, such as extending copyright terms; including anti-circumvention provisions; and protecting rights-management information in its FTAs. The TRIPS Agreement does not mention any obligations regarding rights-management information, which is "electronic information that identifies a protected work, its author, and terms and conditions of use,"[89] 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 technological measures protecting access to copyrighted works. These provisions build on the U.S. Digital Millennium Copyright Act (DMCA) of 1998.[90] 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.

[88] 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.

[89] CRS Report RL33205, *Intellectual Property and the Free Trade Agreements: Innovation Policy Issues*, by (name re dacted) .

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

Trade Secrets and Protection Against Cybertheft

A company's ability to protect its commercially valuable proprietary information may affect its competitiveness or even its survival. Such proprietary information can include blueprints, production processes, marketing strategies, or sales information. Based on a 2010 survey of Australian, European, and U.S. companies about their data security practices, trade secrets constitute an average of two-thirds of the value of firms' information portfolios.[91]

In its *2015 Special 301 Report* (discussed below), USTR described the international protection of U.S. trade secrets as a growing challenge threatening the economic security of the United States. The report highlights concern about inadequate protection and enforcement of trade secret law in certain countries, including as a way to further "indigenous innovation" policies. Companies are reportedly increasingly victimized by outright theft of their trade secrets, and have decried the often lax remedies available to combat such theft. Trade secret theft has taken on new and increased complexities in the digital environment, and the United States is increasingly concerned about trade secret theft through cybercrime. Penalties for trade secret theft vary widely among countries; some countries have no penalties at all while others have civil remedies or criminalize trade secret theft that results from computer hacking. In the United States, remedies for trade secret theft primarily are found in state law.[92]

While the U.S. aim in the intellectual property chapters of the TPP seeks to establish criminal penalties for the theft of trade secrets, it may pursue aspects of this agenda through other trade negotiations or means of economic statecraft. Such an agenda may involve prohibiting countries from: (1) conditioning market access on technology transfer; (2) seeking concessional terms for acquiring or licensing IPR by state-owned enterprises (SOEs); (3) requiring the use of locally owned or developed IPR; (4) promoting the development of local standards to unfairly advantage local firms; and (5) requiring the unnecessary disclosure of confidential business information, or failing to protect such information. The Obama Administration's strategy on mitigating the theft of U.S. trade secrets, released in February 2013, underscores U.S. interest in seeking, in U.S. trade negotiations, new criminal remedy provisions for trade secret theft—similar to remedies provided in U.S. law.[93]

New and Evolving Issues

U.S. trade policy also increasingly is focused on addressing new and evolving issues in international IPR protection and enforcement. The IPR landscape is changing, both due to the growing role of emerging markets in the global marketplace and the increased level of international trade taking place in the digital environment. Some of these issues are discussed below.

[91] Forrester Consulting, *The Value of Corporate Secrets*, Though Leadership Paper Commissioned by Microsoft and RSA, The Security Division of EMC, March 2010, https://www.nsi.org/pdf/reports/The%20Value%20of%20Corporate%20Secrets.pdf; cited in U.S. Chamber of Commerce, *The Case for Enhanced Protection of Trade Secrets in the Trans-Pacific Partnership Agreement*, p. 3.

[92] For more information on U.S. trade secret law, see CRS Report R41391, *The Role of Trade Secrets in Innovation Policy*, by (name redacted).

[93] Executive Office of the President, *Administration Strategy on Mitigating the Theft of U.S. Trade Secrets*, February 2013, p. 4.

Indigenous Innovation

Originally associated with China, "indigenous innovation" is a term that can reflect multiple policy goals, including promoting innovation from domestic companies rather than relying on foreign technology, building domestic R&D capabilities, and increasing the share of overall value added by domestic companies to the domestic economy. Such innovation policies can surface in areas such as government procurement, technical standards, and technology transfer.[94] For example, indigenous innovation policies may require the transfer of technology as a condition for allowing access to a market or for a company to continue to do business in the market.[95] While the goal of increasing domestic manufacturing and innovation is understandable, the U.S. government, industry groups, and other stakeholders express concern that indigenous innovation policies are discriminatory and may unfairly disadvantage U.S. right holders in those countries. China's indigenous innovation policies, for example, have been a source of trade tension with the United States. Although the Chinese government has pledged to separate indigenous innovation from government procurement, U.S. business leaders remain concerned that China's policies may lead to discrimination against foreign firms or run afoul of WTO commitments.[96] While China's indigenous innovation policies remain a focal point of U.S. trade policy, according to the USTR's *2015 Special 301 Report*, such policies appear to be gaining ground in other countries as well, such as India.

Localization Barriers to Trade

Functioning as a type of non-tariff barrier to market access, "forced" localization measures generally refer to those designed to protect, favor, or stimulate domestic industries, service providers, or intellectual property at the expense of foreign counterparts. Localization barriers can take a number of forms, such as requirements for: service providers to process data in the foreign country as a condition of market access; businesses to transfer technology and intellectual property as a condition of approval of foreign investments; or firms to use local content as a condition for manufacturing or for government procurement. For example, with respect to India, U.S. businesses often cite in-country testing requirements and localization requirements for data and servers as limiting market access and constraining innovation in the ITC sector.[97] While some localization barriers may serve data privacy or security objectives, concerns have arisen that some of these measures can be economically distorting. According to USTR, these measures can distort trade, inhibit FDI, and lead other countries to follow suit.[98] Certain localization barriers have been addressed in previous multilateral trade negotiations. For instance, the WTO Agreement on Trade-Related Investment Measures (TRIMs) prohibits "local content" requirements imposed in a discriminatory manner with respect to foreign investment.[99] Other localization barriers, particularly with respect to the digital environment, are considered to be newer trade issues, and are a focus of the TPP and T-TIP negotiations.

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[94] The term "indigenous innovation" can be tied to China's Medium- to Long-term Plan for the Development of Science and Technology, released in January 26, which calls for China to become an "innovation-oriented society" and a global leader in science and technology.

[95] U.S. International Trade Commission, *China: Effects of Intellectual Property Infringement and Indigenous Innovation Policies on the U.S. Economy*, Investigation No. 332-519, USITC Publication 4226, May 2011.

[96] For more information, see CRS Report RL33536, *China-U.S. Trade Issues*, by (name redacted) .

[97] USTR, *2015 Special 301 Report*, p. 23.

[98] USTR, *2015 National Trade Estimate Report on Foreign Trade Barriers*, March 2015, pp. 2-3.

[99] As defined by USTR, "local content" requirements are requirements to purchase domestically manufactured goods or domestically supplied services.

Patent Revocation, Denial and Changes in Thresholds of Patentability

U.S. policymakers, business leaders, and other are increasingly concerned about policy and legal developments in various countries that, from their perspective, are leading to a deterioration of patent protections. India and Canada are among countries of concern.

Recent Pharmaceutical Decisions in India. Since 2012, India has denied or revoked patents for several cancer and hepatitis C drugs developed by several Western pharmaceutical companies. India's Supreme Court has decided to prohibit patents for certain chemical forms absent a showing of "enhanced efficacy," although the products are protected by patents in many other countries. Innovator companies often seek patents of modified versions of originally patented products, a practice sometimes critically referred to as "evergreening." India's patent laws are designed to protect against "evergreening," unless there is a showing of enhanced efficacy. Some argue that through evergreening, pharmaceutical companies make minor modifications to their patents solely to extend their monopoly on the patent, thus, delaying the entry of lower-cost generic versions of the drugs onto the market. USTR argues that modifications can provide new benefits, such as "fewer side effects, decreased toxicity, improved delivery systems, or temperature or storage stability."[100]

India also has issued, or threatened to issue, compulsory licenses for pharmaceuticals. For example, in March 2012, the Indian government issued a compulsory license to an Indian pharmaceutical company to produce a generic version of Nexavar, a kidney cancer drug produced by Bayer. India defended its decision on the basis that the price for the patented drug was too high for most Indians.[101]

Canada and the Eli Lilly-Canada Chapter 11 Case. The USTR noted concerns about Canadian courts' recent decisions regarding the heightened "utility" requirement for pharmaceutical patents. U.S. pharmaceutical companies argue that such decisions contribute to an uncertain business environment in Canada. For example, one U.S. pharmaceutical company challenged Canada under NAFTA's Chapter 11 investor-state dispute settlement mechanism, based on a Canadian court's decision to invalidate the company's patent. USTR has criticized the interpretation of utility in judicial invalidation of pharmaceutical patents, which has led to a NAFTA Chapter 11 investor-state dispute settlement case.[102] On September 12, 2013, the U.S. pharmaceutical company Eli Lilly has filed a Notice of Arbitration against the Government of Canada seeking damages in the amount of $500 million in lost sales stemming from the invalidation of patents for two medicines. In Canada, Lilly claims the patents for 18 drugs have been invalidated since 2002 through the use of the so-called promise doctrine, with an estimated loss of revenue to brand-name pharmaceutical companies of $1.1 billion.[103] According to the Canadian government, the so-called "promise doctrine" "consists of distinct tests for patent validity under Canadian law." Further, "[i]n Canadian patent law, fulfilment of the three core criteria of patentability—novelty, non-obviousness, and utility—is judged no later than *as at the time of filing of the patent application*." A Canadian court reviewing a claim that a patent is invalid on utility grounds "will first seek to determine whether the applicant itself asserted ("or promised") a particular level of utility for its invention in its patent specification." Lilly claims that this standard is

[100] USTR, *2015 Special 301 Report*, p. 49.

[101] "Bayer fails to block generic cancer drug in India's top court," Reuters, December 12, 2014.

[102] Under NAFTA, patents shall be granted "provided that such inventions are new, result from an inventive step, and are capable of industrial application." NAFTA provides that "inventive step," and "capable of industrial application," are synonymous with "non-obvious," and "useful," which underpins the concept of utility. Article 1709(1).

[103] "Canada's Internationally Inconsistent "Promise Doctrine" for Patents," Eli Lilly background document.

discriminatory, contrary to utility standards in other countries and in NAFTA itself, and is adverse to Canada's own interpretation of utility at the time of NAFTA signing.[104] This standard, some argue, makes it easier for generic companies to challenge the usefulness of a patented drug.

In the *2015 Special 301 Report*, USTR states that the United States "continues to have serious concerns about the lack of clarity and the impact of the heightened utility requirements for patents that the Canadian courts have applied recently... These recent decisions, which have affected products that have been in the market and benefitting patients for years, have led to uncertainty for patent holders and applicants, including with respect to how to effectively meet this standard. This unpredictability also undermines incentives for investments in the pharmaceutical sector."

The Government of Canada responded to the accusations on June 30, 2014, claiming that its patent system is consistent with NAFTA and TRIPS; that those agreements do not dictate specific domestic application; that it provided minimum standards of treatment through extensive opportunity for domestic litigation; that invalidating a patent is not an expropriation subject to NAFTA Chapter 11; and that that "NAFTA tribunals are not courts of appeal for disappointed domestic litigants."[105] Other observers have maintained that there is no uniform standard for utility among countries, and no one standard enshrined in NAFTA.[106] The tribunal has not yet issued an award on jurisdiction or on the merits in the dispute.

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 TRIPS, 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, Trade Knowledge, and Folklore.

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

[104] "Canada: Eli Lilly Files Notice of Arbitration in $500 million NAFTA Dispute Against Canada," Bereskin and Parr, LLP, September 24, 2013.

[105] Government of Canada, Statement of Defence (Case UNCT/14/2), June 30, 2014, http://www.international.gc.ca/trade-agreements-accords-commerciaux/assets/pdfs/disp-diff/eli-07.pdf.

[106] "The 'Promise of the Patent' in Canadian Patent Law," Heenan Blaikie, LLP, Flash Bulletin, December 2013.

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 these FTAs recognize the importance of biodiversity and traditional knowledge and pledge the countries to work together to address these issues through the IGC.

U.S. Trade Law

Special 301

Section 301 of the Trade Act of 1974 (P.L. 93-618) as amended, is the principal 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 (see **Table 4**).

The USTR can designate countries in one of several statutorily or administratively created categories:

- **Priority Foreign Country:** A statutory category for those designated by the USTR as having "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 the "greatest adverse impact (actual or potential) on the relevant United States products." 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.[107] If a country is named as a "Priority Foreign Country," the USTR must launch an investigation into that country's IPR practices. 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 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 the limited number of countries outside the WTO, trade sanctions remain a possibility.

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

- **Priority Watch List:** An administrative category created by the USTR for those countries whose acts, policies, and practices warrant concern, but who do not meet all of the criteria for identification as 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:** An administrative category created by USTR to designate countries that have intellectual property protection inadequacies that are less severe than those on the Priority Watch List, but still attract U.S. attention.
- **Section 306 Monitoring.** A tool used by USTR to monitor countries for compliance with bilateral intellectual property agreements used to resolve investigations under section 301.
- **Out-of-Cycle Review.** A tool used by USTR on countries to monitor their progress on intellectual property issues, and which may result in status changes for the following year's Special 301 report.

Table 4. USTR *2015 Special 301 Report*: Country Designations

Special 301 Category	2015 Special 301 Designation
Priority Foreign Country	No countries listed this year
Priority Watch List	Algeria, Argentina, Chile, China, Ecuador, India, Indonesia, Kuwait, Pakistan, Russia, Thailand, Ukraine, and Venezuela
Watch List	Barbados, Belarus, Bolivia, Brazil, Bulgaria, Canada, Colombia, Costa Rica, Dominican Republic, Egypt, Greece, Guatemala, Jamaica, Lebanon, Mexico, Paraguay, Peru, Romania, Tajikistan, Trinidad and Tobago, Turkey, Turkmenistan, Uzbekistan, and Vietnam
Section 306 Monitoring	China
Out-of-Cycle Reviews	• Turkmenistan—evaluating whether specific steps taken by the country merit removal from Watch List • Tajikistan—evaluating whether specific steps taken by the country merit removal from Watch List • Honduras—evaluating whether to place the country on the Watch List • Paraguay—OCR extended to provide additional time for concluding bilateral IPR Memorandum of Understanding • Spain—focusing on steps to combat copyright piracy over the Internet; OCR being conducted although Spain is not listed in the 2015 Special 301 Report • "notorious markets"—online and physical markets, including online markets, that reportedly engage in piracy and counterfeiting (findings published in a separate Notorious Markets List, with the next to be conducted in fall 2015)

Source: CRS adaption from USTR, *2015 Special 301 Report*.

Notes: For the *2015 Special 301 Report*, USTR reviewed the IPR policies and practices of 72 countries, and designated 37 of the countries in one of several categories.

The Special 301 statute provides the overall guideline for identifying countries for the various lists. However, placement on one of the lists is country-specific and takes into consideration a host of factors, including the level and scope of the country's IPR infringement and their impact on the U.S. economy, the strength of the country's IPR laws and enforcement of IPR laws, progress made by the country in improving IPR protection and enforcement in the past year, and 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. In making determinations, the USTR gathers information based on its annual trade barriers reports, as well as consultations with a wide variety of sources, including industry groups, other private sector representative, Congress, and foreign governments.

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 (e.g., integrated circuit designs), 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 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. ITC investigates complaints either brought to it or ones commenced under its own initiative. An administrative law judge provides an initial determination to the ITC which can accept the initial determination 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 and Border Protection (CBP). A general exclusion order directs CBP 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 review period for "policy reasons." A presidential review of a remedial order often considers several relevant factors, including "(1) public health and welfare; (2) competitive conditions in the U.S. economy; (3) production of competitive articles in the United States; (4) U.S. consumers; and (5) U.S. foreign relations, economic and political."[108] The number of Section 337 cases managed by the ITC has trended upward in recent years. The overwhelming majority of Section 337 cases involve allegations by private firms of patent infringement. The number of investigations based on trade secrets is increasing. Investigations concern a range of technologies, including smartphones and other wireless devices, smart televisions, semiconductors, GSP devices, windshield wiper blades, and tires (see **Figure 4**).[109] According to the ITC, there is "substantial overlap between the industries that dominate our IP docket and the four industries determined in a Department of Commerce study to be the most patent-intensive industries in the United States"—computer and peripheral equipment,

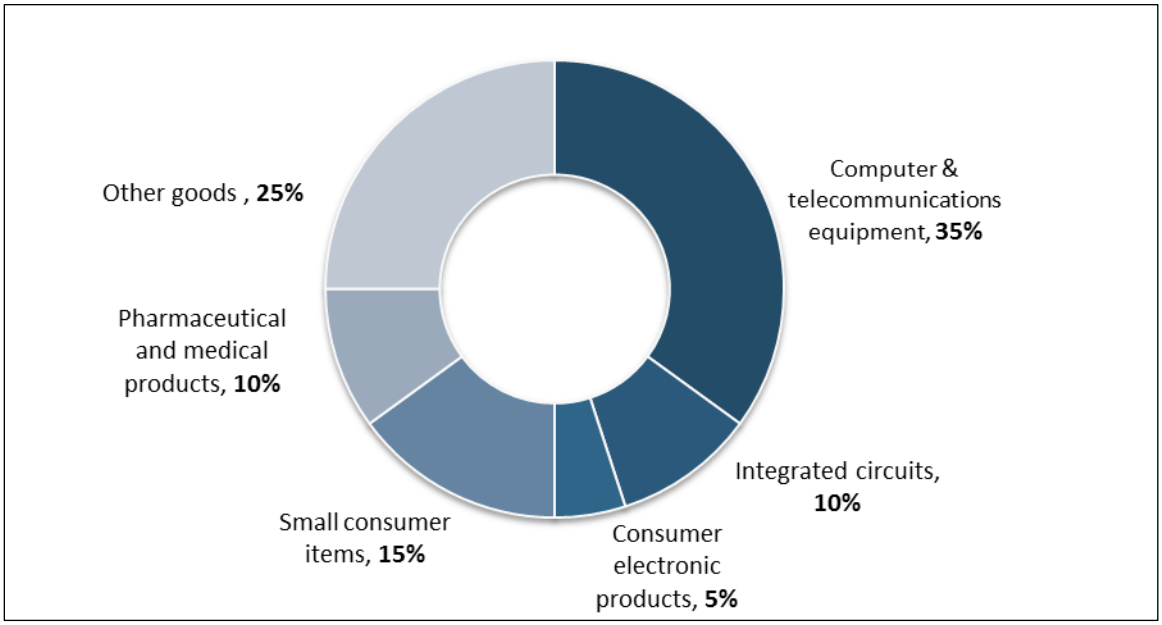
[108] S. Rep. No. 93-1298, 93d Cong. 2d Sess. 199 (1974).

[109] ITC, *Budget Justification Fiscal Year 2016*, p. 7.

communications equipment, semiconductor and other electronic components, and other computer and electronic products.[110]

Figure 4. Products Involved in FY2014 Section 337 Cases

(Percent of Cases)



Source: ITC, *FY2014 At a Glance: Intellectual Property Import Investigations*.

Notes: The ITC reported 100 total active section 337 investigations and related (ancillary) proceedings. ITC cites, as examples of "consumer electronic products," head phones, TVs, ear buds, acoustic-magnetic surveillance equipment. ITC cites, as examples of "small consumer items," toys, cell phone cases, and robotic toys. ITC cites as examples of other goods, chemical compounds, toner cartridges, rubber resins, lighting products, windshield wipers, automobile tires, outdoor grills, and crawler cranes.

Legislative efforts related to Section 337 have focused on addressing jurisdictional problems associated with holding foreign websites accountable for piracy and counterfeiting, renewing congressional and public debate about the balance between protecting U.S. intellectual property and promoting innovation.[111] Congress could take these issues up again, as well as other issues, including the effectiveness of CBP's enforcement of Section 337 exclusion orders. According to a 2008 Government Accountability Office (GAO) report, U.S. companies spend millions of dollars to file Section 337 complaints before the ITC, but that CBP enforcement of exclusion orders is limited because of a lack of resources and other competing priorities.[112] In 2014, the Office of the U.S. Intellectual Property Enforcement Coordinator (IPEC) launched an interagency review of the exclusion order enforcement process, and plans to deliver recommendations for refining the

[110] Ibid., p. 19; Department of Commerce, *Intellectual Property and the U.S. Economy, Industries in Focus*, March 2012.

[111] For example, see S. 2029 and H.R. 3782, the Online Protection and Enforcement of Digital Trade Act introduced in the 112th Congress.

[112] U.S. Government Accountability Office, *Intellectual Property: Federal Enforcement Has Generally Increased but Assessing Performance Could Strengthen Law Enforcement Efforts*, GAO-08-157, March 2008.

process in the coming months.[113] Some Members and stakeholders have raised concerns about the effectiveness, efficiency, and transparency of Section 337.

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.[114] 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. GSP was renewed by the Trade Preferences Extension Act of 2015 (P.L. 114-27), signed by the President on June 29, 2015.

Although 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.[115]

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. USTR reports as "ongoing" its review of the country practices in Indonesia, Ukraine, and Uzbekistan, on the basis of IIPA petitions concerning IPR.[116]

Issues for Congress

Congress has legislative, oversight, and appropriations responsibilities related to IPR and trade policy. What follows are certain key issues that Congress could consider as it fulfills those responsibilities.

U.S. Efforts to Promote IPR Through Trade Policy

Since the inclusion of IPR provisions in NAFTA and the TRIPS Agreement, IPR protection and enforcement have been major U.S. trade policy negotiating objectives. Alongside the growing role of IPR in trade policy, there has been an ongoing debate regarding the appropriateness of this role. From one perspective, IPR could promote trade through innovation, economic growth, and technology transfer from advanced to developing countries. From another perspective, IPR, which grant legal temporary monopolies to rights holders for their creations, could be considered barriers to trade with no place in trade liberalization negotiations. Given the continued use of trade policy to advance IPR objectives, debates also have focused on the appropriate balance between the protection and enforcement of IPR and other public policy objectives, such as access to medicines and the free flow of information, as well as the extent to which these goals are complementary or conflicting. Additionally, there have been debates about the trade policy

[113] The White House, "Fact Sheet – Executive Actions: Answering the President's Call to Strengthen Our Patent System and Foster Innovation," press release, February 20, 2014.

[114] See CRS Report RL33663, *Generalized System of Preferences: Overview and Issues for Congress*, by (name reda cted) .

[115] 91 U.S.C. §2462(b)(2).

[116] USTR, "Active GSP Country Practices Reviews," updated November 2014.

channels used by the United States to promote IPR goals. Some question the appropriateness of using regional and bilateral FTAs for pursuing stronger IPR, contending that such actions take away from the effectiveness of multilateral IPR promotion efforts. Others argue that strong IPR commitments in U.S. regional and bilateral FTAs can provide momentum for developing such disciplines at the multilateral level.

As noted above, Congress passed a new grant of Trade Promotion Authority in June 2015. With its passage, attention turns to the current agreements being negotiated with the TPP countries and with the European Union in the T-TIP. Congress may wish to consider how negotiators have carried out IPR negotiating objectives in these potential agreements. In a potential TPP, for example, Congress may choose to consider how negotiators interpreted the mandate to 'ensure that trade agreements foster innovation and access to medicine," and whether or not the result is consistent with the patent protection provisions found in the May 10, 2007 Bipartisan Trade Agreement. In addition, through the debate over a possible TPP, Congress may wish to examine the negotiating results for new negotiating objectives relating to IPR, such as those concerning indigenous innovation, "forced" localization barriers to trade in the digital environment, and cybercrime.

Enforcement of IPR Commitments

The extent to which U.S. FTA partners and WTO members are upholding their IPR commitments is of congressional concern. To date, the United States has concluded 14 FTAs with 20 countries. Some argue that negotiating high standard FTAs is not enough, and that "FTA commitments are meaningless if they are not consistently implemented an effectively enforced over time."[117]

Questions include whether existing U.S. trade policy tools, such as the "Special 301" process, bilateral consultations, and WTO and FTA dispute settlement mechanisms, are effective in bringing countries into IPR compliance. Aspects of these processes are subject to debate. For example, one question is whether "Special 301" designations are balanced in assessing countries' IPR regimes. Supporters contend that the Special 301 country designations—determined on a case-by-case basis and relying on interagency deliberations and consultations with Congress, foreign governments, and other stakeholders—accurately reflect countries' inadequacies in their IPR regimes. Others argue that the Special 301 is overly industry-driven and that country designations are not given systematically.

Some call for greater use of WTO/FTA dispute settlement mechanisms. The United States has been a complainant in over one-half (17 of 34) of WTO disputes concerning the TRIPS Agreement, and has been a respondent in 4 more. However, only one U.S. case has been filed since the year 2000—against China in 2007 (described above). No disputes have been brought under IPR provisions of U.S. FTAs. Congress may wish to consider the criteria by which USTR initiates cases, or evaluate the resources that may be necessary to investigate and bring additional cases.

[117] U.S. Chamber of Commerce, *Implementation of IP Obligations in U.S. Trade Agreements: An Assessment of U.S. Agreements with Australia, Canada, Chile, and Korea*, November 2014, p. 17. This study sought to provide an "initial assessment of whether U.S. FTA partners are abiding by their IP commitments." It focused on Australia, Canada, Chile, and Korea, countries that it characterized as "regionally and economically diverse." Examining implementation of certain IPR commitments, the study found "positive implementation developments and challenges across all four countries." According to the study, Australia has most successfully implemented its FTA obligations, with South Korea a "close second" (noting that since KORUS is the newest U.S. FTA to enter into force, "it is too early to tell whether Korea is faithfully implementing all of its obligations." It found that Chile and Canada "lag significantly" behind Australia and Korea in terms of implementation of IPR commitments. See Executive Summary.

Addressing IPR Trade Challenges in Emerging Economies

Some policymakers have voiced concern over the effectiveness of current U.S. trade policy in addressing IPR trade challenges associated with emerging economies, such as China, India, and Brazil—countries with which there are no existing U.S. FTAs and with which the United States is currently not negotiating any FTAs. Congress could examine how existing trade policy tools are operating with respect to emerging economies. Beyond this, Congress could explore other options for advancing U.S. IPR trade policy objectives in emerging economies, including in the following areas:

- **U.S. FTA negotiations.** The TPP and T-TIP negotiations are intended to help shape global rules addressing challenges in third countries, such as with respect to localization barriers to trade—issues relevant to emerging economies. Moreover, TPP negotiators seek to craft the TPP as an "open" and "living" agreement that other countries, such as China and India, could ultimately join if they were willing to take on its high standard commitments. Congress could consider to what extent the United States can or should encourage these emerging economies to join the TPP negotiations, and if so, how that might be accomplished.
- **Bilateral Investment Treaties (BITs).** Through the negotiation of BITs, the United States seeks to reduce barriers to foreign investment and strengthen protections for foreign investment.[118] The U.S. Model BIT, the template the United States uses to negotiate BITs and investment chapters of FTAs, treats IPR as a covered form of investment subject to protections. Currently, the United States is negotiating BITs with China and India. Congress could examine the progress of these negotiations, including how IPR issues are being addressed. Should these BIT negotiations be concluded, they would be subject to Senate ratification in order to enter into force.
- **U.S. trade preference programs.** Some stakeholders point to U.S. trade promotion and preference programs as a potential tool for Congress to encourage policy reform in emerging economies. For example, in light of heightened concern over India's intellectual property environment, some stakeholders have called on Congress to remove India from the Generalized System of Preferences beneficiary list.[119] Should Congress take up GSP reauthorization, India's eligibility status could be among the issues examined.
- **WTO TRIPS Agreement.** Congress may examine how the WTO TRIPS Agreement is working with respect to emerging economies, as well as whether there are additional opportunities for seeking redress for violations of TRIPS Agreement commitments through the WTO Dispute Settlement Mechanism with these trading partners. For instance, the United States has seen some success in

[118] See CRS Report R43052, *U.S. International Investment Agreements: Issues for Congress*, by (name redacted) and (name redacted) . U.S. BITs provide investment protections through provisions such as requirements for non-discriminatory treatment, protections against expropriation, and the right to neutral, binding arbitration to resolve disputes investors and host countries.

[119] See CRS Report RL33663, *Generalized System of Preferences: Overview and Issues for Congress*, by (name reda cted) , Withdraw India's GSP Preference If It Continues to Impose Localization Barriers to Trade on Foreign Enterprises, ITIF, January 23, 2013, http://www.innovationfiles.org/withdraw-indias-gsp-preference-if-it-continues-to-impose-localization-barriers-to-trade-on-foreign-enterprises/.

challenging China's copyright practices through the WTO. Some stakeholders also call for the United States to pursue greater trade enforcement action on IPR with respect to other countries. Additionally, Congress may consider the potential for a future update to TRIPS. For instance, IPR commitments in any final Trans-Pacific Partnership or Transatlantic Trade and Investment Partnership FTAs could lead to common approaches for the development of rules through the WTO.

Effectiveness of the U.S. IPR Organizational Structure

A range of U.S. government agencies have responsibilities related to U.S. IPR activities. For an overview of federal agencies and coordinating bodies involved in U.S. IPR-related efforts, see **Appendix B**. Some Members of Congress, private sector representatives, and other stakeholders express concern about whether the present U.S. IPR organizational structure is doing enough to enforce foreign countries' IPR obligations, as well as whether the structure is capable of doing more.

One set of issues centers on coordination. Given the range of federal agencies involved in IPR protection and enforcement, questions have emerged about whether federal IPR activities are sufficiently coordinated in the present U.S. IPR organizational structure (see text box). On one hand, the Administration's establishment of various interagency bodies related to IPR, such as the Intellectual Property Enforcement Coordinator (IPEC), National Intellectual Property Rights Coordination Center (IPR Center), and Interagency Trade Enforcement Center (ITEC), affirms the U.S. commitment to enforcing IPR and the importance of interagency coordination. On the other hand, there are debates about whether the various IPR-related interagency coordinating mechanisms overlap. From one perspective, these interagency bodies focus on differing aspects of IPR protection and enforcement, and in doing so, collectively help to advance U.S. IPR goals in trade policy. From another perspective, the existence of multiple interagency coordinating bodies can contribute to additional bureaucracy.

2013 Joint Strategic Plan on Intellectual Property Enforcement

The U.S. Intellectual Property Enforcement Coordinator (IPEC), assisted by its Advisory Committee, 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 June 2013, the IPEC released its second Joint Strategic Plan on Intellectual Property Enforcement, which noted progress and areas for future activity in 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.

Source: Executive Office of the President, *2013 Joint Strategic Plan on Intellectual Property Enforcement*, June 2013 http://www.whitehouse.gov/sites/default/files/omb/IPEC/2013-us-ipec-joint-strategic-plan.pdf.

Another set of issues centers on federal resources for IPR protection and enforcement. 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 federal funding and resources devoted to it. Some U.S. government 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. Additionally, information is limited on the economic and other impacts of piracy and counterfeiting on the United States. This may complicate the ability of lawmakers to weigh the threat of IPR infringement against the federal resources available for IPR and other government priorities. Furthermore, there could be debates about whether attempts to enhance interagency

coordination, without devoting greater resources to IPR enforcement activities, may translate into greater U.S. IPR enforcement.

Looking Forward

U.S. efforts to protect and enforce IPR through U.S. trade policy are likely to continue to be of interest for Congress. The reliance on IPR as a competitive advantage to drive an innovative U.S. economy is reflected in U.S. trade policy. Congress may set the course of U.S. trade policy concerning IPR through the development of negotiating objectives in any future trade promotion authority. It also may consider the treatment of IPR in ongoing U.S. FTA negotiations for the proposed Trans-Pacific Partnership and Trans-Atlantic Trade and Investment Partnership. It may weigh the balance between greater intellectual property rights in free trade agreements and the ability to conclude agreements containing such provisions with other countries. It may wish to examine how to incorporate the IPR aspects of new issues such as digital trade in U.S. policy.

Congress may also examine the enforcement of U.S. IPR through existing trade agreements, as well as the effectiveness of U.S. trade policy tools such as Special 301. Congressional debates may continue in areas such as how IPR protection and enforcement relate to other public policy goals, such as access to affordable medicines. The organizational structure for IPR protection and the priority to place on such enforcement when allocating budgetary resources also may be of congressional interest.

Appendix A. Patent and Copyright Provisions in the TRIPS Agreement and U.S. FTAs

Intellectual Property Forms	TRIPS Provisions (1994)	General TRIPS-Plus Provisions in FTAs	Scale-down of TRIPS-Plus Standards
Patents			
Patent term extensions	No provisions	Mandatory extensions in cases of unreasonable delays in patent grants/regulatory approval *Jordan (Article 4.23.a),* *Chile (Article 17.9.6; 17.9.2a), Singapore (Article 16.7.7; 18.8.4a), Australia (Article 17.9.8; 17.10.4), Morocco (Article 15.9.7; 15.10.3), CAFTA-DR (Article 15.9.6; 15.10.2), Bahrain (Article 14.8.6),Oman (Article 15.8.6), Korea (Article 18.8.6)*	Optional extensions in cases of unreasonable delays in patent grants/regulatory approval *NAFTA (Article 1709.12)* *Peru (Article 16.9.6), Panama (Article 16.9.6), Colombia (Article 16.9.6)*
Market approval linked to patent status	No provisions *NAFTA (no mention),* *Jordan (no linkage, but patent owner must be notified if another entity is seeking marketing approval for generic version of patented product, Article 4.23.b)*	National regulatory authorities cannot provide marketing approval for a generic version of a patented drug without permission from rights-holder; also requires notification of rights-holder if marketing permitted *Chile (Article 17.10.2b), Singapore (16.8.4c), Australia (Article 17.10.4), Morocco (Article 15.10.4), CAFTA-DR (Article 15.10.2), Bahrain (Article 14.9.4), Oman (15.9.4), Korea (Article 18.9.5)*	Eliminates mandate that regulatory authorities cannot approve a generic drug for marketing if patent for drug in place *Peru (Article 16.10.4), Panama (Article 15.10.4), Colombia (Article 16.10.4)*
Protection for undisclosed test or other data	Members must protect data from unfair commercial use (Article 39.3) *Jordan (Article 4.22)*	Provides for at least five years of data exclusivity from date of approval in country for pharmaceuticals that contain new chemical products *NAFTA (Article 1711.6), Bahrain (Article 14.9.1), Oman (Article 15.9(1-2), CAFTA-DR (Article 15.10.1), Singapore (Article 16.8(1-3)), Australia (Article 17.10.1), Morocco (Article 15.10.1), Chile (Article 17.10.1), Korea (Article 18.9(1-2))*	Provides for at least five years of marketing exclusivity from date of approval in country of first filing if new drug is granted marketing approval within six months in country of second filing *Peru (Article 16.10.2), Panama (Article 15.10.4), Colombia (Article 16.10.2)*
Issuance of compulsory licenses	Some restrictions in issuance of compulsory licenses; circumstances under which licenses can be issued not limited (Article 13) *NAFTA (Article 1709.10),*	Limits issuance of compulsory license to specific cases: Correcting anti-competitive practices, public non-commercial contexts, national emergencies, and other	Not discussed *Chile (no mention), Morocco (no mention), CAFTA-DR (no mention), Bahrain (no mention), Oman (no mention)* *Peru (no mention), Panama (no*

Intellectual Property Forms	TRIPS Provisions (1994)	General TRIPS-Plus Provisions in FTAs	Scale-down of TRIPS-Plus Standards
		extremely urgent situations *Jordan (Article 4.20), Singapore (Article 16.7.6), Australia (Article 17.9.7)*	*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), Bahrain (Article 14.8.(1-2)), Oman (Article 15.8.2, plants not discussed),* *Jordan, (no mention), Singapore (no mention), Australia (no mention), Korea (no mention)*	Countries shall make patents available for plants and animals *Morocco (Article 15.9.2, plants and animals mentioned, plant varieties are not mentioned)*	Members may exclude plants and animals from patentability, but shall take reasonable effort to provide patent protection for plants or animals and maintain protection once offered *Chile (Article 17.9.2, mentions plants but not animals), CAFTA-DR (Article 15.9.2), Peru (Article 16.9.2), Panama (Article 15.9.2), Colombia (Article 16.9.2)*
Copyrights			
Rights-management information	Not discussed *NAFTA (no mention), Jordan (no mention)*	Outlaws removal or alternation of information *Chile (Article 17.5.6), Australia (Article 17.4.8), Singapore (Article 16.4.8), Morocco (Article 15.5.9), CAFTA-DR (Article 15.5.8), Bahrain (Article 14.4.8), Oman (Article 15.4.8), Peru (Article 16.7.5), Panama (Article 15.5.8), Colombia (Article 16.7.5), Korea (Article 18.4.8)*	
Term of protection	No less than 50 years from authorized publication (Article 12) *NAFTA (Article 1705.4), Jordan (no mention)*	No less than 70 years from death of author or authorized publication *Chile (Article 17.5.4), Singapore (Article 16.4.4), Australia (Article 17.4.4), Morocco (Article 15.5.5), CAFTA-DR (Article 15.5.4), Bahrain (Article 14.4.4), Oman (Article 15.4.4), Peru (Article 16.5.5), Panama (Article 15.5.4), Colombia (Article 16.5.5), Korea (Article 18.4.4)*	
Circumvention of copyrighted work	Not discussed *NAFTA (no mention)*	Signatories must agree to prohibit circumvention *Jordan (Article 4.6), Chile (Article 17.5.5), Singapore (Article 16.4.7), Australia (Article 17.4.7), Morocco (Article 15.5.8), CAFTA-DR (Article 15.5.7), Bahrain (Article 14.4.7), Oman (Article 15.4.7), Peru (Article 16.7.4), Panama (Article 15.5.7), Colombia (Article 16.7.4), Korea (Article 18.4.7)*	
ISP Liability	Not discussed *NAFTA (no mention), Jordan (no mention)*	ISPs are provided with limited liability in certain situations of copyright infringement on their servers if they comply with regulations *Chile (Article 17.11.23), Singapore (Article 16.9.22), Australia (Article*	

Intellectual Property Forms	TRIPS Provisions (1994)	General TRIPS-Plus Provisions in FTAs	Scale-down of TRIPS-Plus Standards
		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)	

Source: CRS Analysis of FTA provisions.

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

Appendix B. Overview of IPR-Related U.S. Government Agencies and Coordinating Bodies

What follows is a discussion of key U.S. government agencies and coordinating bodies involved in U.S. efforts to protect and enforce IPR.

Office of the United States Trade Representative (USTR)

The USTR is the lead U.S. trade negotiator and negotiates IPR provisions in U.S. trade agreements, at the multilateral, plurilateral, regional, and bilateral levels. Currently, the USTR is leading free trade agreement negotiations for the United States for the proposed Trans-Pacific Partnership (TPP) and Transatlantic Trade and Investment Partnership (T-TIP), among other negotiations.[120] It also enforces U.S. rights under existing trade agreements. Additionally, 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. The USTR further administers the Generalized System of Preferences (GSP) program, under which a country's eligibility for U.S. trade preferences may be contingent on its IPR protection.

Department of Commerce (Commerce)

Two agencies within the Department of Commerce, the Patent and Trademark Office and the International Trade Administration, address IPR issues.[121]

- The **Patent and Trademark Office (PTO)** administers the U.S. laws pertaining to patents and trademarks. It processes patent and trademark applications, and issues patents and registers trademarks. 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.[122] Its IPR Attaché Program places individuals with technical expertise and experience overseas to promote strong international IPR protection and enforcement, such as through helping to influence laws, regulations, and practices in host countries. 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. The PTO is fully funded through fees generated from patent and trademark applications.
- The **International Trade Administration (ITA)** administers many of the international trade programs of the Department of Commerce, include aspects

[120] See CRS Report R42694, *The Trans-Pacific Partnership (TPP) Negotiations and Issues for Congress*, coordinated by (name redacted) , and CRS Report R43291, *U.S. Trade in Services: Trends and Policy Issues*, by (name redacted)

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

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

involving IPR. The ITA monitors foreign countries' progress in implementing intellectual property agreements; reviews 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.[123]

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. Key units of the DOJ that have IPR enforcement responsibilities are the Criminal Division, U.S. Attorney's Office, the Civil Division, the Federal Bureau of Investigation, and the Office of Justice Programs.

- The **Criminal Division** prosecutes intellectual property crimes involving criminal offenses, namely through its Computer Crime and Intellectual Property Section (CCIPS).
- Federal prosecutors in the **U.S. Attorneys' Offices** pursue computer crime and intellectual property offenses.
- The **Federal Bureau of Investigation (FBI)** has an intellectual property enforcement program focusing on intellectual property crimes that have the most bearing on national and economic security, such as trade secret theft, Internet priority, and counterfeit tracking goods. Its IPR strategic objective is to "disrupt and dismantle state sponsored groups and international and domestic criminal organizations that steal, manufacture, distribute and otherwise profit from the theft of intellectual property."[124] IPR is a top priority of the cyber division, though IPR crimes may be investigated in other divisions. Other IPR priorities for investigations are counterfeit health and safety products and theft of trade secrets.
- The **Civil Division** prosecutes civil actions to recover penalties imposed by the Department of Homeland Security's Customs and Border Protection (CBP, discussed below) with respect to importation of counterfeit goods, brings affirmative cases when U.S. intellectual property rights are infringed, and defends CBP enforcement of the International Trade Commission's Section 337 exclusion orders, among other things.
- The **Office of Justice Program** awards grants to support intellectual property enforcement efforts by state and local law enforcement partners.

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.

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

[124] IPEC, *2013 Joint Strategic Plan on Intellectual Property Enforcement*, June 2013, p. 71.

Department of Homeland Security (DHS)

One of the aims of DHS is to ensure the facilitation of legitimate trade, while enforcing U.S. trade and IPR laws and investigating IPR violations, specifically trademark, counterfeiting, and copyright piracy. Key parts of DHS that are involved in IPR enforcement include U.S. Customs and Border Protection, U.S. Immigration and Customs Enforcement, U.S. Secret Service (USSS), and the National Intellectual Property Rights Coordination Center (IPR Center, discussed in next section).

- Taking the lead in day-to-day IPR enforcement activities at the U.S. border, the **Customs and Border Protection (CBP)** is responsible for detecting and seizing counterfeit and pirated goods entering the United States and determining penalties for infringement.[125] 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. 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.[126]
- **Immigration and Customs Enforcement (ICE)** is charged with investigating violations of U.S. law that are connected with U.S. borders. ICE identifies, investigates, apprehends, and removes international criminal groups and other criminals. ICE conducts inquiries into the importation and distribution of counterfeit goods. ICE activities are closely linked with those of CBP. For instance, when CBP identifies and seizes counterfeit goods, the issue is referred to ICE for criminal investigation. Likewise, information obtained from ICE that is relevant to identifying and apprehending counterfeit shipments is provided to CBP.
- The **U.S. Secret Service (USSS)** investigates violations of laws relating to counterfeiting of obligations and securities of the United States; financial crimes; and computer-based attacks on U.S. financial, banking, telecommunications, and other critical infrastructure. As part of such activities, USSS may find links to IPR violations.

Department of Health and Human Services

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

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

[126] IPR Center, *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.

FDA quality and labeling requirements. Funding for preventing counterfeits from entering the United States is part of overall FDA import safety efforts.[127]

Library of Congress

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.[128]

Department of State

The Department of State represents U.S. views in both bilateral and multilateral arenas. It works to build international consensus for IPR 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 Economics and Business Affairs supports stronger international IPR standards to combat global piracy and counterfeiting.[129]

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.[130]

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. It adjudicates allegations of imported products that infringe U.S. patents, trademarks, and copyrights through its section 337 proceedings. 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; right holders seeking damages must file a civil action with a U.S. federal district court.[131]

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

[128] IPR Center, *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.

[129] Ibid., pp. 17-18. Additional information about the State Department is available at http://www.state.gov.

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

[131] ITC website, http://www.usitc.gov.

Coordinating and Advisory Bodies

The USTR leads interagency coordination of U.S. trade policy formulation, negotiation, and implementation. Beyond this general mechanism, the U.S. government also has interagency intended to specifically coordinate IPR protection and enforcement activities, as well as private sector advisory bodies that provide input into the formulation of U.S trade policy. Certain key coordinating and advisory bodies are outlined below.

Office of the U.S. Intellectual Property Enforcement Coordinator (IPEC)

The IPEC, located in the Office of Management and Budget (OMB) of the Executive Office of the President, provides executive direction and coordination of federal agencies involved in IPR enforcement. The position of the U.S. Intellectual Property Enforcement Coordinator, subject to Senate confirmation, was statutorily established in October 2008, through the Prioritizing Resources and Organization for Intellectual Property Act of 2008 (P.L. 110-403).[132] Among its key responsibilities are to develop and implement a "Joint Strategic Plan on Intellectual Property Enforcement" for combating counterfeiting and piracy; provide assistance to the USTR in conducting trade negotiations relating to IPR enforcement abroad; and chair an Advisory Committee composed of representatives from the OMB; Departments of Justice, Commerce, State, Homeland Security, Agriculture; FDA; AID; and the Register of Copyrights.

National Intellectual Property Rights Coordination Center (IPR Center)

The Department of Homeland Security houses the IPR Center, an interagency task force whose mission is "to ensure national security by protecting the public's health and safety, the U.S. economy, and our war fighters, and to stop predatory and unfair trade practices that threaten the global economy." Established by ICE in 2002, the IPR Center's role is to improve and coordinate federal intellectual property functions to more effectively combat IPR-infringing products. It is led by the ICE Homeland Security Investigations (HSI) Director, with Deputy Directors from HSI and CBP. According to USTR, the IPR Center can be distinguished from ITEC (discussed below) because of the former's focus on the law enforcement response to IPR theft (primarily coordinating investigation and prosecution of IPR infringers under U.S. criminal laws) and the latter's focus on enforcement of U.S. rights under trade agreements across a range of issues, one of which is IPR.[133]

Interagency Trade Enforcement Center (ITEC)

The ITEC is an interagency coordinating body established in February 28, 2012, by Executive Order. Its aim is to strengthen and coordinate enforcement of U.S. rights under international free trade agreements and of U.S. trade laws through a "whole-of-government" approach.[134] The ITEC

[132] 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.

[133] USTR, "ITEC Frequently Asked Questions."

[134] The White House, Office of the Press Secretary, "Executive Order—Establishment of the Interagency Trade Enforcement Center," February 28, 2012; USTR, "Organization: Overview of the Functional Responsibilities of our Offices," https://ustr.gov/about-us/organization

is housed within the USTR with a designated director from the USTR; a designated deputy director from the Department of Commerce; and support from the Departments of State, the Treasury, Justice, Agriculture, Commerce, and Homeland Security, as well as the Director of National Intelligence. The Administration has emphasized the need for creating the ITEC in order to better combat unfair trade practices by countries such as China.[135]

Private Sector Advisory Committee System

The USTR manages a private sector advisory committee system for trade policy, intended to provide information and advisory on U.S. negotiating objectives and bargaining positions before the United States enters into trade agreements, the operation of existing U.S. trade agreements, and other U.S. trade policy matters.[136] Statutorily established under section 135 of the Trade Act of 1974(P.L. 93-618), the private sector advisory system includes 16 Industry Trade Advisory Committees (ITACs), which are jointly administered by the USTR and Department of Commerce. ITAC membership draws from industry and labor. The ITACs reflect a range of U.S. economic sectors and policy issues, and one of the ITACs focuses on IPR.[137]

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[135] World Trade Online, "Trade Enforcement Unit Will Not Dilute U.S. Standard for Bringing WTO Cases," March 1, 2012.

[136] USTR, "Advisory Committees," http://www.ustr.gov/about-us/intergovernmental-affairs/advisory-committee.s

[137] USTR, "Industry Trade Advisory Committees (ITAC)," http://www.ustr.gov/about-us/advisory-committees/industry-trade-advisory-committees-itac.