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TPP: Intellectual Property Rights (IPR)

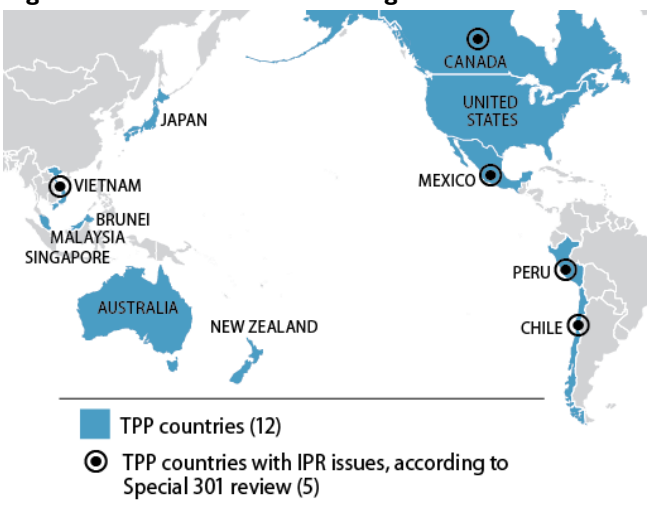
Background

The Trans-Pacific Partnership (TPP) is a proposed free trade agreement (FTA) among the United States and 11 Asia-Pacific countries that would reduce and eliminate tariff and non-tariff barriers on goods, services, and agriculture, and establish trade rules and disciplines, including on IPR protection, which expand on World Trade Organization commitments ("WTO-plus").

IP—creations of the mind embodied in physical and digital objects—are a key source of U.S. comparative advantage. IPR are time-limited rights that governments grant to inventors and artists to exclude others from using their inventions and creations without permission. Advancing IPR protection globally has been a U.S. trade negotiating objective since 1988 (P.L. 100-418), first reflected in the North American Free Trade Agreement (NAFTA) and WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). The 2015 Trade Promotion Authority (TPA, P.L. 114-26) includes prior U.S. trade negotiating objectives for U.S. trade agreements to "reflect a standard of protection similar to that found in U.S. law" ("TRIPS-plus"), and new objectives to combat cyber theft and protect trade secrets. TPP and IPR debate focuses on how to protect and enforce IPR to incentivize innovation, while also securing public benefits from these innovations.

The TPP area is a mix of developed countries, historically IP generators, and developing countries, historically IP importers, but now are growing sources of innovation. The region presents a range of IPR challenges (**Fig. 1**), such as high counterfeiting and piracy rates, including in the digital environment, and weak enforcement of IPR laws. TPP potentially could address IPR concerns in the broader region, including with respect to China and India.

Figure 1. TPP Countries' IPR Regimes



Source: U.S. Trade Representative, *2016 Special 301 Report.*

IP Chapter

The IP chapter aims to support technological innovation to benefit both producers and users, while promoting a balance of rights and obligations. It is enforceable through dispute settlement. It includes phase-in periods for some countries to implement certain provisions. General obligations include upholding international agreements and not discriminating against foreigners on IPR. Specific provisions are discussed below.

Selected IPR Provisions in TPP

A number of provisions in TPP reflect new or updated issues for a U.S. FTA, including in the following areas:

Biologics. Contains provisions on data exclusivity period for biologics, large-molecule drugs developed from living organisms.

Copyright balance. Provides for incorporation of "fair-use" exceptions in country's law.

Internet Service Providers (ISPs). Requires "notice and takedown" to address ISP liability while allowing alternative systems for certain countries (e.g., "notice and notice").

Geographical indications (GIs). Requires administrative procedures for recognizing and opposing GIs, and specific GI commitments in international agreements.

Trade secrets. Requires criminal procedures and penalties for trade secret theft, including cyber theft; clarifies that state-owned enterprises (SOEs) are subject to trade secret obligations.

Enforcement. Extends enforcement to the digital environment.

Patents

Patents protect new innovations, such as pharmaceutical products, chemical processes, business technologies, and computer software. TPP aims to establish consistent and harmonized patent regimes in the region. Some provisions specific to pharmaceuticals aim, based on U.S. trade negotiating objectives, to "encourage innovation and access to medicine." Yet, stakeholders disagree on whether TPP appropriately incentivizes research and development for new medicines while also allowing affordable access to medicines through market entry of generic medicines. Patent rules include:

Patent protection of new products and processes, as well as new uses, methods, or processes of a known product (based on TRIPS's 20 years of minimum protection).

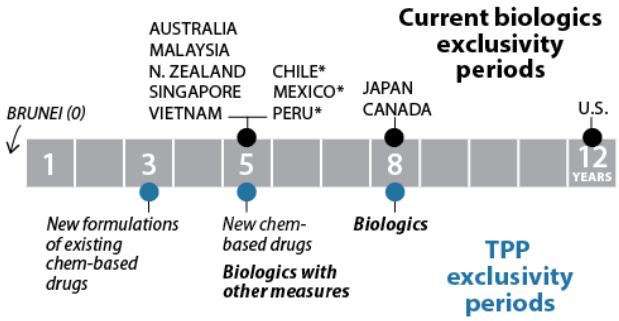
Adjustments of patent terms for "unreasonable" delays in the patent examination or regulatory approval processes—with phase-in periods for Brunei, Malaysia, and Vietnam.

Protection of test data (data innovators submit for regulatory approval on which generics may later rely):

> ***Chemical-based (small-molecule) drugs***: Five years of data exclusivity for new drugs, and three years for new formulations of existing drugs.

Biologics: Eight years of data exclusivity or, five years plus "other measures" to deliver a "comparable outcome." The appropriate period of exclusivity for biologics remains among the most controversial issues in the consideration of TPP (**Fig. 2**).

Figure 2. Data Exclusivity in TPP Countries



Source: CRS.

Notes: *Country does not differentiate data exclusivity for biologics and small-molecule drugs, but has five-year period for the latter.

Notification system and procedures (e.g., judicial or administrative proceedings) to assert patent rights or to challenge a patent's validity. More flexible than patent linkage (regulatory authority cannot grant marketing approval to a generic without the patent holder's permission), which is common to many prior U.S. FTAs.

Copyrights and Related Rights

Copyright provides creators of artistic and literary works with the exclusive right to authorize or prohibit other from reproducing, communicating, or distributing their works. Debate exists over balancing copyright protections while protecting the free flow of information, with digital trade raising new issues. Building on TRIPS, TPP includes:

Copyright terms of life plus 70 years, or 70 years from publication for most works, higher than the TRIPS baseline of life plus 50 years—with phase-in periods for Brunei, Canada, Japan, Malaysia, New Zealand, and Vietnam.

Penalties for circumventing technological protection measures (TPMs), such as encryption.

"Fair use" directive to "endeavor to achieve an appropriate balance" between users and rights holders in their copyright systems, including digitally, through exceptions for legitimate purposes (e.g., criticism, comment, news reporting, teaching, research).

Legal framework and "safe harbors" to allow legitimate online internet intermediaries to develop their business while providing enforcement against digital copyright infringement, as well as "notice and takedown" to address intermediary liability while allowing alternative systems (e.g., "notice and notice" in Canada). U.S. law takes a "notice and takedown" approach.

Trade Secrets

A trade secret is confidential business information (e.g., formula, customer list) that is commercially valuable because it is secret. TPP require criminal procedures and penalties for trade secret theft, including through cyber-theft and by state-owned enterprises (SOEs).

Trademarks

Trademarks protect distinctive commercial names, marks, and symbols. TPP, among other things, provides trademarks with a renewable, 10-year period of protection (as in U.S. law) and removes administrative requirements to enable easier protection and enforcement of trademarks.

Geographical Indications (GIs)

GIs are geographical names that protect the quality and reputation of a distinctive product from a region (e.g., Champagne, Florida oranges). The United States aims to address GI protections that can improperly constrain U.S. agricultural market access in other countries by protecting terms viewed as "common." TPP has procedures for recognizing and opposing GIs, guidelines for determining when a name is common, and transparency requirements for GI protection in international agreements.

Industrial Designs

Industrial designs are the ornamental or aesthetic aspects of a product. The industrial designs section is new to U.S. FTAs. It adds protections beyond TRIPS for designs embodied in a part of an article, or a part of an article "in the context of the article as a whole." It also has hortatory language on improving design registration systems.

Enforcement

TPP includes commitments on civil, criminal, and other national enforcement for IPR violations, such as copyright enforcement in the digital environment, criminal penalties for trade secret theft and camcording, *ex-officio* authority to seize counterfeit trademark and pirated copyright goods at the border. The IP chapter is enforceable through TPP's government-to-government dispute settlement provisions.

IP in Investment Chapter

TPP's investment chapter treats IP as a form of investment that benefits from protections such as non-discriminatory and minimum standard of treatment, compensation for expropriation, and investor-state dispute settlement (ISDS) to address alleged breaches of TPP parties' obligations. ISDS cases such as Philip Morris' suit against Australia for a plain-packing tobacco requirement affecting its trademark (dismissed for lack of jurisdiction) and Eli Lilly's suit against Canada for a patent utility standard invalidating its pharmaceutical patents (pending) have fueled debate over investor protections and governments' regulatory ability.

Issues for Congress

TPP raises a number of possible issues for Congress, including whether it advances U.S. trade negotiating objectives and protects IP and other interests such as public health in the Asia-Pacific. Treatment of biologics may be an especially prominent issue in congressional debate. Other issues include implementation of IPR obligations by TPP parties and the agreement's applicability to enhancing multilateral "rules for the road." See CRS Report R44489, *The Trans-Pacific Partnership (TPP): Key Provisions and Issues for Congress*, and CRS In Focus IF10033, *Intellectual Property Rights (IPR) and International Trade*.

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