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USMCA: Intellectual Property Rights (IPR)

Background

The United States-Mexico-Canada Agreement (USMCA) is a proposed free trade agreement (FTA) negotiated among the three parties to update and replace the 1994 North American Free Trade Agreement (NAFTA). On November 30, 2018, President Trump and the leaders of Mexico and Canada signed USMCA. Congress would need to pass the legislation to implement the agreement before it can enter into force.

USMCA would make notable changes to NAFTA provisions on intellectual property (IP)—creations of the mind embodied in physical and digital objects. IPR are time-limited rights that governments grant to inventors and artists to exclude others from using their inventions and creations without permission. IP is a key source of U.S. comparative advantage; advancing IPR protection globally has been a U.S. trade negotiating objective since 1988 (P.L. 100-418). IPR trade agreement provisions were first included in NAFTA and, subsequently, the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). The 2015 Trade Promotion Authority (TPA, P.L. 114-26) retains 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 adds new objectives to combat cyber theft and protect trade secrets.

Select IPR Provisions in USMCA

Several provisions in USMCA reflect new or updated issues not in current U.S. FTAs, including the following:

Biologics. Requires a 10-year data exclusivity period for biologics, large-molecule drugs developed from living organisms.

Internet Service Providers (ISPs). Establishes flexibilities to address ISP copyright liability.

Geographical indications (GIs). Requires administrative procedures for recognizing and opposing GIs, which protect distinctive products from certain regions, including guidelines for determining “common” names. Also includes transparency and due process procedures for GIs that parties protect through international agreements.

Trademarks. Extends trademark protection to sounds and “collective marks” and removes administrative requirements to enable easier trademark protection and enforcement.

Trade secrets. Requires criminal procedures and penalties for trade secret theft, including cyber theft; clarifies that state-owned enterprises must protect trade secrets.

Enforcement. Extends IPR enforcement to the digital environment.

IP-intensive goods and services are an important part of U.S. trade with Canada and Mexico. The United States has expressed concern over certain IPR policies in both countries in recent years.

IPR Chapter of USMCA

The IPR chapter aims to support technological innovation to benefit both producers and users, while promoting a balance of rights and obligations. It is enforceable through government-to-government dispute settlement. General obligations include upholding international agreements and providing “national treatment”—not discriminating against foreigners on IPR. Some provisions in the IPR chapter have phase-in periods for Canada and Mexico. (IPR issues also arise in the USMCA investment chapter; as a form of investment, IPR benefits from USMCA investor protections. See CRS In Focus IF11167, *USMCA: Investment Provisions*, by Christopher A. Casey and M. Angeles Villarreal.)

Patents

Patents protect new inventions, such as pharmaceutical products, chemical processes, business technologies, and computer software. USMCA defines **patentable subject matter** as new products and processes, as well as new uses, methods, or processes of a known product. Under TRIPS, patented inventions must receive a minimum term of 20 years of protection. USMCA requires **adjustments of patent terms** for “unreasonable” delays in the patent examination or regulatory approval processes. “Unreasonable delays” include a delay of more than five years from the date of filing or three years after a request for examination of an application, whichever is later.

USMCA includes a **notification system and procedures** (e.g., judicial or administrative proceedings) to assert patent rights or to challenge a patent’s validity. These procedures are more flexible than “patent linkage”—a provision common to many prior U.S. FTAs whereby regulatory authority cannot grant marketing approval to a generic drug without the patent holder’s permission.

Regulatory Exclusivities

Some USMCA provisions specific to pharmaceuticals aim, based on U.S. trade negotiating objectives, to “encourage innovation and access to medicine.” Yet debate exists on whether USMCA appropriately incentivizes research and development for new medicines while also allowing affordable access to medicines through market entry of generic medicines. In USMCA, the debate has centered on regulatory exclusivity for **biologic drugs**—drugs made from living organisms (see figure below).

Unlike most patented products, pharmaceuticals must go through a regulatory approval process before they can be marketed. Patent holders (generally, brand-name drug companies) must submit test data to the regulatory authority—the Food and Drug Administration (FDA) in the United States—to make the case for a drug’s safety and effectiveness. The market approval process runs concurrently with any applicable patent term. Thus, the

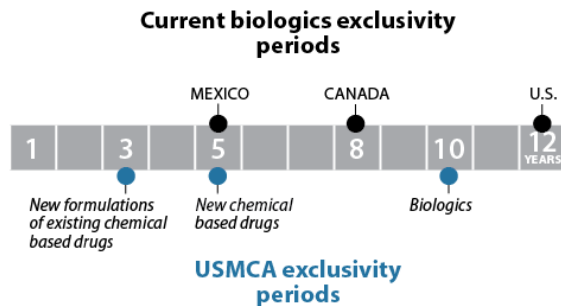
monopoly protection afforded by the patent term effectively is shortened by the time it takes for marketing approval.

A follow-on pharmaceutical, such as a generic drug or biosimilar biologic, can obtain approval via an abbreviated process by relying upon the test data generated to support approval of the reference (brand-name) drug. To balance interests in competition while encouraging innovation, federal law establishes periods of exclusivity that limit FDA's ability to approve marketing applications for follow-on pharmaceuticals under certain circumstances.

Regulatory exclusivity prevents a competing firm from relying on the reference product's data to obtain regulatory approval of a generic drug or biosimilar for a set period of time. In practice, regulatory exclusivities may delay the development of the generic product during that time, which may overlap with, or in some circumstances run beyond the expiration of any applicable patents. For chemical drugs, U.S. law provides a general exclusivity period of 5 years, which U.S. FTAs post-NAFTA have incorporated.

Regulatory exclusivity for biologics was first addressed in the proposed Trans-Pacific Partnership (TPP). U.S. law currently provides a 12-year period of exclusivity for biologics. USMCA would require a period of protection of at least 10 years. This standard would require Canada and Mexico to raise their exclusivity periods by 2 and 5 years, respectively, and would have no immediate effect on the United States (see **Figure 1**).

Figure 1. Regulatory Exclusivity in USMCA Countries



Source: CRS.

Copyrights and Related Rights

Copyrights provide creators of artistic and literary works with exclusive rights to reproduce, publicly perform and display, and distribute their works. Debate exists over balancing copyrights and the free flow of information, and digital trade raises new issues. USMCA includes:

- **Copyright terms** of life plus 70 years, or 70 years from publication for most works, higher than the TRIPS minimum term of life plus 50 years.
- **Civil and criminal penalties** for circumventing technological protection measures, such as digital locks.
- **“Safe harbors”** to allow legitimate online internet intermediaries to develop their business while providing enforcement against digital copyright infringement.
- **“Notice and takedown”** systems to address intermediary liability by which right holders notify online service providers of infringing content to request removal of that content, 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. USMCA requires criminal procedures and penalties for trade secret theft, including through cyber-theft and by state-owned enterprises.

Trademarks

Trademarks protect distinctive commercial names, marks, and symbols. USMCA, 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., Chiapas coffee, Florida oranges, Canadian whiskey). 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,” such as parmesan cheese. USMCA contains due process 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. USMCA provides a minimum term of 15 years of protection for industrial designs, compared to 10 years in NAFTA. It also requires parties to provide an electronic design system for applications and information.

Enforcement

USMCA 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, and *ex-officio* authority for customs officials to seize counterfeit trademark and pirated copyright goods.

Issues for Congress

USMCA's approach to IPR and U.S. trade policy is at the forefront of congressional debate and a potential vote on implementing the agreement. A central issue is whether USMCA advances U.S. trade negotiating objectives and protects IPR and innovation and other interests, such as affordability of pharmaceuticals. Treatment of biologics is especially actively debated in this regard. Some Members of Congress favor eliminating the 10-year regulatory exclusivity requirement for biologics in USMCA; they argue that if USMCA enshrines a 10-year period, it would restrict the ability of Congress to lower that period in future policy discussions. Other Members hold that exclusivity periods are critical for innovation and development of biologics. Additional issues include concerns over the implementation of IPR obligations by USMCA parties and USMCA's potential precedent to enhance multilateral standards. See also CRS Report R44981, *NAFTA Renegotiation and the Proposed United States-Mexico-Canada Agreement (USMCA)*, by M. Angeles Villarreal and Ian F. Fergusson, and CRS In Focus IF10033, *Intellectual Property Rights (IPR) and International Trade* by Shayerah Ilias Akhtar and Ian F. Fergusson.

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