THE TRANS-PACIFIC PARTNERSHIP TRADE AGREEMENT AND INTELLECTUAL PROPERTY

1301 PENNSYLVANIA AVENUE, NW, SUITE 1075
WASHINGTON, DC 20004
1-800-USA-DEBT
www.cagw.org
NOVEMBER 2015

WILLIAM CHRISTIAN, DEBORAH COLLIER, THOMAS A. SCHATZ, AND ELIZABETH WRIGHT

Citizens Against Government Waste

Citizens Against Government Waste (CAGW) is a private, nonprofit, nonpartisan organization dedicated to educating the American public about waste, mismanagement, and inefficiency in the federal government.

CAGW was founded in 1984 by J. Peter Grace and nationally-syndicated columnist Jack Anderson to build public support for implementation of the Grace Commission recommendations and other waste-cutting proposals. Since its inception, CAGW has been at the forefront of the fight for efficiency, economy, and accountability in government.

CAGW has more than 1 million members and supporters nationwide. Since 1984, CAGW and its members have helped save taxpayers more than $1.4 trillion. CAGW publishes special reports, its official newspaper *Government WasteWatch*, and the monthly online newsletter *WasteWatcher* to scrutinize government waste and educate citizens on what they can do to stop it. Internet, print, radio, and television news outlets regularly feature CAGW's publications and experts.

William Christian, Director of Government Affairs

Deborah Collier, Director of Technology and Telecommunications Policy

Thomas A. Schatz, President

Elizabeth Wright, Director of Health and Science

1301 Pennsylvania Avenue, NW
Suite 1075
Washington, DC 20036
1-800-USA-DEBT
www.cagw.org

The Trans-Pacific Partnership Trade Agreement and Intellectual Property

Introduction

In the semantics of trade negotiations, words matter. They also make a difference in legislation. The Bipartisan Congressional Trade Priorities and Accountability Act (TPA) (Public Law 114-26) established the parameters within which a president can negotiate a treaty with other nations. In order to assure trading partners that these agreements will be approved forthwith, Congress must consider them under "fast-track" procedures and vote up or down without amendments or filibusters.

The TPA includes more than a dozen transparency and accountability provisions, including allowing every member of Congress to read the negotiating text and attend negotiating rounds. When the president announces that he will sign a trade agreement, Congress will have 30 days to inspect the agreement before it is made public. After it is made public, the president must wait another 60 days before the agreement can be signed. TPA specifically affirms that only Congress can change U.S. law.

Finally, TPA provides an opportunity for Congress to stop the expedited consideration of a trade agreement with an "off switch." This unprecedented safeguard allows for consideration of a Consultation and Compliance Resolution (CCR) by either chamber of Congress if either of the respective committees of jurisdiction (House Ways and Means or Senate Finance) reports a trade agreement without a favorable recommendation or if a member of Congress introduces a CCR with other than a favorable recommendation. The CCR would state that the president failed to comply or consult with Congress on trade negotiations in accordance with the TPA and, therefore, fast-track procedures would not apply to the bill to implement such a trade agreement. This decision can be made by either chamber, without the consent of the other chamber or the approval of the president.

On October 5, 2015, the U.S. Trade Representative (USTR), speaking on behalf of the Trans-Pacific Partnership (TPP) countries, announced that negotiations for the TPP Agreement (TPPA) had been concluded. The 12 countries involved in these negotiations are Australia, Brunei Darussalam, Canada, Chile, Japan, Malaysia, Mexico, New Zealand, Peru, Singapore, United States, and Vietnam. According to the USTR, U.S. exports to TPP countries totaled $698 billion (44 percent of U.S. goods exported overseas) in 2013.

While the full language of the trade deal has not yet been publicly released, the TPPA encompasses 30 chapters that range in scope from trade remedies and investments to labor and environmental issues.[1] Chapter 18 of the agreement specifically discusses the rights and responsibilities of each TPP member nation in protecting intellectual property (IP). The published summary of the agreement will be the primary source of information on the TPPA in this report.

[1] Summary of the Trans-Pacific Partnership Agreement, October 5, 2015, https://ustr.gov/about-us/policy-offices/press-office/press-releases/2015/october/summary-trans-pacific-partnership.

Copyright and Online Piracy

The Internet has brought many benefits to users worldwide. Unfortunately, the wide exposure of content around the world has eroded copyright protection, particularly with the advent of online digital file sharing. Although the illegal copying and distribution of music, television shows, and movies have been made easier with the advent of file sharing, the practice, at least for music, dates back to cassette and 8-track tapes.

The companies and organizations hosting pirated versions of songs, films, and television shows on their websites care little about the impact of their illegal activities on filmmakers and songwriters. They seem to believe that the copyright laws are free to be broken and everyone should be able to share copies of songs, television shows, and movies.[2] This trend continues despite efforts to take down infringing content. On September 27, 2014, *The New York Times* reported that according to Tru Optik, a media analytics company, "nearly 10 billion movies, television shows and other files, including games and pornography, were downloaded globally in the second quarter of 2014."[3]

The TPPA addresses online piracy by requiring member nations to commit to protecting copyrighted material, including performances, and audio media such as songs, movies, books, and software through "technological measures and rights management information."[4] Chapter 18 includes an obligation for parties "to continuously seek to achieve balance in copyright systems," and "to establish or maintain a framework of copyright safe harbors" that limits the liability of copyright infringement for Internet Service Providers (ISPs).[5] However, these obligations do not permit member nations to force ISPs to monitor their systems for infringing activities in order to qualify for these safe harbors.

Patents and Trademarks

The patent regime prescribed in the agreement is based on the World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property (TRIPS Agreement) as well as international best practices. Article 27 of the TRIPS Agreement dictates the terms of protection and processes for filing patents in a member country. It requires that patents be made available for any inventions, products, or processes in all fields of technology that are new, involve an inventive step, and are capable of industrial application, without discrimination as to the place of invention, the field of technology, and whether the products are imported or locally produced.[6]

---

[2] Laura Sydell, "Pirates Turn Deaf Ear to Independent Filmmaker," National Public Radio, "All Tech Considered," November 30, 2010, http://www.npr.org/blogs/alltechconsidered/2010/12/01/131677403/pirates-turn-deaf-ear-to-independent-filmmaker.

[3] Jenna Wortham, "The Unrepentant Bootlegger," *The New York Times*, September 27, 2014, http://www.nytimes.com/2014/09/28/technology/the-unrepentant-bootlegger.html?_r=0.

[4] Summary of the Trans-Pacific Partnership Agreement.

[5] Ibid.

[6] Part II, Standards Concerning the Availability, Scope and Use of Intellectual Property Rights, Section 5, Patents, Agreement on Trade-Related Aspects of Intellectual Property, Annex 1C of the Marrakesh Agreement Establishing the World Trade Organization, signed in Marrakesh, Morocco, April 15, 1994, https://www.wto.org/english/tratop_e/trips_e/t_agm0_e.htm.

There are some exclusions to items that can be considered patentable under TRIPS and subsequently the TPPA, including inventions that could be exploited commercially and cause disruptions to public order or morality; or that could protect humans, animals, plants, or health. In addition, diagnostic, therapeutic, and surgical methods for treating humans, or animals other than microorganisms; essential biological processes, or the production of the microbiological process of plants or animals; and plants other than microorganisms cannot be patented under these agreements.[7]

The global economy has created the opportunity for many brand names and trademarked products, including apparel, automobiles, beverages, clothing, household cleaners, fast food chains, liquor, and tobacco, to become well-known across international boundaries. Companies spend hundreds of millions of dollars on advertising and marketing, hoping that their brands will become iconic.

When brands become widely successful and well-recognized, consumers seek them out. Such highly-visible trademarks span language barriers and lifestyles. The value of individual branding can be seen in the reverse side of the equation, when protesters in other countries attack symbols and facilities of U.S.-based companies to object to certain policies or practices. In such cases, the company more or less is the country.

Counterfeiters are well aware of the value of a familiar trademark. They copy the packaging on products ranging from toothpaste to deodorant to tennis shoes in an effort to cash in on the market. Other frequently counterfeited items include batteries, extension cords, perfume, shampoo, and toys.[8]

The TPPA provides and reinforces protection of trademarks that are used to differentiate products in the global marketplace. Title 18 also "requires certain transparency and due process safeguards with respect to the protection of new geographical indications," including those indications covered under international agreements.[9] The TPPA summary emphasizes that the relationship between trademarks and geographical indications is confirmed and understood, and provides "safeguards regarding the use of commonly used terms."[10] Based on this information, the trademark provisions appear to be consistent with the use of existing international agreements for patents.

Biologic Drugs

Data and market exclusivity for biologic drug development is the most controversial aspect related to IP in the TPPA. There are reports that a complicated compromise has been agreed to among the trading countries. On October 4, 2015, *The Wall Street Journal* reported, "Under the bilateral deal, whose exact language is believed to be incomplete, countries in the trade bloc would have an alternative of either providing eight years of exclusivity to biologic drugs, or providing five

---

[7] Lisa L. Mueller, "A Review of the Patent Related Provisions of the TPP- Patentable Subject Matter and Grace Periods, *The National Law Review,* October 14, 2015, http://www.natlawreview.com/article/review-patent-related-provisions-tpp-patentable-subject-matter-and-grace-periods.
[8] Cristina Lourosa-Ricoardo, "The Latest in Counterfeit Goods," *The Wall Street Journal*, December 4, 2011, http://online.wsj.com/news/articles/SB10001424052970204012004577070190846665320.
[9] Summary of the Trans-Pacific Partnership Agreement.
[10] Ibid.

years of so-called data exclusivity plus up to three more years under a regulatory framework."[11] Current U.S. law allows 12 years of reference product exclusivity for biologics.

Data and market exclusivity are separate from patent protection. The Food and Drug Administration (FDA) states, "Patents are granted by the patent and trademark office anywhere along the development lifeline of a drug and can encompass a wide range of claims. Exclusivity is exclusive marketing rights granted by the FDA upon approval of a drug and can run concurrently with a patent or not. Exclusivity is a statutory provision and is granted to an NDA [new drug application] applicant if statutory requirements are met. (See 21 C.F.R. 314.108.) Exclusivity was designed to promote a balance between new drug innovation and generic drug competition."[12]

Because pharmaceuticals are heavily regulated by the FDA, it takes several years for a drug to be approved for marketing while the patent clock is ticking. Currently, in the U.S., a drug's patent expires 20 years from the date of filing. The average time it takes for a drug to go from the research bench to the pharmacy is at least 10 years and can cost $2.6 billion.[13] Therefore, different regulatory exclusivities, such as data or market exclusivity, have been codified to assure that innovators receive a return on their investment and thus, encourage further innovation. After the IP or exclusivity interests expire, generic manufacturers are free to compete.[14]

The Drug Price Competition and Patent Term Restoration Act of 1984 (P.L. 98-417), more commonly known as "Hatch-Waxman," provided the FDA with a way to streamline the approval process for generic drugs. The law also guarantees some certainty to innovator drug companies that their safety and efficacy testing data, which is expensive and takes a long time to produce, will be protected for a certain period of time under data exclusivity. During the data exclusivity period, the FDA cannot rely on the innovator's data to approve a generic for the marketplace. Prior to 1984, there was no separate provision to address generic versions of brand-name drugs. Generic companies often had to do their own safety and efficacy studies even though their drugs were chemically identical to the previously-approved drug, which was a costly and unnecessary process.[15]

In the U.S., for example, orphan drugs get seven years of market exclusivity, a new chemical entity gets five years of market exclusivity, and a pediatric drug gets six months added to an existing patent or exclusivity protection.

In 2010, Congress provided the FDA with a legal framework for bringing a "generic" version for a biologic drug, more appropriately called a biosimilar, to the marketplace via the Biologics Price Competition and Innovation Act (BPCIA) of 2009 that was included in the Affordable Care Act. The three major changes created by BPCIA are (1) an expedited licensure pathway for new versions of

---

[11] William Mauldin, "U.S., Australia Agree on Complicated Compromise on Biologic Drugs," *The Wall Street Journal*, October 4, 2015, http://on.wsj.com/1MJfVIn.
[12] Food and Drug Administration, "Frequently Asked Questions on Patent and Data Exclusivity," http://1.usa.gov/1xKDgTN.
[13] PhRMA, "Pharmaceutical Research and Development, The Process Behind New Medicines," http://onphr.ma/10rS3lH.
[14] John R. Thomas, "The Role of Patents and Regulatory Exclusivities in Pharmaceutical Innovation," Congressional Research Service (CRS #R42890), January 7, 2013, pp. 2-4, http://bit.ly/1jBBdAH.
[15] Ibid.

previously-marketed biologic drugs; (2) data protection and marketing exclusivity periods for biologic drugs; and, (3) patent dispute resolution procedures.[16]

A January 7, 2013 Congressional Research Service document explained that BPCIA established two periods of regulatory exclusivity to brand-name biologics. These are:

> (A) EFFECTIVE DATE OF BIOSIMILAR APPLICATION APPROVAL.—Approval of an application under this subsection may not be made effective by the Secretary until the date that is 12 years after the date on which the reference product was first licensed under subsection (a).
> (B) FILING PERIOD.—An application under this subsection may not be submitted to the Secretary until the date that is 4 years after the date on which the reference product was first licensed under subsection (a).[17]

There had been a great deal of discussion on whether the 12-year exclusivity period meant data or market exclusivity and the FDA in a public hearing notice referred to it as a "12-year period of marketing exclusivity." However, several members of Congress wrote letters to the FDA explaining that the 12-year period "acted as a data exclusivity." Other members explained that the exclusivity "only protects the FDA from allowing another manufacturer to rely on the data of an innovator to support another product. Importantly, it does not prohibit or prevent another manufacturer from developing its own data to justify FDA approval of a similar or competitive product." Other members stated that the FDA can begin reviewing biosimiar applications during the 12-year exclusivity period.[18]

The FDA released guidance in August 2014 that stated "approval of a 351(k) [biosimilar] application may not be made effective until 12 years after the date of first licensure of the reference product, which under the statute excludes the date of licensure of supplements and certain other applications. A 351(k) application for a biosimilar or interchangeable biological product cannot be submitted for review until 4 years after the date on which the reference product was first licensed under section 351(a) of the PHS Act."[19]

The biologic manufacturers have argued that 12 years of data exclusivity is necessary to encourage investment in biologic drugs because they are more complicated and challenging to research and develop and bring to the marketplace.[20] The generic drug industry has argued that, although it fully supports IP protection, recent free trade agreements have "reflected a growing emphasis on the protection of intellectual property rights while failing to ensure timely introduction of generic products in the market."[21]

Data exclusivity, or as it is often called in other countries "regulatory data protection," varies among the TPPA member states from zero to 12 years. With respect to biologics, of the 12 countries in the TPPA, the only countries besides the U.S. that offer more than five years of data exclusivity for

---

[16] Kevin Noonan, "Expert Q&A on Biosimilar Patent Litigation Under the BPCIA," Legal Solutions Blog, December 4, 2014, http://blog.legalsolutions.thomsonreuters.com/corporate-counsel/expert-qa-biosimilar-patent-litigation-bpcia/.
[17] John R. Thomas (CRS #R42890), p. 8.
[18] Ibid, pp. 8-9.
[19] Food and Drug Administration, "Guidance for Industry-Reference Product Exclusivity for Biological Products Filed Under Section 351(a) of the PHS Act," August 2014, http://1.usa.gov/1jEnwB0.
[20] BIO, "The Trans-Pacific Partnership and Innovation in the Bioeconomy: The Need for 12 Years of Data Protection for Biologics," http://bit.ly/1D5ok9o.
[21] GPhA Letter to Stanford K. McCoy, Assistant U.S. Trade Representative for Intellectual Property Protection, Office of the U.S. Trade Representative, March 18, 2011, http://bit.ly/1M7cLNl.

biologics are Canada and Japan, which provide eight years. Australia, New Zealand, Singapore, and Vietnam offer five while Malaysia offers up to five, depending on the given data protection in the originator country. Chile, Mexico, and Peru do not specifically grant data protection to biologics. By comparison, the European Union offers 10 years of data regulatory exclusivity.[22]

President Obama has included in his budget proposals since 2011 that biologic exclusivity protection should be reduced from 12 to seven years. This idea has not gone anywhere in Congress.

The reports on the agreement seem consistent about the length of time for regulatory exclusivity. It therefore seems apparent that the Obama administration has transferred its desire for a shorter regulatory exclusivity to the TPPA negotiations and acceded to the demands of the member countries within the TPPA, many of which have a questionable track record on intellectual property.

Summary

Since the final language of the TPPA has not been released, the summary provides a basic understanding of the agreement. Based on what has been revealed to date, however, the outcome related to IP is somewhat disappointing. The biggest stumbling block related to IP for moving the TPPA forward will be the provisions related to biologics. Agreeing to what appears to be five years of exclusivity when the U.S. currently has 12 is not a compromise; it is a cave-in.

On the other hand, the summary of the TPPA reveals that efforts to weaken copyright protections failed and countries that sign the agreement will be held to the higher standards found in the U.S. Patent protection will follow already-established guidelines in the TRIPS agreement. Countries that sign the TPPA will also be required to protect brands and trademarks. These and other provisions related to enforcement and administration should reduce uncertainty related to the protection of IP in the TPP countries.

When the president indicates that he will sign the agreement, Congress will have 30 days in which to review the proposal before it is released to the general public. Following that 30-day period, the public will be able to review the TPPA for an additional 60 days before the president can sign the agreement. This 90-day period will provide the opportunity for Congress and the general public to comment on aspects of the agreement, as was agreed upon in the TPA.

Over the long term, trade agreements have proven to be beneficial to the U.S. and global economies. The TPPA should be thoroughly vetted with this in mind.

[22] Michael Mezher, "Trade Talks Stumble Over Biologics Data Exclusivity," Regulatory Professional Affairs Society, February 11, 2015, http://bit.ly/1Gn0B7q.