



SETTING A NEW STANDARD

HOW THE USMCA COULD LAY THE FOUNDATION FOR
21ST CENTURY IP PROTECTION



GIPC
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The U.S. Chamber of Commerce's Global Innovation Policy Center (www.theglobalipcenter.com) is working around the world to champion intellectual property rights as vital to creating jobs, saving lives, advancing global economic growth, and generating breakthrough solutions to global challenges.

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This report was conducted by Pugatch Consilium (www.pugatch-consilium.com) a boutique consultancy that provides evidence-based research, analysis, and intelligence on the fastest growing sectors of the knowledge economy. Authors of this report are Meir Pugatch and David Torstensson.

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FROM CUTTING EDGE TO NEEDING A MAKEOVER: 24 YEARS OF NAFTA

Background

The North American Free Trade Agreement (NAFTA) entered into force on January 1, 1994. At the time, it was widely considered as the first international trade agreement that included specific obligations to protect innovative and creative products through intellectual property (IP) rights.¹ Indeed, NAFTA was the precursor to the Trade Related Aspects of Intellectual Property Rights (TRIPS) Agreement—considered by many to be the most comprehensive and ambitious multilateral agreement ever reached in the IP domain²—which was signed a year later and has been ratified by 164 economies. The renegotiation of NAFTA presents an opportunity for an in-depth examination of the IP provisions of this important trade agreement between three economies that together represent 28% of the world’s GDP.³ For a quarter of a century, NAFTA has stood as a model for a regional trade agreement. At the time of ratification and implementation, NAFTA was a pioneer in the IP space and in many respects established a higher floor than did other international treaties, including the subsequent TRIPS agreement.

This is particularly the case for high-tech sectors and IP-intensive industries. IP-intensive industries are a pillar of the U.S. economy. A 2016 study by the Economics and Statistics Administration and the U.S. Patent and Trademark Office (USPTO) finds that IP-intensive companies generated almost 40% of total U.S. economic output and, directly and indirectly, supported over 45 million jobs, or 30% of total U.S. employment.⁴ America’s future prosperity and competitiveness depend on maintaining and nurturing this part of its economy.

Our neighbors to the North and South also play a key role in our economy. Canada and Mexico are two of the United States’ largest and most important trading partners. In 2017, trilateral trade accounted for close to 30% of America’s total trade, or over USD1.1trillion.⁵

The United States-Mexico-Canada Agreement (USMCA) is a significant step forward in strengthening this trilateral relationship. The Agreement provides the potential for a clear and forward-looking international benchmark on IP rights and would set not only an important precedent for future American trade agreements, but also provide a global standard for what IP protection in the 21st century should look like.



International IP Index – Zoom-in

First released in 2012, the International IP Index evaluates the IP systems of 50 economies around the world. The 6th edition of the Index provides a critical perspective on the IP standards that influence both long- and short-term business and investment decisions by the world’s leading innovators and creators. Not only does it assess the state of the international IP environment, it also provides a clear road map for any country that wishes to be competitive in the 21st-century knowledge-based global economy. Large or small, developing or developed, economies from across the world can utilize the insights about their own national IP environments—as well as that of their neighbors and international competitors—to improve their own performance and better compete at the highest levels for global investment, talent, and growth.

This report—otherwise known as Index ‘zoom-in’—accomplishes two goals:

1. benchmarks NAFTA vis-à-vis the International IP Index; and
2. benchmarks the USMCA vis-à-vis the International IP Index.

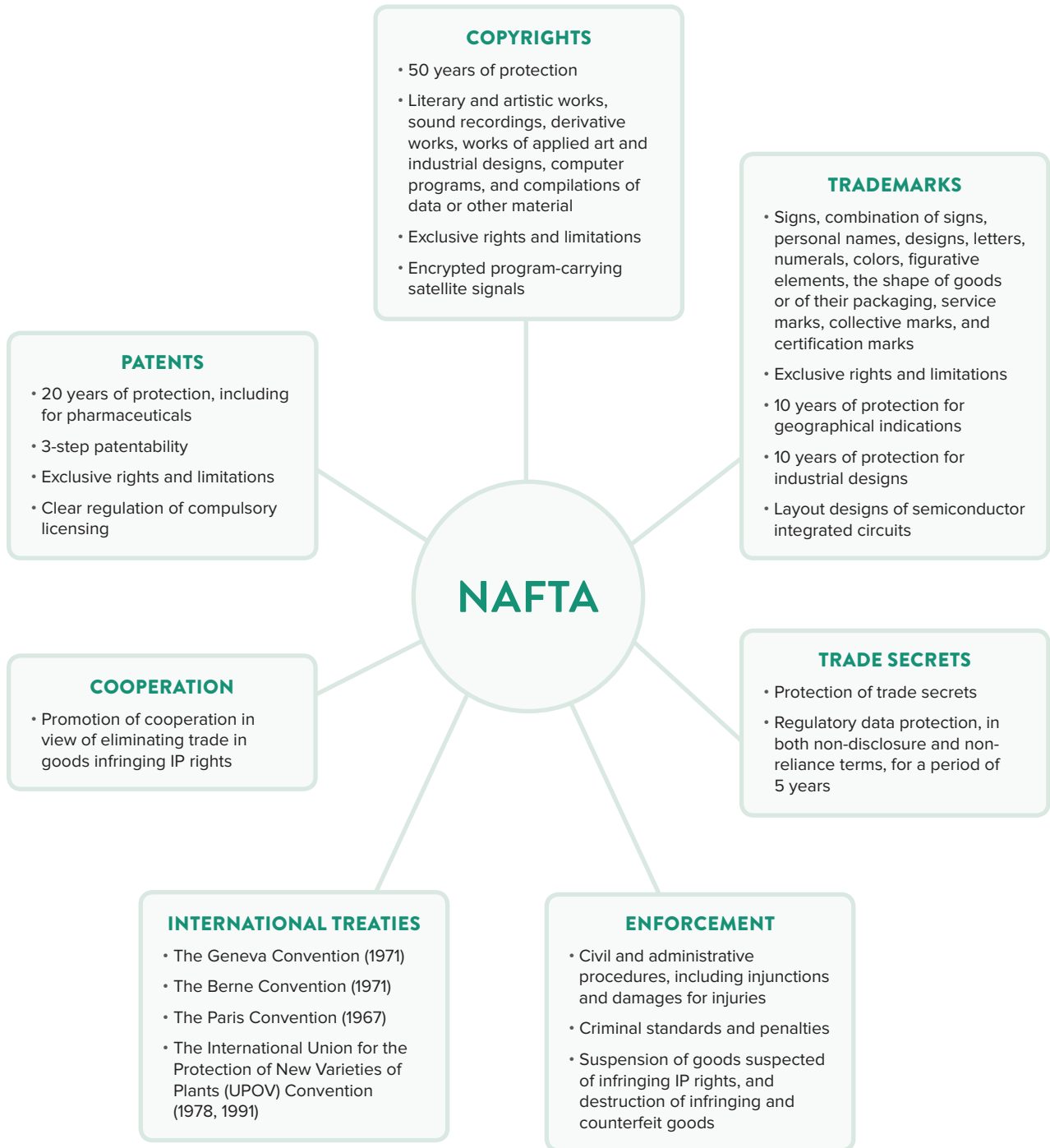
The Basics of NAFTA’s IP Provisions

NAFTA’s chapter 17 on intellectual property is fairly comprehensive, providing not only a minimum level of IP protection but also mechanisms for border enforcement and dispute settlements, and deterrence through penalties and criminal procedures. The chapter also requires that contracting parties adhere to international treaties and conventions, and it ensures that all parties through national treatment maintain all provisions of the chapter.

Figure 1 shows the main IP rights provisions included in NAFTA.



Figure 1: Protection of IP Rights under NAFTA, by Category





As Figure 1 suggests, NAFTA's IP chapter covers important aspects of nearly all categories that constitute the Index. NAFTA also includes unique provisions that have shaped international standards of IP protection over the past quarter of a century, such as:

- **Patentability:** NAFTA required that patent protection will be granted for 20 years “without discrimination as to the field of technology, the territory of the Party where the invention was made and whether products are imported or locally produced,”⁶ using the three-step general rule for patentability (that the invention is *new*, involves an *inventive step*, and is *capable of industrial application*).⁷
- **Limitations on compulsory licensing:** NAFTA defined that each license shall be considered on its own merits, that the use shall be non-exclusive and non-assignable, authorized predominantly for domestic use, and that the rights-holder shall be paid adequate remuneration.⁸ Together with the enactment of Bill C-91 in 1992 and World Trade Organization (WTO) negotiations, NAFTA led to the complete reversal of Canada's long-standing pharmaceutical policy, which since 1923 had relied on the use of compulsory licensing and been a core tenant of Canadian health policy.⁹
- **Pharmaceutical data exclusivity:** NAFTA included an obligation to provide the legal means to prevent the disclosure of (and reliance on) confidential information, including undisclosed test or other data necessary to determine the safety and effectiveness of pharmaceutical products.
- **Enforcement:** NAFTA included substantial provisions relating to the enforcement of IP rights, including civil and criminal procedures, penalties, and measures to prevent the distribution of counterfeit goods and other products that infringe IP rights.

The Devil Is in the Details: Methodology for comparing NAFTA Line by Line with the IP Index

While the NAFTA treaty at first glance appears to cover most, if not all, of the IP rights categorized and measured in the Index, a closer reading of the treaty's articles reveals significant gaps.

To illustrate these gaps, this paper benchmarks NAFTA and USMCA vis-à-vis the methodology used in the 6th edition of the Index, *Create*, similar to how TRIPS and Trans-Pacific Partnership (TPP) treaties were benchmarked vis-à-vis the Index in 2017.¹⁰

It is worth noting that the purpose of this exercise is to approximate the strength of NAFTA and the USMCA relative to the Index. The discussion is not intended to provide a *definitive* score—for reasons outlined below there are methodological challenges that make such conclusions difficult. Nevertheless, it is useful to assess how the provisions of NAFTA and USMCA compare with the indicators included in the Index and calculate an approximate Index score.

To generate an Index approximation for NAFTA, it is assumed for methodological purposes that NAFTA is the minimum IP law in force and that the contracting parties have implemented the principles and rules in NAFTA in full. (As the Index has detailed since 2012, this has not always



been the case. In both Canada and Mexico rights-holders have faced – and continue to face – key challenges with regards to the availability and enforcement of many IP rights defined in NAFTA. In Canada, for example, this has included the patentability of biopharmaceutical innovation and a judicially established doctrine of utility. From the mid-2000s, Canadian Federal Courts issued a high number of decisions on the basis of patent utility in relation to biopharmaceutical patents. Only in June 2017 did the Canadian Supreme Court reject this so-called promise doctrine stating that it “is unsound” and “an interpretation of the utility requirement that is incongruent with both the words and the scheme of the Patent Act” and that “promises are not the yardstick against which utility is to be measured.”) In that light, all NAFTA provisions that may be considered equivalent to the relevant indicators in the Index have been isolated and translated into scores.

This does not include seven indicators from the Index which are inherently not applicable or possible to examine. These include numerical indicators from the Index such as rates of physical counterfeiting and estimated rates of software piracy, which are not part of the remit of NAFTA or the USMCA and thus cannot form a point of comparison. Similarly, IP as an economic asset (indicator 26), Coordination of IP rights enforcement efforts (indicator 34), Consultation with stakeholders during IP policy formation (indicator 35) and Educational campaigns and awareness raising (indicator 36) are also excluded from the comparison for similar reasons. Finally, the metric benchmarking whether a country has at least one FTA with substantive and/or specific IP provisions (indicator 40) is excluded as well. However, the remaining indicators covering membership of and ratification of international treaties (indicators 37, 38, and 39), including the WIPO Internet Treaties; the Singapore Treaty on the Law of Trademarks; and the Patent law Treaty are included.

Leaving these indicators aside, it is possible to compare the remaining Index indicators to NAFTA’s and the USMCA’s IP provisions.

Clearly, some parts of NAFTA are fully equivalent to the Index indicators, whereas others only partially address the Index criteria. Examining NAFTA vis-à-vis these relevant 33 indicators, the provisions in NAFTA correspond—in full or in partial equivalence—to only 20 of the Index’s indicators. Looking, for example, at patents and NAFTA article 1709, patent protection is granted for a term of 20 years from the date of filing (or 17 years from the date of grant), to “any inventions, whether products or processes, in all fields of technology, provided that such inventions are new, result from an inventive step and are capable of industrial application,” and “without discrimination as to the field of technology, the territory of the Party where the invention was made and whether products are imported or locally produced.”¹¹ This can be compared with the Index’s patentability requirements metric (indicator 2), which reads: “The extent to which patentability requirements are in line with international standards of novelty, inventive step, and industrial applicability.”¹² On this basis, NAFTA receives a full point for this indicator. In contrast, with respect to term restoration due to the regulatory approval process, NAFTA article 1709.12 provides that parties “may extend the term of patent protection ... to compensate for delays caused by regulatory approval processes.” The term of protection is not defined, resulting in a score of 0.5. As discussed in more detail below, this can be contrasted with the Index in which the benchmark term of restoration is 5 years.



Copyright and related rights are a similar story. Article 1705.4 of NAFTA provides copyright protection for a term of 50 years. This compares with the Index’s benchmark of 95 years (the baseline term of protection for certain works in the United States), and thus NAFTA receives a score of 0.53 for indicator 9.

Another area where NAFTA is not fully equivalent to the Index pertains to regulatory data protection (RDP) term (indicator 23). The Index uses the benchmark term of protection of 8+2 (10) years of data and market exclusivity protection used in the European Union (EU) for small- and large-molecule products. Conversely, NAFTA’s article 1711.6 provides only a 5-year term of protection, leading to a score of 0.5.

An update is in order: NAFTA fails to achieve 50% of the total Index score.

Translating NAFTA provisions into scores for the above described and relevant 33 indicators, the NAFTA agreement ultimately receives an overall Index score of 15.93, or 48.3%.¹³

As figures 2 and 3 show, this represents less than 50% of the total Index score, with gaps between NAFTA and the Index that range from 25% in the trade secrets and related rights indicators to 70% in the copyrights, related rights, and limitations indicators.

Considering the technological developments and economic realities of today, 25 years after NAFTA was first introduced, it is not surprising that overall NAFTA standards represent a rather low bar of national IP protection compared with those necessary to build a 21st-century knowledge-, innovation-, and creativity-based economy.

Yet, even the standards included in the initial Trans-Pacific Partnership (TPP) agreement fall well short of the 21st century IP protections embodied in the Index. As figure 3 demonstrates, the TPP receives an overall Index score of 23.79. This is the result of a number of gaps relative to the Index, including the term of regulatory data protection, provisions on ISP liability, and the text on localization and licensing barriers. Thus, the IP chapter in the modernized NAFTA agreement must go beyond the standards included in the TPP-12 agreement in order to create a new gold standard for IP in free trade agreements.



Figure 2: Approximating NAFTA on the Index, Scores by Category

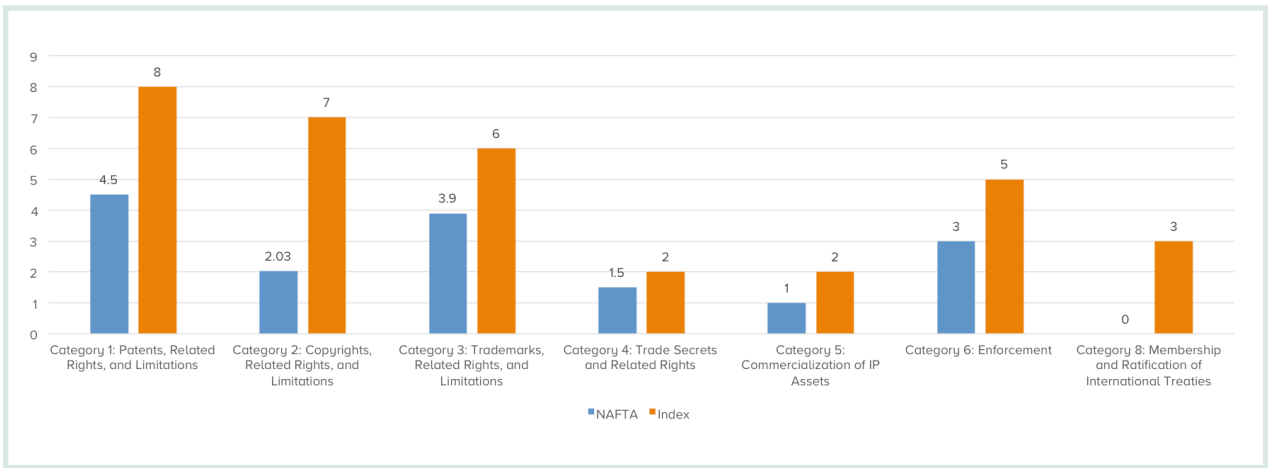
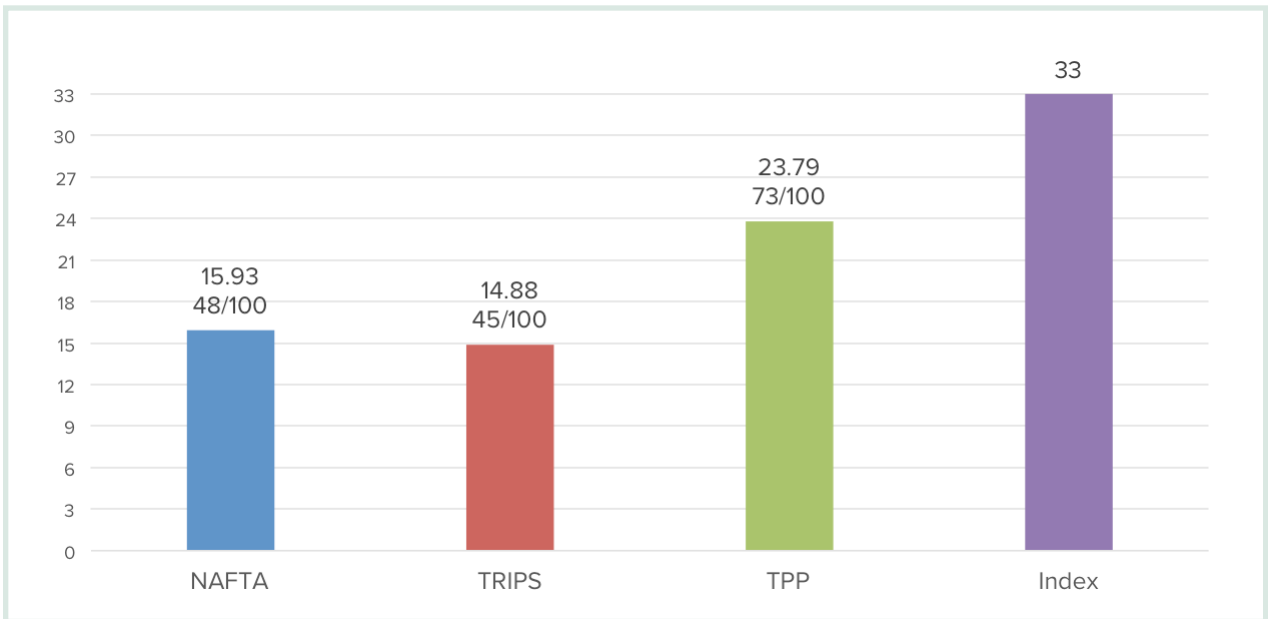


Figure 3: Approximating NAFTA, TRIPS, and TPP on the Index, Total Score





Building an IP Chapter for the 21st Century: Where Are the Gaps in NAFTA?

As mentioned, several provisions in NAFTA only partially meet the standards of the indicators used in the Index. In addition, of the 33 indicators examined, 13 (39%) are missing altogether from NAFTA.

Category 1: Patents, Related Rights, and Limitations

Looking at patents and related rights, NAFTA's provisions regarding term restoration are not defined. Article 1709.12 provides that parties "may extend the term of patent protection ... to compensate for delays caused by regulatory approval processes." But unfortunately, article 1709.12 does not reference the length and extent of the term of protection. This omission has had significant and long-standing consequences. Neither Mexico nor Canada have introduced adequate term restoration mechanisms. Up until the conclusions of the negotiations for the Comprehensive Economic and Trade Agreement (CETA) in 2014, Canada was one of only a handful of high-income Organisation for Economic Co-operation and Development (OECD) economies in the world that did not provide for a term of restoration for patent years lost due to regulatory and administrative approval processes for biopharmaceuticals. Following the implementation of CETA in 2017, Canada has now introduced a new regulatory scheme that allows for some compensation for delays in obtaining marketing approval for biopharmaceutical products.

The relevant amendments made to the Patent Act (sections 106–134) and implementing regulations published in the *Canada Gazette* provide a maximum restoration period of 2 years through a Certificate of Supplementary Protection (CSP) mechanism. While this is a positive step and an improvement in Canada's biopharmaceutical IP environment, significant areas of concern remain. Under section 116(4), the Canadian government retains the right to reduce the term of protection at its discretion. Specifically, this subsection states that "the Minister may, if he or she is of the opinion that that person's [the rights-holder's] failure to act resulted in a period of unjustified delay in the process of obtaining the authorization for sale, reduce the term of the certificate when issuing it by the amount of that period." No further definition of what constitutes an "unjustified delay" has been provided in any of the relevant regulations, which leaves a broad scope for interpretation with the Canadian government. Moreover, the implementing regulations contain a "Timely Submission Requirement," which sets a timeline for the submission of CSP applications based on the regulatory status of a given product in a set of "prescribed economies." The net effect is that the availability of a CSP is contingent upon early market entry. Equally troublingly, the law also contains an export claw-out, with section 115(2) effectively exempting the infringement of CSP protection if the production of an analogous product is for the purpose of exports. This stands in stark contrast to the standards established and used in the Index. Patent term restoration for pharmaceutical products (indicator 6) is measured by the current baseline rate of 5 years, which is used in both the United States and the EU. This protection is aimed at restoring the patent term granted to innovative pharmaceutical products due to the prolonged research, development, and regulatory approval periods of such products.



Category 2: Copyrights, Related Rights, and Limitations

Copyright is the category of IP rights in which technological developments have left NAFTA the furthest behind. When NAFTA negotiated, the internet was in its infancy. Music was primarily bought and sold via the compact disc (CD), which by the mid-1990s had overtaken both vinyl records and cassettes as the primary way consumers bought and sold music. By 2000, annual CD sales in the United States were just under 1 billion albums.¹⁴ Today, CD sales are less than 100 million albums annually, and major American retailers are no longer carrying the medium. For example, major American electronics retailer Best Buy announced in early 2018 that it would no longer sell CDs in its stores.¹⁵ As CD sales have decreased, users are increasingly accessing music online. In 2010, an estimated 28.8% of the world's total population (just under 2 billion people) had access to the internet.¹⁶ By the end of 2017, this figure had doubled to 4.2 billion internet users (or 54.4% of the global population). Technological advances and the globalized use of the internet has resulted in new, complex routes of illicit activity and new challenges for rights-holders, such as the illegal distribution of copyright-protected materials through streaming and torrent websites, pirated software, and more. Given the importance of the online environment to creators and copyright holders, the Index includes clear and unambiguous standards with respect to online infringement in four separate indicators relating to copyright. They are:

10. Legal measures that provide necessary exclusive rights that prevent infringement of copyrights and related rights (including web hosting, streaming, and linking);
11. Expedient injunctive-style relief and disabling of infringing content online;
12. Availability of frameworks that promote cooperative action against online piracy; and
14. Digital rights management legislation.

Together, these indicators provide a set of standards and protections that rights-holders and creators require to operate within a digital and online sphere. The challenge of protecting copyright online is constantly evolving alongside new technologies and mechanisms for infringement. Given the growth in online piracy globally, it is critical that new mechanisms are made available that enable rights-holders to effectively enforce their copyright. One area where new standards and methods of enforcement are being developed is through injunctive-style relief mechanisms. Specifically, the Index's indicator 11 (introduced in the 6th edition of the Index) measures the existence and extent of an official national government or judicial injunctive relief-type mechanism available to rights-holders upon request. Given the scale and speed of online infringement, the mechanism should provide for the effective and timely disabling of access to websites that have the primary function of providing access to infringing content online, whether from a national or a foreign source. Another area of copyright protection that has seen modern legal developments is the term of protection offered. Currently, NAFTA articles 1705.4 and 1706.2 provide a minimum term of protection of only 50 years for copyrighted works (excluding applied art and photographs); this is significantly shorter than the baseline term of 95 years used in the Index.

Category 3: Trademarks, Related Rights, and Limitations

Looking at trademarks and related rights, two particular gaps stand out.



First, as with copyrights, NAFTA lacks provisions relating to online purchases and infringement, in this case concerning relevant enforcement mechanisms against online sale of counterfeit goods. As more consumers use the internet, online shopping is growing in popularity. While still smaller than brick-and-mortar shopping, e-commerce accounts for a growing share of total global retail sales. In 2017, total e-commerce sales worldwide were estimated at USD2.3trillion, up by nearly 25% from 2016.¹⁷ E-merchants and online platforms such as e-Bay, Amazon, Alibaba, Mercado Libre, and others account for a growing share of global retail sales. Unfortunately, as online shopping becomes more popular, so too does the proliferation and sale of counterfeit goods. For example, many online merchants are included in the Office of the U.S. Trade Representative's (USTR) 2018 *Notorious Markets List*, such as DHGATE.com, Indiamart, and Taobao.¹⁸ The Index metric on availability of frameworks that promote action against online sale of counterfeit goods (indicator 19) measures the existence of clear rules and standards for the expeditious removal of trademark infringing material by online service providers upon obtaining knowledge of the infringement. The indicator accounts for whether the overall system unduly burdens such providers, promotes cooperation between internet service providers and rights-holders to address the infringement of trademark rights, and respects and protects consumers' rights.

However, only a few countries (including Canada and Mexico) have in place effective mechanisms to combat the increased sale of counterfeit goods through online sales platforms and merchants. There are private initiatives—such as e-Bay's Verified Rights Owner Program—where online merchants have measures in place to combat the sale of counterfeit goods. There are also some examples of countries where relevant primary or secondary legislation does include an obligation on the part of online platforms and merchants to take down IP-infringing material upon notification by a rights-holder. For example, in the EU, principles and obligations were established with regard to the E-Commerce Directive and online platforms in the 2011 European Court of Justice Case C-324/09, *L'Oréal SA and others v. eBay International AG and others*. But overall, the mechanisms in place are outweighed by the sheer quantity of counterfeit goods available online.


Second, NAFTA's term of protection for industrial design is substantially lower than international standards and benchmarks used in the Index. The industrial designs term of protection metric (indicator 20) uses the baseline term of 25 years—the maximum afforded in the European Union—as a benchmark. In contrast, NAFTA article 1713.5 provides for a minimum protection of 10 years for industrial design.

Category 4: Trade Secrets and Related Rights

NAFTA's article 1711 covers trade secrets and related rights, including provisions for RDP.

Under NAFTA, information is defined as a trade secret if it:

- is not generally known among or readily accessible to persons who normally deal with the kind of information in question;
- has actual or potential commercial value because it is secret; and
- is kept secret by the person lawfully in control of it.



The contracting parties are obliged to provide the legal framework for preventing trade secrets from unauthorized disclosure, acquisition, or use in a manner contrary to honest commercial practices. Furthermore, NAFTA's provisions prohibit contracting parties from limiting the duration of protection for trade secrets and from impeding the voluntary licensing of trade secrets through, for example, discriminatory conditions that dilute the value of the trade secrets.

But by modern standards, NAFTA's provisions on trade secrets are relatively limited. For example, unlike modern trade secret legislation in many economies, NAFTA does not include criminal procedures and penalties for unauthorized and willful disclosure, acquisition, and access to a trade secret.

Additionally, NAFTA's data and market exclusivity provisions for submitted pharmaceutical test data are low by international standards. NAFTA was one of the pioneers in terms of RDP; it was the first international treaty to define a term of protection and require contracting parties not only to safeguard this data from unfair commercial use but also to explicitly disallow reliance on this data for the approval of follow-on pharmaceutical products. Article 1711.6 provides a clear and unambiguous minimum term of protection of 5 years. But as medical technology has changed and the research and development (R&D) process for biopharmaceuticals has become longer, more resource-intensive and riskier standards of data exclusivity have evolved. Today the EU provides a term of protection according to the 8+2+1 formula. New biopharmaceutical products are entitled to 8 years of data exclusivity, 2 years of marketing exclusivity (in which generic companies would be allowed to submit bioequivalence tests), and an additional year of protection for new indications of existing products. This is explained in article 10 of Directive 2001/83/EC.¹⁹ While the United States has maintained its 5-year term of protection, it has a separate and distinct term of protection for biologics: the Biologics Price Competition and Innovation Act of 2009 provides 12 years of data protection to biologics (i.e., 12 years until a biosimilar can be approved), with no filing of biosimilar applications for the first 4 years and an extra 6 months (added to both the 4 years and the 12 years) for submission of studies on pediatric use.²⁰ With respect to the Index, indicator 23 (Regulatory data protection term) uses as the benchmark the EU's 10-year (8+2) term of exclusivity for new biopharmaceutical products containing new active ingredients regardless of molecular size and/or complexity.

Category 6: Enforcement

Additional notable gaps within NAFTA include a lack of provisions relating to border enforcement. Given the increase in counterfeit goods imported to North America from China and Hong Kong, NAFTA's border provisions must be strengthened to better protect North America consumers. Seizure data from the United States, the EU, and Japanese customs authorities from 2010 to 2014 reveal that the amount of counterfeit goods seized from China or Hong Kong accounts for some 85% of counterfeit goods imported into the world's three largest markets (with a shared market value of nearly USD2 trillion each year). Indeed, of counterfeit goods seized by the U.S. Customs and Border Protection (CBP), China's share as the economy of origin has increased from 12.5% in 1995 to 73.6% in 2005. Additionally, of counterfeit goods seized by the EU and Japanese customs authorities, China's share of counterfeit goods increased in 2008 from 55% and 53.9% to more than 72% and 75.8%, respectively, in 2013.



Because of the increase in trade in counterfeit goods, NAFTA's border enforcement mechanisms require modernization to address two major deficiencies:

1. there is no requirement of parties to provide their customs and border officials with *ex officio* authority, instead relying on a notification regime; and
2. there is no requirement to take action against suspected goods in transit.

Article 1718.1 states that:

Each Party shall adopt procedures *to enable a right holder*, who has valid grounds for suspecting that the importation of counterfeit trademark goods or pirated copyright goods may take place, *to lodge an application in writing* with its competent authorities, whether administrative or judicial, for the suspension by the customs administration of the release of such goods into free circulation. *No Party shall be obligated to apply such procedures to goods in transit.* [Emphasis added]

This is in contrast with the Index's effective border measures metric (indicator 32), which is measured by (1) the extent to which goods, in transit, suspected of infringement may be detained or suspended and (2) the extent to which border guards have the *ex officio* authority to seize suspected counterfeit and pirated goods without complaint from the rights-holder.

Category 8: International Treaties

Similarly, over the past two decades several international IP treaties have been promulgated and now form an important internationally accepted and recognized standard of IP protection and enforcement. The Index includes three specific such treaties:

1. the World Intellectual Property Office (WIPO) Internet Treaties (which consists of the WIPO Copyright Treaty and the WIPO Performances and Phonogram Treaty);
2. the Singapore Treaty on the Law of Trademarks; and
3. the Patent Law Treaty.

All three are recognized as representing 21st-century standards of IP protection within their respective areas. The importance of these treaties to global IP standards is reflected by the requirement that contracting parties in recent international trade agreements (including CETA, the EU-Mexico Agreement, and the original Trans-Pacific Partnership) join these treaties.

Table 1 provides NAFTA's scores within the Index's 40 indicators and summarizes the main gaps in NAFTA vis-à-vis the Index.

Table 1: NAFTA Scores and Gaps Vis-à-Vis the Index

INDEX INDICATORS	NAFTA
Category 1: Patents, Related Rights, and Limitations	
1. Patent term of protection	1
2. Patentability requirements	1
3. Patentability of computer-implemented inventions	1
4. Pharmaceutical-related patent enforcement and resolution mechanism	0
5. Legislative criteria and active use of compulsory licensing of patented products and technologies	1
6. Patent term restoration for pharmaceutical products	0.5
7. Membership in Patent Prosecution Highways (PPHs)	0
8. Patent opposition	0
Category 2: Copyrights, Related Rights, and Limitations	
9. Copyright (and related rights) term of protection	0.53
10. Legal measures that provide necessary exclusive rights that prevent infringement of copyrights and related rights (including web hosting, streaming, and linking)	0.5
11. Expeditious injunctive-style relief and disabling of infringing content online	0
12. Availability of frameworks that promote cooperative action against online piracy	0
13. Scope of limitations and exceptions to copyrights and related rights	1
14. Digital rights management legislation	0
15. Clear implementation of policies and guidelines requiring that any proprietary software used on government information and communications technology (ICT) systems should be licensed software	0
Category 3: Trademarks, Related Rights, and Limitations	
16. Trademarks term of protection (renewal periods)	1
17. Ability of trademark owners to protect their trademarks: requisites for protection	1
18. Legal measures available that provide necessary exclusive rights to redress unauthorized uses of trademarks	0.5
19. Availability of frameworks that promote cooperative private action against online sale of counterfeit goods	0
20. Industrial design term of protection	0.4
21. Legal measures available that provide necessary exclusive rights to redress unauthorized use of industrial design rights	1
Category 4: Trade Secrets and Related Rights	
22. Protection of trade secrets	1
23. RDP term	0.50
Category 5: Commercialization of IP Assets	
24. Barriers to market access	0.5
25. Regulatory and administrative barriers to the commercialization of IP assets	0.5
Category 6: Enforcement	
29. Civil and procedural remedies	1
30. Pre-established damages and/or mechanisms for determining the amount of damages generated by copyright infringement	1
31. Criminal standards including minimum imprisonment and minimum fines	1
32. Effective border measures	0
33. Transparency and public reporting by customs authorities of trade-related IP infringement	0
Category 8: Membership and Ratification of International Treaties	
37. WIPO Internet Treaties	0
38. Singapore Treaty on the Law of Trademarks	0
39. Patent Law Treaty	0
TOTAL SCORE	15.93



Category 1: Patents, Related Rights, and Limitations
• Lack of requirement for a pharmaceutical-related patent enforcement and resolution mechanism
• Patent term restoration undefined
• No requirement for membership in PPHs
• No reference to the design of patent opposition frameworks
Category 2: Copyrights, Related Rights, and Limitations
• Insufficient term of protection for copyrights
• No provision of mechanisms for expeditious injunctive-style relief and disabling of infringing content online
• No reference to the online enforcement of copyright, including web hosting, streaming, and linking
• No reference to frameworks that promote cooperative action against online piracy
• No provisions on Digital Rights Management legislation
• No provisions on Internet Service Provider (ISP) liability
• No requirement of policies/official guidelines requiring that any proprietary software used on government ICT systems should be licensed software
Category 3: Trademarks, Related Rights, and Limitations
• No requirement for cooperative private action against online sale of counterfeit goods
• Insufficient term of protection for industrial designs
Category 4: Trade Secrets and Related Rights
• Lack of criminal procedures and penalties imposed on unauthorized disclosure, acquisition, or use of a trade secret in a manner contrary to honest commercial purpose
• Insufficient term of protection for RDP
Category 6: Enforcement
• Lack of provision requiring ex officio authority for customs officials, and authority to detain goods in transit that are suspected of infringing IP rights
• No requirement for transparency and public reporting by customs authorities of trade-related IP infringement
Category 8: Membership and Ratification of International Treaties
• No requirement to sign and ratify the WIPO Internet Treaties, the Singapore Treaty on the Law of Trademarks, and the Patent Law Treaty

Overall, compared with the Index, NAFTA achieves an Index score of 15.93, or 48.3%—less than half of the available score. From these results it is clear that there remains quite a lot of work to do in most categories and in IP rights measured in the Index.

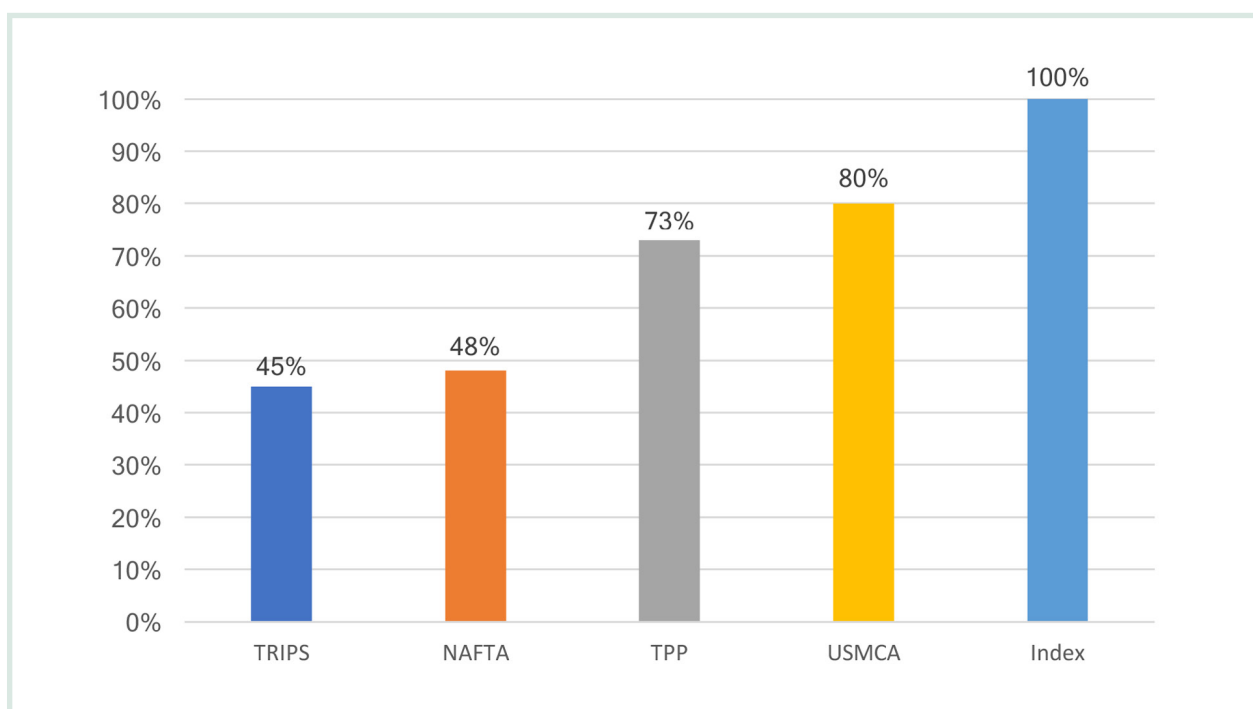
Stronger IP protection through the USMCA: An opportunity for gaining a competitive edge and achieving economic and societal aspirations

While NAFTA was significant in its time for inclusion of IP obligations in a regional trade agreement, as discussed dramatic changes in technology and the structure and integration of the global economy require future trade agreements to be more comprehensive and detailed than preceding free trade agreements (FTAs). In fact, U.S. FTAs NAFTA have made continuous progress towards improving the baseline of IP obligations. The USMCA builds on that experience, providing a global standard for what IP protection in the 21st century should look like and for others a foundation to build upon for future agreements. Chapter 20 of the USMCA includes 21st century IP provisions such as:

- Stronger pharmaceutical-related IP protection including regulatory data protection terms of 5 years for new chemical entities (NCEs) and 10 years for biologics;
- More effective trade secret protection including criminal sanctions;
- *Ex officio* border enforcement against all suspected counterfeit goods including goods in-transit; and
- Some strengthened copyright provisions, including a longer term of protection, digital rights management (DRM)/technological protection measures (TPM), and retains the longstanding exceptions and limitations provision in U.S. FTAs, limited to the long-standing, internationally recognized *Berne* three-step test.

To illustrate the strength of the USMCA’s IP chapter, we have benchmarked the Agreement against relevant indicators from the Index using the same methodology as above with NAFTA.²¹ Below Figure 4 shows the results and the USMCA’s score on the Index.

Figure 4: Comparing TRIPS, NAFTA, TPP, and the USMCA with the Index




As Figure 4 suggests the USMCA’s IP-related provisions are a significant upgrade over NAFTA, TRIPS, and the original TPP agreement. As this comparison shows, the USMCA comes the closest yet in achieving an IP standard that is comparable to U.S. law and the standards reflected in the Index. This is also illustrated by Table 2 below which provides an overview of how the USMCA’s IP provisions score on the relevant indicators from the Index’s 40 indicators.



Table 2: USMCA scores and gaps vis-à-vis the Index

INDEX INDICATORS	NAFTA
Category 1: Patents, Related Rights, and Limitations	
1. Patent term of protection	1
2. Patentability requirements	1
3. Patentability of computer-implemented inventions	1
4. Pharmaceutical-related patent enforcement and resolution mechanism	1
5. Legislative criteria and active use of compulsory licensing of patented products and technologies	1
6. Patent term restoration for pharmaceutical products	0.5
7. Membership in Patent Prosecution Highways (PPHs)	0.5
8. Patent opposition	0
Category 2: Copyrights, Related Rights, and Limitations	
9. Copyright (and related rights) term of protection	0.76
10. Legal measures that provide necessary exclusive rights that prevent infringement of copyrights and related rights (including web hosting, streaming, and linking)	0.5
11. Expeditious injunctive-style relief and disabling of infringing content online	0
12. Availability of frameworks that promote cooperative action against online piracy	0.5
13. Scope of limitations and exceptions to copyrights and related rights	1
14. Digital rights management legislation	1
15. Clear implementation of policies and guidelines requiring that any proprietary software used on government information and communications technology (ICT) systems should be licensed software	1
Category 3: Trademarks, Related Rights, and Limitations	
16. Trademarks term of protection (renewal periods)	1
17. Ability of trademark owners to protect their trademarks: requisites for protection	1
18. Legal measures available that provide necessary exclusive rights to redress unauthorized uses of trademarks	0.75
19. Availability of frameworks that promote cooperative private action against online sale of counterfeit goods	0
20. Industrial design term of protection	0.6
21. Legal measures available that provide necessary exclusive rights to redress unauthorized use of industrial design rights	1
Category 4: Trade Secrets and Related Rights	
22. Protection of trade secrets	1
23. RDP term	0.75
Category 5: Commercialization of IP Assets	
24. Barriers to market access	0.75
25. Regulatory and administrative barriers to the commercialization of IP assets	0.75
Category 6: Enforcement	
29. Civil and procedural remedies	1
30. Pre-established damages and/or mechanisms for determining the amount of damages generated by copyright infringement	1
31. Criminal standards including minimum imprisonment and minimum fines	1
32. Effective border measures	1
33. Transparency and public reporting by customs authorities of trade-related IP infringement	1
Category 8: Membership and Ratification of International Treaties	
37. WIPO Internet Treaties	1
38. Singapore Treaty on the Law of Trademarks	1
39. Patent Law Treaty	1
40. Post-TRIPS FTA	1
TOTAL SCORE	27.36



Compared with NAFTA the USMCA scores higher across the board on all Index categories and contains either in full or partially almost all comparable indicators measured in the Index.

Online copyright protection

As more and more people around the world connect to their favourite content digitally and online the availability of infringing content poses a direct and very significant threat to the creative industries. The USMCA does contain some specific references to this threat and provides some relevant remedies. For example, articles 20.H.2: Right of Reproduction and 20.H.3: Right of Communication to the Public both outline rights-holder's exclusive rights with reference to the online space. For instance, article 20.H.2 clearly states that "Each Party shall provide to authors, performers and producers of phonograms the exclusive right to authorize or prohibit all reproduction of their works, performances or phonograms in any manner or form, **including in electronic form.** [Emphasis added]" Similarly, 20.H.3: Right of Communication to the Public provides a broad and clear right of communication to the public via all means including electronic distribution. The article states that:

...each Party shall provide to authors the exclusive right to authorize or prohibit the communication to the public of their works, by wire or wireless means, including the making available to the public of their works in such a way that members of the public may access these works from a place and at a time individually chosen by them [Emphasis added].

However, the USMCA is unclear on the required type of notification and safe harbour regime. On the one hand, article 20.J.11 is quite clear that a notice and take-down regime should be in place with there being a clear requirement that to be exempt from any secondary liability ISPs should "expeditiously remove or disable access to material residing on their networks or systems upon obtaining actual knowledge of the copyright infringement or becoming aware of facts or circumstances from which the infringement is apparent, such as through receiving a notice of alleged infringement from the right holder or a person authorized to act on its behalf". On the other hand, the "Annex to Section J" provides a pretty substantial carve-out for Canada's existing notice-and-notice regime:

In order to facilitate the enforcement of copyright on the Internet and to avoid unwarranted market disruption in the online environment, Article 20.J.11.3, Article 20.J.11.4, and Article 20.J.11.6 (Legal Remedies and Safe Harbours) shall not apply to a Party provided that, as from the date of agreement in principle of this Agreement, it continues to...(e) induce Internet Service Providers carrying out the function referred to in Article 20.J.11.2(c) (Legal Remedies and Safe Harbours) to remove or disable access to material upon becoming aware of a decision of a court of that Party to the effect that the person storing the material infringes copyright in the material.

While it is positive that this provision references a secondary liability for infringement-type of principle, there are significant problems with Canada's existing notice and notice regime. While the 2012 amendments to the Canadian Copyright Act contained a clear system of notification



between rights holders and ISPs, they did not provide an equivalent takedown mechanism or obligation on the part of ISPs and providers of “information location tools.” Consequently, with this carve-out the Agreement fails to uphold what is a pretty fundamental part of combating online piracy in the 21st century.

Similarly, there is no requirement in the Agreement for one of the most forward-looking and effective means of limiting access to infringing content: injunctive-style relief. First pioneered in Europe injunctive style relief allows rights-holders to get immediate and effective relief against online infringement. Economies that have introduced some system of injunctive style relief include a growing number of EU Member States, Australia and Singapore. Illegal, often foreign based, websites such as *The Pirate Bay* have been effectively disabled and, when appropriately implemented, overall piracy rates have decreased measurably in the economies that have introduced these measures. The USMCA does not contain any language or thinking on such a mechanism.

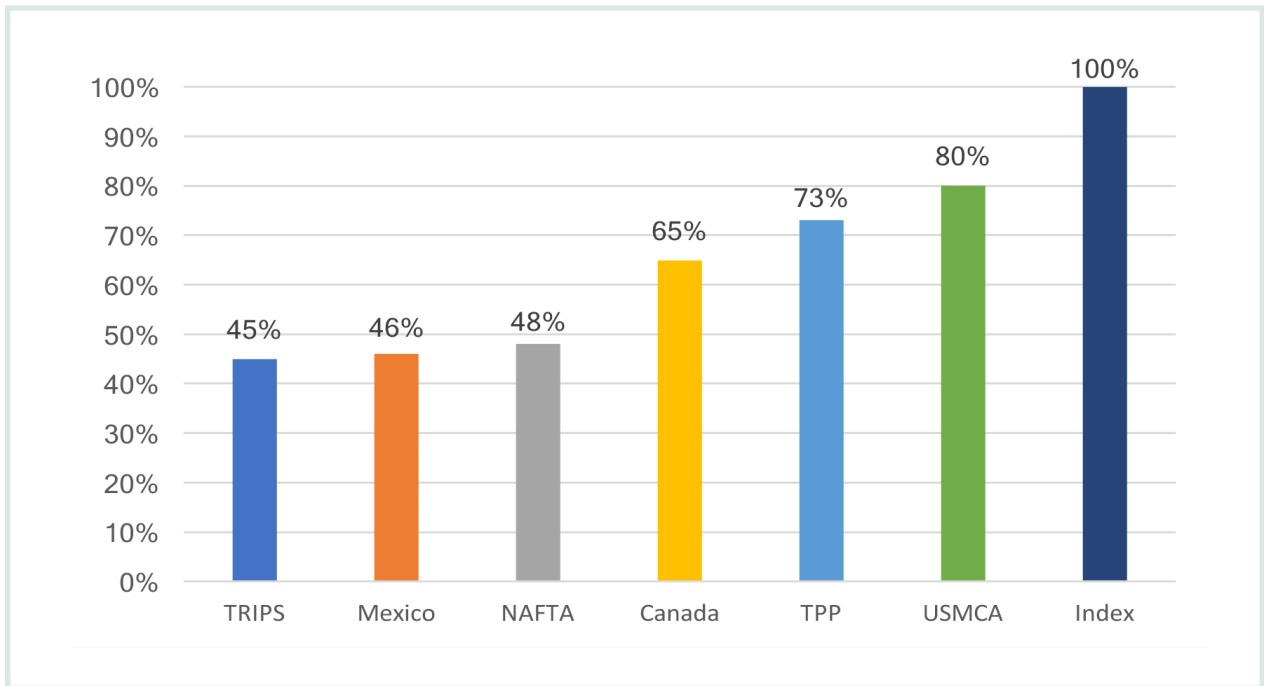
Canadian cultural industries exception

The biggest threat to the USMCA in establishing a strong global baseline for IP protection lies in its exclusion of a whole swathe of the Canadian economy. Under Article 32.6 of the Agreement Canada’s cultural industries have received an exception. This article states that “This Agreement does not apply to a measure adopted or maintained by Canada with respect to a cultural industry.” It remains unclear what this will mean in practice. Do the relevant IP provisions of the USMCA, including for copyright protection, not apply to Canada’s cultural industries? If this cultural exception is applied and understood to mean that the copyright provisions of the USMCA do not apply to Canada’s cultural industries this would result in a nearly 10% drop in the USMCA’s IP Index score.

The USMCA and Canada and Mexico – a game-changer?

How would the USMCA impact the national IP environments in Canada and Mexico? Like the above comparison it is also possible to benchmark and compare Canada’s and Mexico’s IP environment to TRIPS, NAFTA, the TPP and the USMCA. Using the same methodology as described above, below Figure 5 shows this comparison.

Figure 5: Comparing TRIPS, NAFTA, TPP, and the USMCA with the Index



As Figure 5 illustrates both Canada’s and Mexico’s national IP environments as compared to the Index are far behind the standards captured in the USMCA with Canada 15% behind and Mexico a full 34%. Implementing and applying the USMCA would thus be a significant boost to both economies Index scores across all categories. For Mexico specific areas of improvement would include: a longer and more clearly defined term of biopharmaceutical RDP of 5 years for new chemical entities and 10 years for biologics; more effective trade secret protection including criminal sanctions; *ex officio* border enforcement against all suspected counterfeit goods including goods in-transit; and strengthened copyright provisions. Canada would also benefit from these measures – particularly extending the period of RDP from the current 8 to 10 for large molecules and providing border officials with *ex officio* authority to act against suspected counterfeit goods in-transit – although there is still uncertainty about the impact of the copyright provisions given Canada’s cultural industries exception.



Why does it matter? Summing up the benchmarking exercise

The global landscape of free trade agreements has evolved substantially in the past two and a half decades since the introduction of NAFTA and TRIPS, with an increasing number of bilateral and multilateral agreements placing a stronger emphasis on IP protection.²² In this sense, trade agreements with strong IP standards help drive economic development and growth in the contracting economies. For example, a 2016 study examining the impact of trade agreements with complex IP chapters on the composition of trade over a period of 20 years reveals that these trade agreements tend to have a positive impact on trade in IP rights-induced goods.²³ The study finds that middle-income economies that are contracting parties to trade agreements with comprehensive IP chapters tend to export substantially more IP-intensive goods, compared with middle-income economies that are not.

Within this context, the USMCA can help provide the necessary protections so that North America can derive the greatest economic benefit from the Agreement.

Inputs = Outputs – How IP Rights Are Not a Cost but a Driver of Innovation and Economic Growth

The empirical evidence on the impact of IP rights on economic activity is quite clear: the most up-to-date data on the benefits of IP protection reveal that IP rights are, in fact, a critical instrument for economies seeking to enhance access to innovation, grow domestic innovative output, and enjoy the dynamic growth benefits of an innovative economy. Conversely, weak IP protection stymies long-term strategic aspirations around innovation and development. Yet maximizing the benefits of IP rights is about not just understanding the outcomes that they help to generate but also *how* they do so. Effective innovation strategies comprise policies that account for not only the end objectives but also the path that leads to these outcomes, the way in which innovation and creativity occur, and the necessary enabling factors. In this sense, policymakers need to understand that IP rights and incentives must be part of the discussion from the beginning. Incentives to innovate and create are not a cost or something to be added on later: strong and clear IP incentives have to be in place from the beginning for innovation and related economic activity to take place.

What does this mean for NAFTA and its contracting parties?

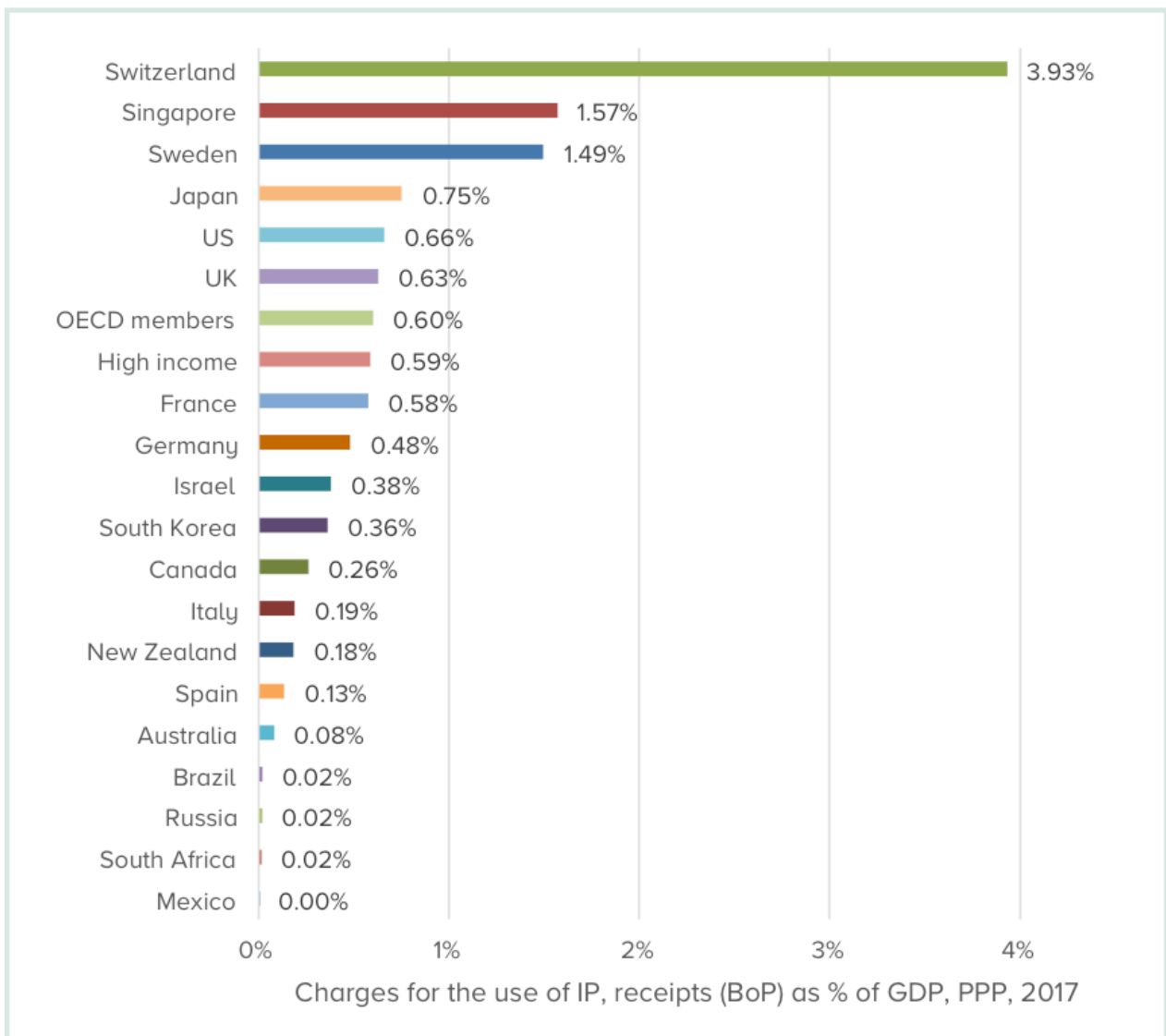
Although structurally the economies of Mexico and Canada differ greatly, higher IP standards through NAFTA represents potential new opportunities for growth and development in both. Simply look at the level of actual income generated by IP assets currently.²⁴ This is a broader reflection of both the number of such assets generated in an economy and the relative quality and international competitiveness of those assets, as indicated by nonresident purchases. High rates of income from IP-derived assets suggest that those assets being generated are internationally competitive and attractive. Conversely, lower levels of income suggest that the assets being produced are not attractive, are very low in terms of volumes being produced, or, in a worst of all worlds, both.



Looking specifically at the data on receipts for the use of IP for NAFTA’s contracting parties and additional socioeconomic peers, two things stand out:

1. first, the low levels of income derived from IP assets (in terms of receipts for the use of IP) compared with levels of the top performers on the Index; and
2. second, by comparison, the subdued growth rate in Canada and Mexico; since 2000, growth in this income has been much weaker in Canada compared with other economies starting at roughly similar levels, while in Mexico it has largely stood still.

Figure 6: Charges for the Use of IP, Receipts, as a Percentage of GDP Purchasing Power Parity (PPP), 2017, Selection of Index Economies and Aggregates

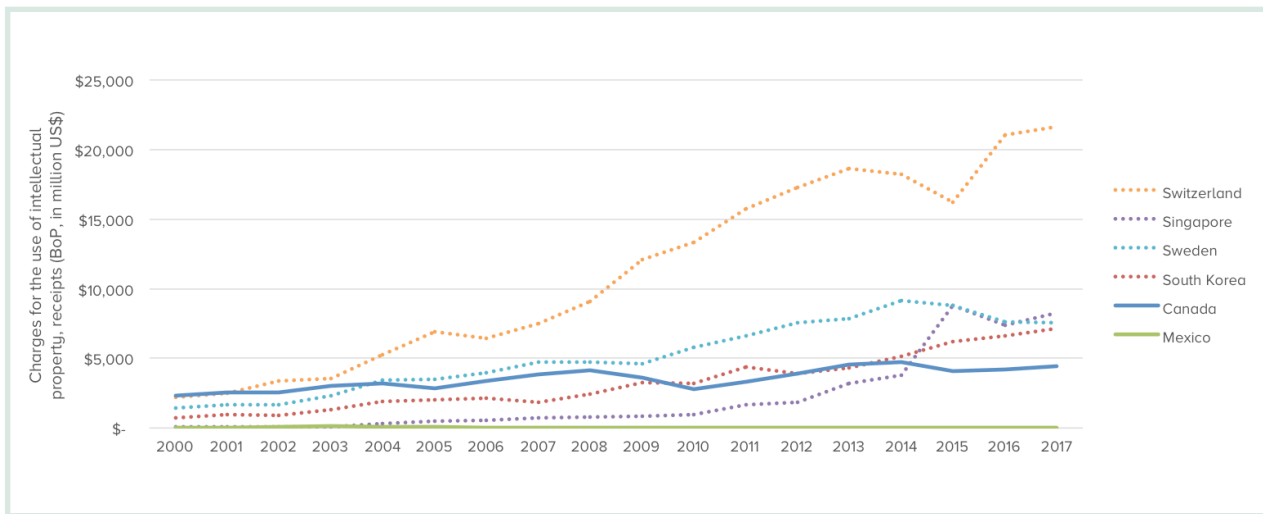


Source: The World Bank, 2018; analysis: Pugatch Consilium



As Figure 6 illustrates, in 2017 receipts for charges for the use of IP amounted to 0.26% and 0.0003% of Canadian and Mexican GDP, respectively. Most top-performing economies on the Index derived considerably higher levels of income. Interestingly, the absolute amount of income derived from IP assets in gross terms in Canada in the year 2000 was roughly the same as Switzerland's, at just under USD2.5 billion, even though Canada's population is more than four times that of Switzerland. Yet, over the course of the next 17 years, while Canada has seen growth in this income (reaching over USD4.45 billion in 2017), comparator economies—which were starting at either the same rate or a lower one in 2000—saw significantly *stronger* levels of growth, as illustrated in Figure 7.

Figure 7: Charges for the Use of IP, Receipts (in Million USD), 2000–2017, Canada, Mexico, Singapore, South Korea, Sweden, and Switzerland



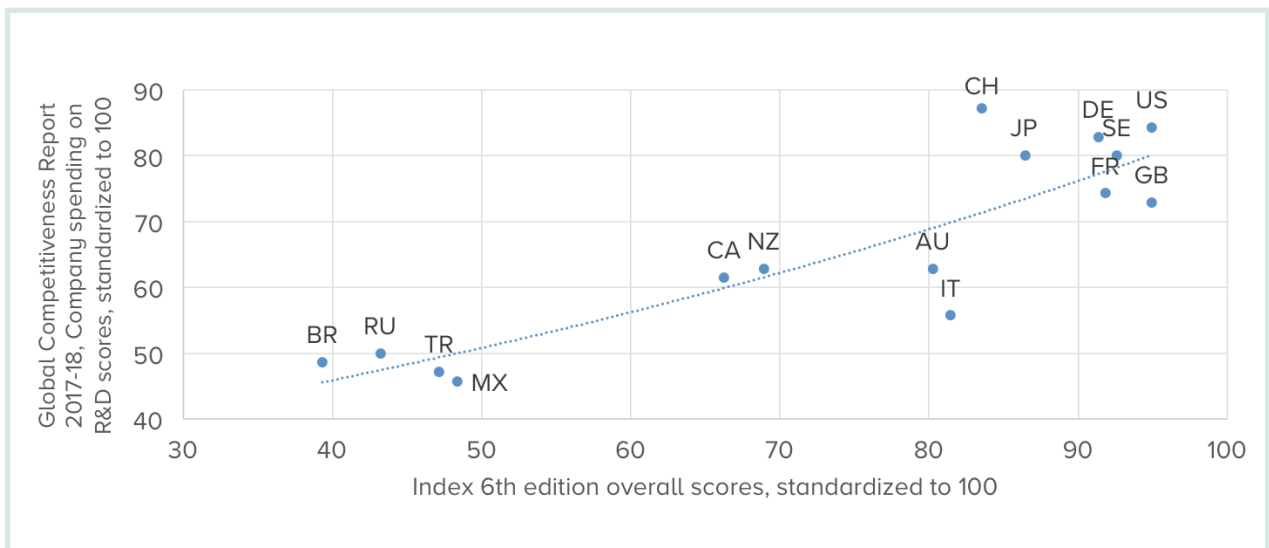
Source: The World Bank, 2018; analysis: Pugatch Consilium

IP Protection Facilitates the Necessary “Inputs” to the Knowledge-Based Economy

Why do IP incentives matter?

Essentially, there is a stronger likelihood that an idea or discovery will be supported by adequate investment in a robust IP environment, where investors are able to protect the end result through IP rights, thereby creating a tangible commercial asset. Looking at executives’ propensity to spend on R&D activities,²⁵ a key measure of innovation, economies that provide the necessary conditions for commercializing innovation—namely, robust IP protection—are generally more attractive to private sector investment in R&D. Both Mexico’s and Canada’s relatively low scores here reflect their relatively weaker performance on the IP Index.

Figure 8: Association between Index (6th Edition) Scores and the Global Competitiveness Report 2017–18, Company Spending on R&D Scores, Selected Economies²⁶



Sources: World Economic Forum/Executive Opinion Survey (2017), company spending on R&D scores; GIPC (2018)

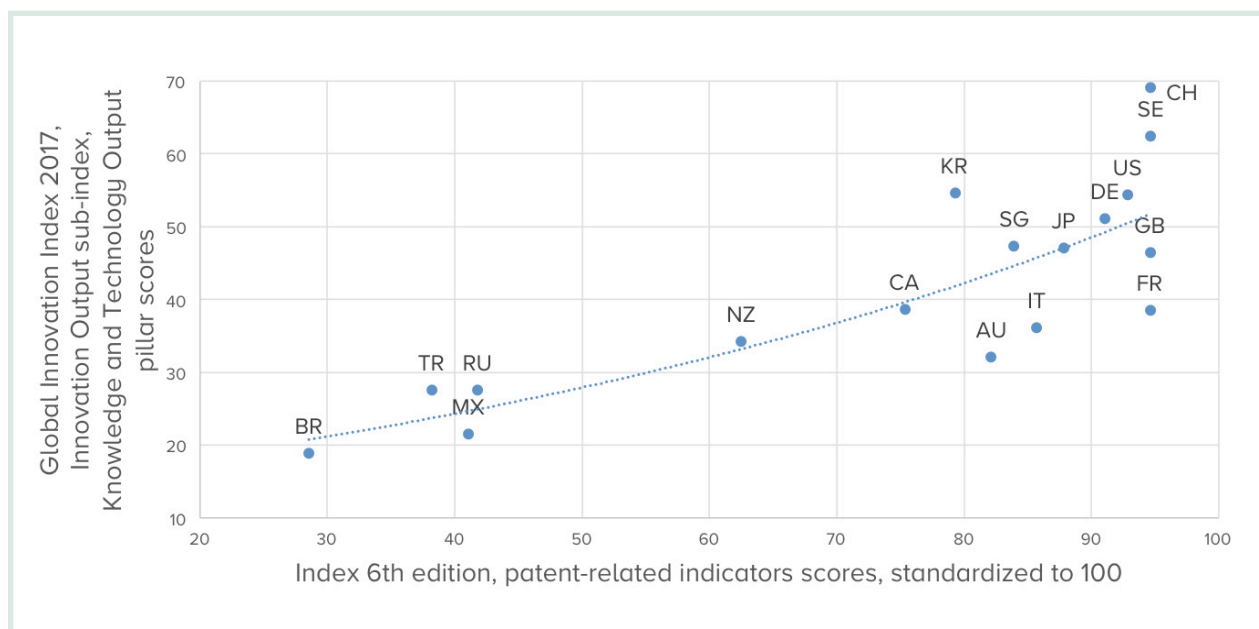


IP Protection Induces Growth of the High-Tech Sectors

Globalization is increasingly forcing economies to become more competitive by moving up the value chain—mostly through productivity gains and technology development. Effective application of advances in technology, in addition to entrepreneurship and innovative approaches to the creation and delivery of goods and services, leads to increases in productivity.

Knowledge and technology outputs—a strong indicator for robustness and growth in the high-tech sector in a given economy—shows a strong link to patent protection. In fact, economies with robust IP systems tend to produce up to 80% more knowledge and technology outputs. As the Figure 10 shows, there is room for growth for both Canada’s and Mexico’s levels of innovation output.

Figure 9: Association between the Index (6th Edition) Patent-Related Indicators Scores, and the Global Innovation Index 2017, Innovation Output Sub-Index Knowledge and Technology Output Pillar Scores, Selected Economies²⁷



Sources: Global Innovation Index, WIPO/INSEAD (2017), Innovation Output Sub-Index, Knowledge and Technology Output Pillar; GIPC (2018)



The USMCA: Setting a 21st century standard for IP protection

Historically trade agreements have been fundamental in helping to raise international standards for the protection and enforcement of IP rights. TRIPS, NAFTA and numerous U.S. and EU led bilateral and regional agreements have helped improve the global environment and set a proverbial floor for rights-holders around the world. Given that it has been close to a quarter of a century since the conclusion of the Uruguay Round and a truly global trade agreement – the Doha Round has been ongoing since 2001 but effectively shelved since 2015 – new bi- and pluri-lateral agreements become increasingly important in improving international IP standards.

As this document and benchmarking of the USMCA vis-à-vis the Index has shown, the USMCA's IP-related provisions are a significant upgrade over NAFTA, TRIPS, and the original TPP agreement. The USMCA comes the closest of all these treaties in achieving an IP standard that is comparable to the Index. In this respect a successful conclusion to the USMCA gives not only North America the chance to reap the benefits of strengthening the region's collective IP environment, but also helps lay the foundation for a 21st century standard of IP protection.



LIST OF ABBREVIATIONS

Algeria DZ	Russia RU
Argentina AR	Saudi Arabia SA
Australia AU	Singapore SG
Brazil BR	South Africa ZA
Brunei BN	South Korea SK
Canada CA	Spain ES
Chile CL	Sweden SE
China CN	Switzerland CH
Colombia CO	Taiwan TW
Costa Rica CR	Thailand TH
Ecuador EC	Turkey TR
Egypt EG	Ukraine UA
France FR	United Arab Emirates AE
Germany DE	United Kingdom UK
Hungary HU	United States US
India IN	Venezuela VE
Indonesia ID	Vietnam VN
Ireland IE	
Israel IL	
Italy IT	
Japan JP	
Jordan JO	
Kenya KE	
Malaysia MY	
Mexico MX	
Morocco MA	
Netherlands NL	
New Zealand NZ	
Nigeria NG	
Pakistan PK	
Peru PE	
Philippines PH	
Poland PL	




ENDNOTES

- 1 Hussain I. (2012) NAFTA and Intellectual Property Rights. In: *Reevaluating NAFTA*, p. 83, Palgrave Macmillan, New York
- 2 Pugatch, M. P. (2004), *The International Political Economy of Intellectual Property Rights*, pp. 129, 131; ICTSD, WHO, UNCTAD (2006), *Guidelines for the Examination of Pharmaceutical Patents: Developing a Public Health Perspective – A Working Paper*, p. vii.
- 3 World bank, GDP (current US\$), 2016.
- 4 Economics and Statistics Administration and the USPTO (2016), *Intellectual Property and the U.S. Economy: 2016 Update*, Washington DC, 2016, pp. ii-iii.
- 5 United States Census Bureau (2018) Top Trading Partners - December 2017, Data are goods only, on a Census Basis, in billions of dollars, unrevised.
- 6 NAFTA, Articles 1709.7; 1709.12.
- 7 With the terms “inventive step” and “capable of industrial application” viewed to be synonymous with the terms “non-obvious” and “useful”, respectively. North American Free Trade Agreement (“NAFTA”), December 17, 1992, (1993), 32 I.L.M. 289, Chapter 17, Article 1709.1. Emphasis added.
- 8 NAFTA, Article 1709.10 (a)(d-f)(h).
- 9 Torstensson, D. and Pugatch, M. P. (2008). *Courting Confusion? Where is Canada’s Intellectual Property Policy Heading? The Stockholm Network Experts’ Series on Pharmaceutical Intellectual Property Rights*, London.
- 10 See: U.S. Chamber of Commerce, Global Intellectual Property Center, U.S. Chamber International IP Index: The Roots of Innovation, Fifth Edition, February 2017, pp. 12-16.
- 11 North American Free Trade Agreement (“NAFTA”), December 17, 1992, (1993), 32 I.L.M. 289, Chapter 17, Articles 1709.1; 1709.7; 1709.12.
- 12 International and best practices are defined here as those principles established in TRIPS article 27: “Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.”
- 13 Broken down by relevant categories, the NAFTA Agreement scores on the Index are:
Category 1: Patents, Related Rights, and Limitations – 4.5 out of 8
Category 2: Copyrights, Related Rights, and Limitations – 2.03 out of 7
Category 3: Trademarks, Related Rights, and Limitations – 3.9 out of 6
Category 4: Trade Secrets and Related Rights – 1.5 out of 2
Category 5: Commercialization of IP Assets – 1 out of 2 relevant indicators
Category 6: Enforcement – 3 out of 5 relevant indicators
Category 7: Systemic Efficiency – No relevant indicators
Category 8: Membership and Ratification of International Treaties – 0 out of 3 relevant indicators.
- 14 F Richter (2018) “The Rise and Fall of the Compact Disc”, *Statista*, February 16 2018
- 15 E Christman (2018) “Best Buy to Pull CDs, Target Threatens to Pay Labels for CDs Only When Customers Buy Them”, *Billboard*, February 2 2018
- 16 Internet World Stats, Usage and Population Statistics, Internet Growth Statistics, (Accessed May 2018): <https://www.internetworldstats.com/emarketing.htm>



- ¹⁷ International Post Corporation (2017) *State of e-commerce: global outlook 2016-21*, (Accessed May 2018): <https://www.ipc.be/en/knowledge-centre/e-commerce/articles/global-e-commerce-figures-2017>
- ¹⁸ USTR (2018) *2017 Notorious Markets List*, Washington DC 2018, pp. 11-25.
- ¹⁹ DIRECTIVE 2001/83/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL. The article reads: By way of derogation from Article 8(3)(i), and without prejudice to the law relating to the protection of industrial and commercial property, the applicant shall not be required to provide the results of pre-clinical tests and of clinical trials if he can demonstrate that the medicinal product is a generic of a reference medicinal product which is or has been authorised under Article 6 for not less than eight years in a Member State or in the Community. A generic medicinal product authorised pursuant to this provision shall not be placed on the market until ten years have elapsed from the initial authorisation of the reference product. The first subparagraph shall also apply if the reference medicinal product was not authorised in the Member State in which the application for the generic medicinal product is submitted. In this case, the applicant shall indicate in the application form the name of the Member State in which the reference medicinal product is or has been authorised. At the request of the competent authority of the Member State in which the application is submitted, the competent authority of the other Member State shall transmit within a period of one month, a confirmation that the reference medicinal product is or has been authorized together with the full composition of the reference product and if necessary other relevant documentation. The ten-year period referred to in the second subparagraph shall be extended to a maximum of eleven years if, during the first eight years of those ten years, the marketing authorisation holder obtains an authorisation for one or more new therapeutic indications which, during the scientific evaluation prior to their authorisation, are held to bring a significant clinical benefit in comparison with existing therapies.
- ²⁰ In the period following passage of the legislation there was some debate on the issue – President Obama has issued a proposal to cut the period to seven years. In response, a bipartisan group of at least 50 in Congress sent the President a letter urging him to maintain the 12 year period set out in the legislation. See: MedPage Today, “Lawmakers Defend Biologics’ 12-Year Exclusivity”, 18 October 2011, <http://www.medpagetoday.com/Washington-Watch/Washington-Watch/29108>
- ²¹ The USMCA mapping also includes Indicator 40.
- ²² Valdés, R. and Tavengwa, R. (2012), Intellectual property provisions in regional trade agreements, WTO Staff Working Papers, World Trade Organization (WTO), Economic Research and Statistics Division, <https://www.econstor.eu/bitstream/10419/80069/1/729502635.pdf>.
- ²³ Maskus, K. E. and Ridley, W. (2016) Intellectual Property-Related Preferential Trade Agreements and the Composition of Trade, Robert Schuman Centre for Advanced Studies, Research Paper No. 2016/35, http://cadmus.eui.eu/bitstream/handle/1814/43244/RSCAS_2016_35.pdf?sequence=1.
- ²⁴ As defined by the World Bank, charges for the use of intellectual property are “payments and receipts between residents and nonresidents for the authorized use of proprietary rights...and for the use, through licensing agreements, of produced originals or prototypes...and related rights.” [World Bank, Databank, Science and Technology Indicators, Charges for the use of intellectual property, receipts (BoP, current US\$), indicator source note]. Such rights and nonrelated rights include, for example, patents, trademarks, copyrights, industrial designs, use of prototypes and satellite broadcasts. The data is collected globally and on a like-for-like basis making it possible to compare countries both over time as well as vis-à-vis one another. Consequently, this indicator is a very robust and useful tool for comparison purposes. However, there are also some significant drawbacks. Primarily, there is a lack of specificity and granularity in this data in that it covers all major forms of IP assets. As a result, it is not possible to isolate, say, receipts generated by patent or trademark assets from licensing fees generated by copyright assets. Still, this is a measure of real value when attempting to estimate the relative contributions of the total IP-based sector to a given national economy and thus give a good sense of the relative volume and attractiveness of IP assets being generated in a given economy.
- ²⁵ As measured in the Global Competitiveness Report by the World Economic Forum’s Executive Opinion Survey

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- ²⁶ The company R&D spending score is based on responses to the question, “In your country, to what extent do companies spend on research and development?” in the World Economic Forum’s Executive Opinion Survey, 2016–17, where 1 = do not spend on R&D and 7 = spend heavily on R&D (standardized to 100).
- ²⁷ Knowledge creation, impact, and diffusion is measured by the Global Innovation Index, Innovation Output subindex, Knowledge and Technology Outputs pillar score. This score comprises variables such as patenting activity, growth of high-tech businesses, and knowledge-based exports. Source: Global Innovation Index 2017. Patent-related indicators consist of indicators that fall under the Patent category of the Index, as well as those indicators in Trade Secrets, Commercialization of IP Assets, Enforcement, and International Treaties categories that are relevant to patents (specifically 1–8, 23–25, 29, 31, and 39–40).



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