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USMCA: Intellectual Property Rights (IPR)

The United States-Mexico-Canada Agreement (USMCA) is a comprehensive free trade agreement (FTA) that entered into force among the three countries in 2020. It updated and replaced the 1994 North American Free Trade Agreement (NAFTA). Chapter 20 of USMCA contains rules to protect and enforce intellectual property rights (IPR). Congress could have an interest in: overseeing implementation of USMCA's IPR commitments; examining the deal's balance on IPR rules to promote innovation and other policy aims; and considering to what extent, if any, USMCA should serve as a precedent for IPR rules in future U.S. trade deals.

IPR provisions of USMCA, particularly on patent and regulatory protections, were contentious for some Members of Congress and stakeholders after USMCA was initially signed by the three countries in 2018 ("original USMCA"); these provisions underwent changes. Some Members and civil society groups had criticized the provisions in the original USMCA as contributing to rising drug costs. Other Members and pharmaceutical industry groups argued that they fostered U.S. innovation. After negotiations between Congress and the U.S. Trade Representative (USTR), the United States, Canada, and Mexico agreed to a protocol of amendment that changed some of the original USMCA's IPR provisions. These changes may support generic competition. The final USMCA, which entered into force in 2020 after enactment of implementing legislation (P.L. 116-113), incorporated the changes made by the protocol.

IPR and Trade Background

IPR are time-limited protections 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). NAFTA was the first U.S. FTA to include IPR provisions and served as a model for the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). While NAFTA was significant to the use of trade policy to advance IPR internationally, it predated widespread internet use and other technological advances.

The now-expired 2015 Trade Promotion Authority (TPA, P.L. 114-26) reflected prior U.S. negotiating objectives for U.S. trade agreements to "reflect a standard of protection similar to that found in U.S. law," and it added new objectives to combat cyber theft and protect trade secrets. Congress approved USMCA under the 2015 TPA.

IPR Chapter of USMCA

The IPR chapter of USMCA aims to support technological innovation to benefit both producers and users, while promoting a balance of rights and obligations. General obligations include upholding international agreements and providing "national treatment"—that is, not discriminating against foreign nationals on IPR. Some provisions have separate phase-in periods for Canada and Mexico. IPR obligations are enforceable through USMCA's general government-to-government dispute settlement. (USMCA investor protections also apply to IPR. See CRS In Focus IF11167, *USMCA: Investment Provisions*.)

Patents

Patents protect new and useful inventions (e.g., medicines, chemical processes, business technologies, and computer software). USMCA defines patentable subject matter as new products and processes. Unlike some U.S. FTAs, USMCA does not provide patent protection for new uses, methods, or processes of existing inventions.

Under TRIPS, patented inventions must receive a minimum of 20 years of protection. As patents are usually filed before regulatory approval is granted, the effective term may be less than 20 years. USMCA requires adjustments of patent terms for "unreasonable" delays in patent examination or regulatory approvals to restore some of the patent term. "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 has a notification system and procedures (e.g., judicial or administrative) to assert patent rights or to challenge a patent's validity. USMCA lacks the "patent linkage" required in some U.S. FTAs, whereby regulatory authorities (e.g., the U.S. Food and Drug Administration, FDA) cannot grant marketing approval to a generic drug without the patent holder's permission.

Regulatory Exclusivities

USMCA's pharmaceutical provisions aim to "encourage innovation and access to medicine," and the IPR chapter reaffirms the WTO Doha Declaration on TRIPS and Public Health. Stakeholders debated USMCA's balance on incentivizing innovation for new medicines while allowing for affordable medicines through market entry of generics.

Regulatory exclusivity for biologic drugs (drugs made from living organisms), in particular, was a contested issue in the USMCA negotiations. During a regulatory exclusivity period, regulatory authorities cannot approve a generic or biosimilar version of a drug, regardless of patent rights (see **text box**). The original USMCA required at least 10 years of protection for biologics, but the amended version of the USMCA dropped this provision. The 10-year exclusivity period would not have changed the 12-year exclusivity period in U.S. law, but it would have increased the periods in Canada and Mexico, eight and five years, respectively. Some Members of Congress approved eliminating the 10-year exclusivity period from the original USMCA, arguing that it would have restricted the ability of Congress to lower that period in the United States in the future. Some also approved eliminating it to support competition in the pharmaceutical market. Other Members opposed dropping the exclusivity period, arguing that it is critical for innovation and development of biologics in North America.

USMCA has a five-year exclusivity period for new chemical-based drugs, like NAFTA. USMCA does not have a three-year exclusivity period for new formulations of such existing drugs; while the original UMSCA added this provision, the amended version dropped it.

Regulatory Approval and Exclusivity for Drugs

Unlike most patented products, pharmaceuticals are subject to a regulatory approval process before they can be marketed. Patent holders (typically, brand-name drug companies) must submit test data to the regulatory authority (e.g., the FDA) to demonstrate 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, can obtain approval via an abbreviated process by using the reference (brand-name) drug's test data. To balance interests in competition while encouraging innovation, U.S. law sets periods of exclusivity that limit the FDA's ability to authorize marketing of follow-on pharmaceuticals under certain circumstances.

Regulatory exclusivity prevents the regulatory authority from approving a generic drug or biosimilar or precludes a competing firm from using the reference product's data to obtain regulatory approval for a period of time. As such, regulatory exclusivities provide an additional form of protection that may overlap with, or in some cases run beyond, the term of any applicable patents. U.S. law provides a general exclusivity period of 5 years for chemical drugs and 12 years for biologics.

Copyrights

Copyrights provide the authors of creative works (e.g., books, music, fine art) with exclusive rights to reproduce, publicly perform and display, and distribute their works. Debate exists over balancing copyrights and information flows. Digital trade and emerging technologies (e.g., artificial intelligence) raise new issues about infringement and enforcement. USMCA includes:

- *Copyright terms* of life of the author plus 70 years, or 70 years from first 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 internet service providers (ISPs) to develop their business while enforcing against digital copyright infringement.
- *"Notice and takedown"* for ISP liability—right holders notify ISPs of infringing content to request its removal, while allowing for 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., a formula) that is commercially valuable because it is secret. USMCA requires criminal procedures and penalties for trade secret theft, including through cyber-theft and misappropriation by state-owned enterprises. USMCA's Digital Trade chapter protects against forced disclosure of proprietary computer source code and algorithms, which could enhance trade secrets protection.

Trademarks

Trademarks protect distinctive commercial names, marks, and symbols. USMCA 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 to protect the quality and reputation of a distinctive product from a region (e.g., Chiapas coffee, Canadian whiskey, Florida oranges). The United States aims to address GI protections that may impede U.S. access to foreign agricultural markets by protecting terms viewed as "common" (e.g., parmesan cheese). USMCA has due process procedures to recognize and oppose GIs, guidelines to determine when a name is common, and transparency obligations for GI protection in international agreements.

Industrial Designs

Industrial designs are a product's ornamental or aesthetic aspects. USMCA raises the minimum term of protection for industrial designs to 15 years, from 10 years in NAFTA. It also requires parties to provide an electronic industrial design system for applications and information.

Enforcement

USMCA includes commitments on civil, criminal, and other national enforcement for IPR violations, such as copyright enforcement online, criminal penalties for trade secret theft, and *ex-officio* authority for customs officials to seize counterfeit or pirated goods.

USMCA Monitoring

USTR monitors USCMA implementation by Canada and Mexico. For example, Canada extended its general copyright protection term from the life of the author plus 50 years to life plus 70 years, and Mexico amended its copyright law to implement its commitments. At the same time, U.S. government concerns persist about Canada and Mexico's IPR regimes. USTR's 2024 "Special 301" report identified both Canada and Mexico on its Watch List, citing, for example, issues in their enforcement of IPR.

Issues for Congress

USMCA's approach to IPR renewed issues raised in past FTA debates. These issues include whether USMCA's IPR provisions advance and appropriately balance the promotion of innovation and other societal aims, such as public health. Amid heightened interest in supply chains and economic resiliency, Congress could examine whether IPR commitments in USMCA contribute to U.S. comparative leadership in innovation and the North American trading bloc's global competitiveness. Other issues include continued implementation of IPR obligations by Canada and Mexico and enforcement of USMCA by the Administration. Congress also may assess whether USMCA could set precedents on IPR rules for potential future U.S. FTAs or executive trade initiatives, and/or shape multilateral IPR rules and standards. See CRS In Focus IF10997, *U.S.-Mexico-Canada (USMCA) Trade Agreement*.

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