4. THE GLOBAL IP ENVIRONMENT IN 2018

At the top of the agenda: How discussions about the protection of IP shaped international relations in 2018

The protection of IP lies at the heart of the current trade dispute between the United States and China.

The combination of China's rapid economic growth development, the integration of the global economy, and profound technological changes has brought international IP policy to the forefront. Chinese policymakers have long recognized the need to shift domestic economic activity away from low added-value industrial production into higher-value knowledge creation and high-tech, advanced manufacturing and Research & Development. Successive Chinese administrations have emphasized the need for investing in Research & Development capacity, technology development, and human capital to incentivize innovation. Specific policies and plans range from the "Five-Year Plans" to plans for "Science and Technology Development" to the more recent "Made in China 2025." Underlying many of these policies and plans is a focus on local technology acquisition and development. This focus has manifested itself in mandatory and coercive localization and partnering requirements. Since the mid-2000s, China has introduced and implemented a range of policies making access to the Chinese market conditional on the sharing of technology and IP with domestic entities. These policies include the transfer of proprietary technologies in procurement, joint ventures, and standardization processes; local manufacturing requirements; and limitations on investment by foreign entities, without guarantee they will be protected from unauthorized disclosure, duplication, distribution, and use. Although some policies have been revoked, many of these policies are still in place and continue to be introduced.

As the Index has described over the past half-decade, these policies violate established international principles of free and fair trade.

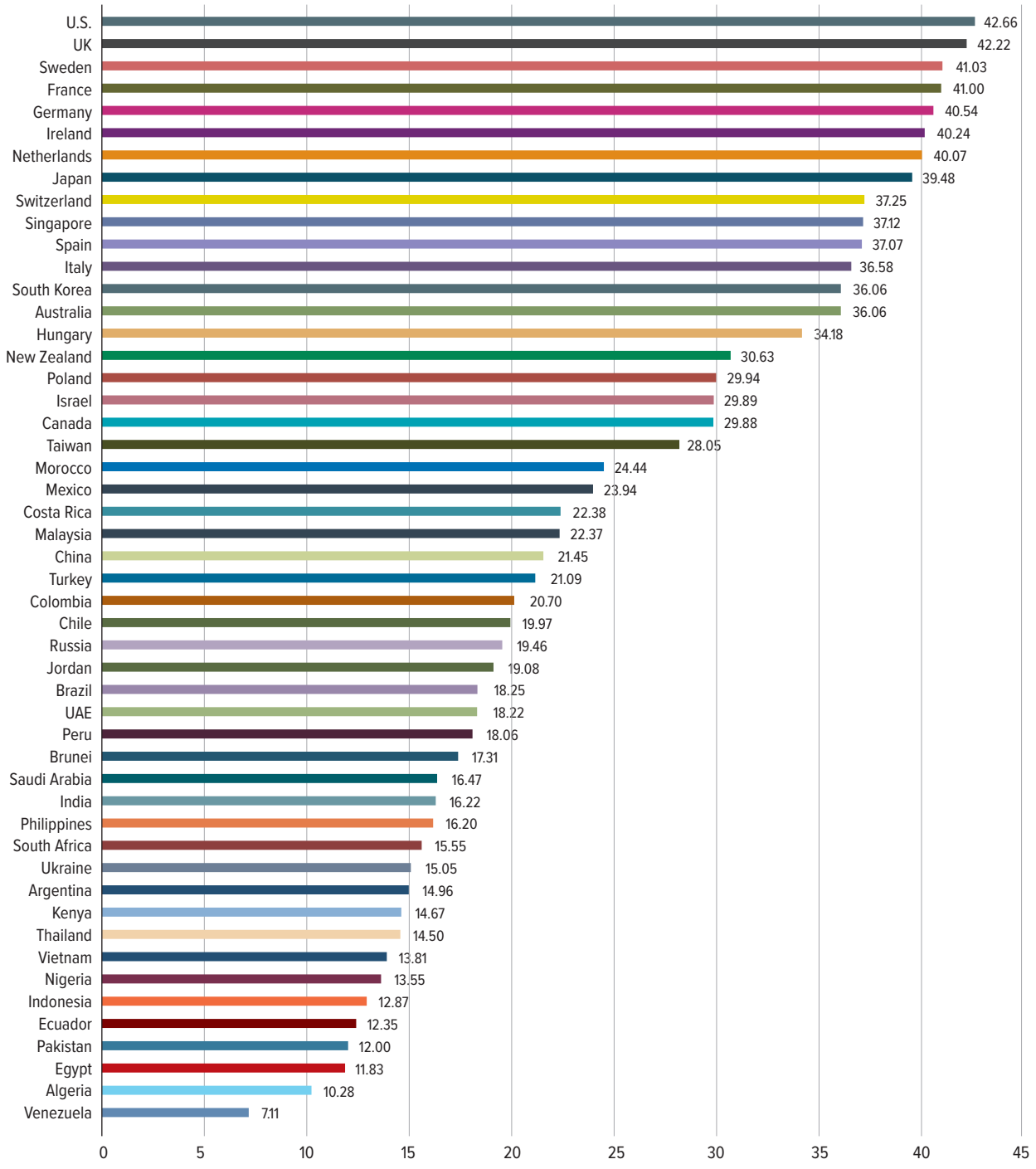
In the long run, the policies are also unlikely to help China develop its own technological and advanced R&D capacity. Indeed, it is clear from the accumulated work and evidence of the Index and its sister publications that China stands the best chance of achieving its social and economic objectives not through intensified policies of local content requirements and technology acquisition—surreptitious or overt—but through focusing on transparency, fair trade, and nondiscriminatory pro-innovation reforms.

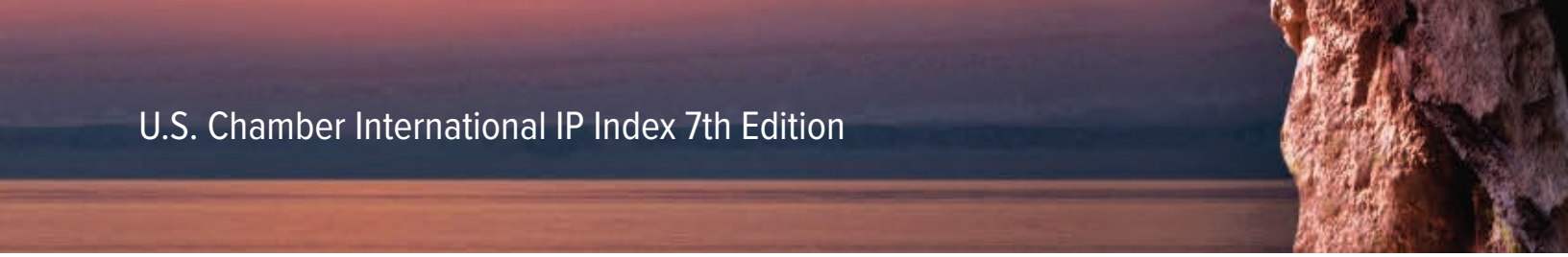
The results of the 7th edition of the Index bear this out.

The 7th edition of the Index: Overall results and analysis

How have economies fared in this edition of the Index? And what do the results of the 7th edition tell us about the state of the global IP environment? Figure 1 shows the overall results for the 7th edition of the Index.

Figure 1: U.S. Chamber International IP Index 2019, overall scores





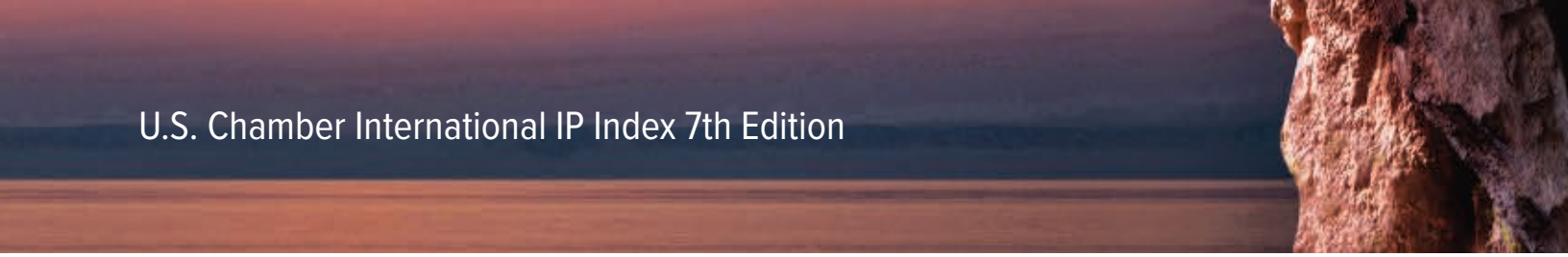
What is perhaps most striking about the overall results of the 7th edition is the substantial movement of economies up and down the overall standings and rankings of the Index. Table 4 compares all 50 economies' performance in the 6th edition and the 7th edition standardized to a percentage.

Table 4: Change in overall score and rank, 6th edition versus 7th edition

	6th Ed.	7th Ed.	Change in Overall Score	Change in Rank
U.S.	94.95	94.80	-0.16%	0
UK	94.93	93.82	-1.17%	0
Sweden	92.57	91.18	-1.50%	0
France	91.85	91.10	-0.81%	0
Germany	91.35	90.09	-1.37%	0
Ireland	89.95	89.42	-0.59%	0
Netherlands	88.31	89.04	0.82%	0
Japan	86.45	87.73	1.48%	0
Switzerland	83.55	82.78	-0.92%	1
Singapore	83.63	82.49	-1.37%	-1
Spain	81.45	82.38	1.13%	2
Italy	81.46	81.29	-0.21%	0
South Korea	82.87	80.13	-3.31%	-2
Australia	80.27	80.13	-0.17%	1
Hungary	75.54	75.96	0.56%	0
New Zealand	68.92	68.07	-1.24%	0
Poland	66.39	66.53	0.21%	0
Israel	65.43	66.42	1.52%	1
Canada	66.25	66.40	0.23%	-1
Taiwan	59.62	62.33	4.56%	0
Morocco	54.86	54.30	-1.01%	0
Mexico	48.38	53.20	9.95%	2
Costa Rica	49.80	49.73	-0.13%	-1
Malaysia	49.92	49.70	-0.43%	-1
China	47.70	47.67	-0.07%	0
Turkey	47.15	46.87	-0.61%	0
Chile	42.12	44.38	5.37%	2

Table 4: Change in overall score and rank, 6th edition versus 7th edition, *continued*

	6th Ed.	7th Ed.	Change in Overall Score	Change in Rank
Colombia	45.67	45.99	0.7%	0
Russia	43.21	43.24	0.05%	0
Jordan	43.47	42.40	-2.48%	-2
Brazil	39.31	40.56	3.18%	2
UAE	40.68	40.49	-0.46%	0
Peru	41.00	40.13	-2.11%	-2
Brunei	37.52	38.46	2.50%	1
Saudi Arabia	38.74	36.60	-5.51%	-1
India	30.07	36.04	19.89%	8
Philippines	34.49	36.00	4.38%	1
South Africa	34.27	34.56	0.85%	1
Ukraine	35.69	33.44	-6.29%	-2
Kenya	35.94	32.60	-9.30%	-4
Thailand	31.37	32.22	2.71%	0
Argentina	28.88	33.24	15.08%	6
Vietnam	32.97	30.69	-6.93%	-3
Nigeria	30.95	30.11	-2.72%	-2
Indonesia	30.35	28.60	-5.77%	-2
Ecuador	28.99	27.44	-5.36%	-1
Pakistan	26.02	26.67	2.48%	0
Egypt	25.25	26.29	4.10%	0
Algeria	23.81	22.84	-4.11%	0
Venezuela	17.12	15.80	-7.73%	0



Almost half the Index economies (23 out of 50) have seen their scores and national IP environments changed, as defined as a positive or negative movement of 2% or more. Relatively few economies have stood still, as defined by a movement of less than 0.5%. Of note is that 11 economies have experienced substantial movement, as defined by a positive or negative movement of 5%. The most substantial movement can be seen from **India**, which has surged almost 20% and climbed 8 places in the IP Index rankings from 44th to 36th. As is discussed below in its Economy Overview, India has taken several noteworthy steps to improve its IP system in 2018 and also performed well on the new indicators included in the Index this year. Substantial challenges persist, particularly regarding India's patenting and IP enforcement environments. Nevertheless, this improvement is a real accomplishment, and Indian policymakers should be congratulated on their successful efforts in 2018. Equally, both **Argentina** and **Mexico** saw substantial increases of 15% and 9.95%, respectively, driven primarily by an overall strong performance on the new indicators. On the other hand, **Kenya**, **Venezuela**, **Vietnam**, **Ukraine**, **Indonesia**, **Saudi Arabia**, and **Ecuador** all saw a 5% drop or more. The main drivers for this vary from economy to economy, but none of these 7 economies performed well on the new indicators added to the Index. And continued developments related to localization and local content policies and negative changes to the legal environment in Vietnam, Saudi Arabia, Venezuela, and Ecuador contributed to their slide.

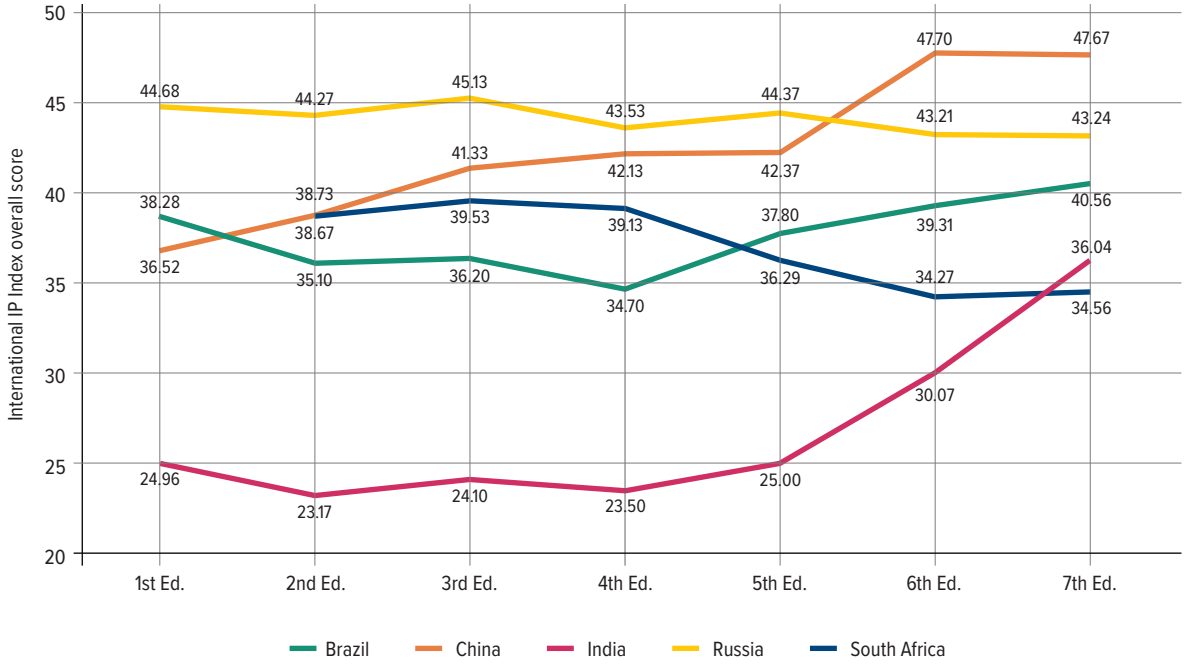
Still on top? EU member states and the United States

Looking at the top of the sample, not much has changed from past editions of the Index. The top 10 remains the same, with the only change in ranking being **Switzerland** moving up from 10th to 9th, displacing **Singapore**. Score-wise, the **UK**, **Sweden**, **France**, **Germany**, and **Ireland** all saw their scores drop. In large measure, this was due to a mixed performance on the new indicators included in the Index. Conversely the U.S. saw its lead over its competitors increase. It had a strong performance on the new indicators and also, as discussed below in its Economy Overview, saw an increase in score as a result of policy reforms to its patent opposition regime.

Pulling ahead, standing still, and regressing: How the BRICS are moving in different directions and at different speeds

One of the recurring themes of the Index over the years has been the relatively weak performance of the BRICS economies (**Brazil**, **Russia**, **India**, **China**, and **South Africa**). Despite their growing global economic importance, stated emphasis on structural reforms, and changing the composition of their economies to more strongly focus on knowledge creation and innovation-driven growth, their Index scores barely moved. Apart from China, whose score rose notably between 2012 and 2016 throughout the first four editions of the Index, the BRICS essentially stood still with their percentage scores virtually unchanged. However, as Figure 2 shows there was a real and sustained divergence of movement over the past three editions of the Index from 2017 to 2019.

Figure 2: Overall total score, percentage of available scores, first to 7th edition of the Index, BRICS



What stands out from Figure 2 is how **China** and **India** have surged over the past two editions of the Index. India in particular has seen a remarkable increase from the 5th edition to the 7th edition of the Index, rising from 25% of the available score to over 36% in the 7th edition. What's driving this? A combination of real IP reforms on the ground and a strong overall performance on many of the new indicators included in the Index over the past two editions. In 2018, key developments in India include its accession to the World Intellectual Property Organization (WIPO) Internet Treaties and the agreement on a patent prosecution highway (PPH) with Japan.

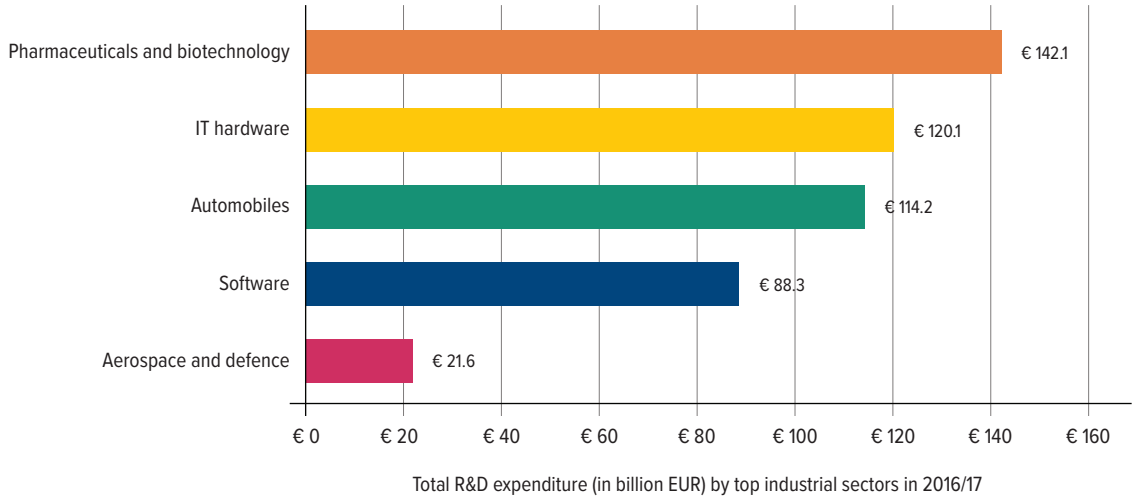
As noted above, China stands at a crossroads. On the one hand, rights holders have seen real and substantial improvements to the national IP environment over the course of the past seven years. Meaningful changes have been made to the Chinese legal code, and enforcement efforts, although still facing a daunting challenge, have improved. Yet, in key areas relating to technology transfer, licensing, and localization requirements, Chinese policy remains more or less wedded to a backward-looking agenda. For China to take the next leap on the Index, its government must implement further policy changes in these critical areas.

Looking at the other BRICS, **Brazil** and **Russia** have largely stood still over the past 7 years. As the largest economy in Latin America, Brazil has the potential to be a driver of regional IP policy and knowledge creation. Russia's policy environment is dominated by an over-arching protectionism and drive toward mandatory localization. There have been pockets of reform and sustained efforts—see, for example, in the enforcement of copyright online—but overall, Russia's IP environment remains relatively weak by international standards. Indeed, stripping out its high performance on Category 8: Membership in and Ratification of International Treaties, Russia's overall performance sinks considerably. **South Africa**, like Brazil, remains largely a story of possibility. As the largest economy in Africa, it too has the potential to become a regional leader in IP policy. Unfortunately, South Africa's government policy discussions (including the 2018 *IP Policy*) have focused primarily on ways in which the country could better access existing and developed forms of IP rather than on the way its IP can be created, commercialized, and become an industrial asset.

Growing headwinds: Zooming in on the biopharmaceutical sector

The biopharmaceutical sector is one of the most R&D-intensive sectors in the world. The industry invests significantly more in R&D in absolute terms and as a percentage of sales than any other. Figure 3, from the EU's 2017 Industrial R&D Investment Scoreboard (which measures the total amount of corporate R&D spending by the top companies in the world) shows that the biopharmaceutical sector spent over EUR140 billion in corporate R&D in 2017. This was well ahead of the second and third largest spenders in the technology hardware and equipment industry and automotive industry.

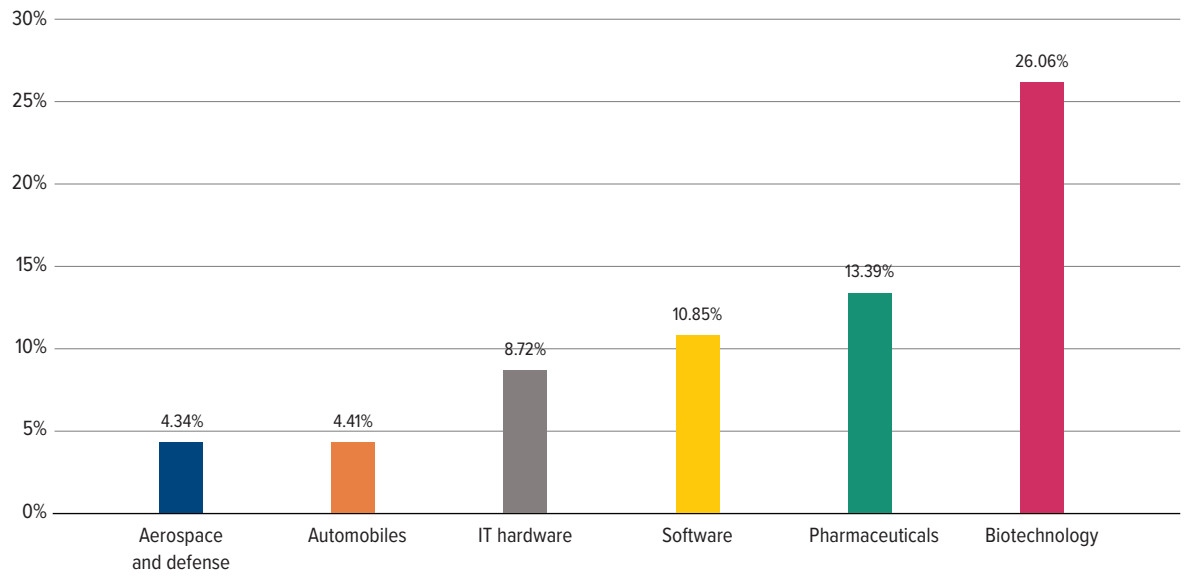
Figure 3: 2017 EU Industrial Investment Scoreboard, top industrial sectors, total R&D expenditure, billions EUR[2]



Sources: European Commission (2017). The above EUR sums correspond to USD at current exchange rates (December 2018) to USD161.977, USD136.9, USD130.74, USD100.645, and USD24.62, respectively, for the industries listed above.

Similarly, looking at R&D intensity (i.e., the percentage of sales invested in research), the pharmaceutical and biotechnology industries stand out. As Figure 4 illustrates, R&D intensity in both industries is considerably higher than other industries.

Figure 4: 2017 EU Industrial Investment Scoreboard, top industrial sectors, R&D intensity, select industries[3]

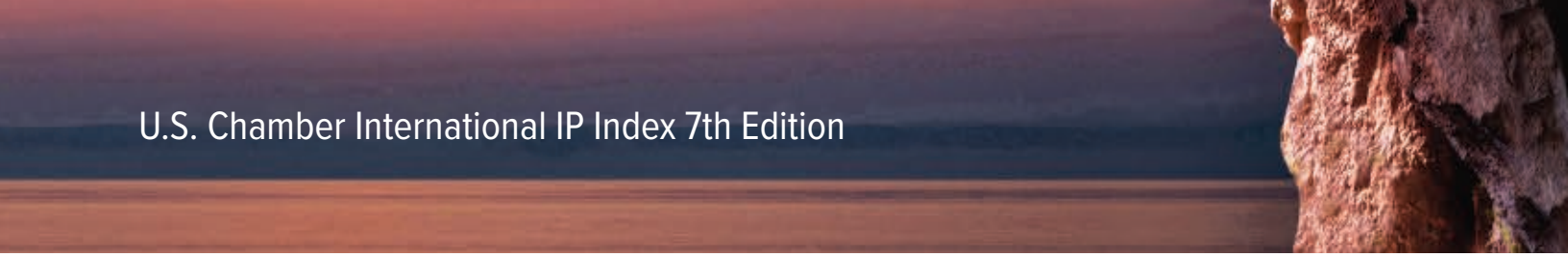


Source: European Commission (2017)

What's driving this R&D investment?

In short, innovation. Developing new medicines is a long-term, high-risk, resource-intensive process. The fixed costs in terms of laboratory, research facilities, and researchers are high. Compared with many other high-tech industries—for example, computer software—developing the next ground-breaking treatment for cancer or Alzheimer's disease requires more than just a laptop and a great idea. As medicines become more targeted and technically sophisticated, the cost of development rises dramatically. In 1979, the total cost of developing and approving a new drug stood at USD138 million. Almost 25 years later, in 2003, this figure was estimated at USD802 million.[4] In 2012, the total cost of drug development was estimated to be approximately USD1.5 billion.[5] Research from Tufts University in 2016 suggests that it costs USD2.6 billion, on average, to develop a new drug.[6]

International experience and the basic economics of the biopharmaceutical industry show how critical IP rights are to incentivizing and supporting research and development of new medical technologies and products.[7] In particular, patents and other forms of exclusivity for biopharmaceuticals, such as regulatory



data protection (RDP) and special exclusivity incentives for the protection and production of orphan drugs, enable research-based companies to invest vast sums in R&D and the discovery of new drugs, products, and therapies. On average, only 1 to 2 of every 10,000 synthesized, examined, and screened compounds in basic research will successfully pass through all stages of R&D and go on to become a marketable drug. IP rights provide a limited-term market exclusivity that gives firms sufficient time to recoup R&D investments made ahead of competition from additional market entrants that bore none of the costs of early-stage investment, research and development, and product commercialization. Many drugs and therapies may not have been discovered without the legal rights provided to innovators through IP laws.

Despite this evidence and a direct link between biopharmaceutical innovation and IP protection, economies around the world are actively reducing, overriding, or eliminating these incentives and rights. Interestingly, the weakening of the principle of IP rights is taking place in some of those economies that have benefited ***the most*** from clear and unambiguous IP protection.

Most striking of all is that the **European Commission** has introduced a legislative proposal to provide European manufacturers of generic drugs and biosimilars with a supplementary protection certificate (SPC) manufacturing exemption.[8] The overriding purpose of the proposal is to provide European manufacturers of generic drugs and biosimilars a competitive advantage by weakening IP protection for innovators.[9] Unfortunately, the Commission appears to have lost sight of the fact that IP rights, including SPC protection, have been central to the success of Europe's research-based biopharmaceutical industry. As an industry, the research-based biopharmaceutical sector is one of Europe's biggest success stories. European biopharmaceutical companies are some of the largest, most innovative, and successful in the world. Not only does this industry have a long track record of producing life-saving medical innovations that have been, or are currently being, used by millions of patients around the world, but it is also an engine of economic growth in the EU. Figures from the European Federation of Pharmaceutical Industries and Associations show that the European research-based industry provided nearly 740,000 direct jobs (with over 113,000 in high-skill R&D jobs), over EUR33.5 billion in R&D investments, and over EUR238 billion in production in 2015 alone.

Many troubling assumptions underlie the Commission's proposal. The proposal assumes that there is an actual market and demand for European generic manufacturers. Yet, what this market is or where the demand for generic medicines produced in Europe would come from is not at all clear. The markets that per definition will be targeted by European generic manufacturers under an SPC exemption are economies that do not provide IP protection and exclusivity for products under SPC protection in the EU for which the SPC exemption would apply. In all likelihood, generic follow-on products are already on the market in many of these economies and, critically, being produced by local manufacturers that are often preferred partners in local drug procurement. For those markets where equivalent protection mechanisms are in place, it is highly unlikely that an SPC exemption would grant the European generic and biosimilar manufacturers an exclusive status for early market entry of their products across the globe. Instead of benefiting the European generics industry, it is much more likely that we will see a contagion of policies to undermine IP protection if other economies emulate Europe. This could result in a race toward the bottom in weakening global IP standards. In the end, this policy may end up providing a minimum benefit for European generic manufacturers but have a negative impact on the research-based industry.

Similarly, **South Korea** a country that has had a fairly robust and consistent IP rights framework in place over the past few years, introduced measures that weaken biopharmaceutical IP protection in 2017 - 2018. Specifically, recent decisions by the Intellectual Property Trial and Appeal Board of the Korean Intellectual Property Office and the Patent Court considerably curtail patent term restoration for biopharmaceuticals. These decisions are based on a strict interpretation of the relevant term restoration regulations that limits its application to only the approved drug product itself and not to the patented invention. This opens the way to the marketing (during the extension term) of follow-on, patent-infringing products based on a different form of the same ingredient.

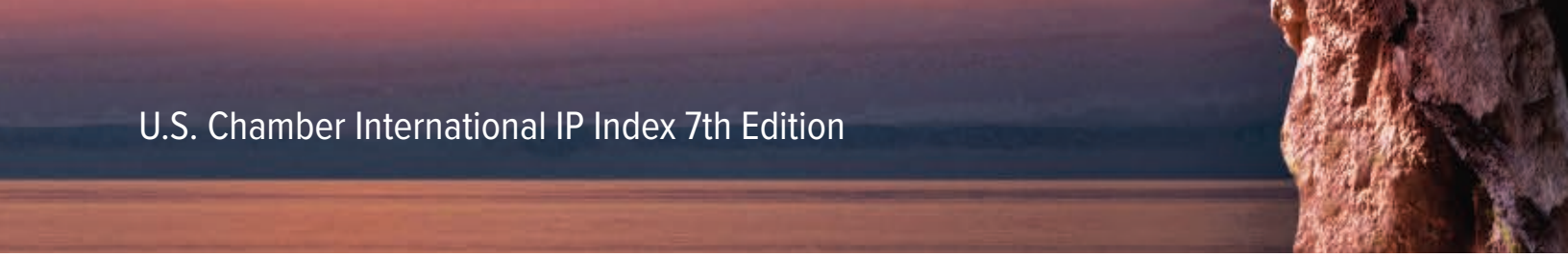
Outside the OECD and in emerging markets, many economies are also embracing weakening standards of IP protection for biopharmaceuticals.

In the Middle East, the relevant authorities in both the **UAE** and **Saudi Arabia** have, in effect, decided to override patent protection established by law in both economies. In 2017, the Saudi Food and Drug Authority effectively overrode the country's patent linkage regime by issuing a market approval for a follow-on product to Daclatasvir, a medicine under a registered patent held by Bristol-Myers Squibb.[10] This followed similar actions taken in 2016 when two generic versions of Gilead's sofosbuvir (a breakthrough medicine to treat hepatitis C) were approved within the five-year data exclusivity window of the products (first marketed in 2014).[11] Similarly, in the past few years, authorities in the UAE have authorized generic versions of products that were still on patent in the economy of origin. This development seriously undermines the life sciences IP environment in the UAE since patents on the majority of pharmaceutical products are not protected in the UAE, but protection is mostly based on foreign patents.

In another negative development over the past few years, more economies are attempting to use compulsory licensing, or threats of compulsory licensing, to further health policy and improve access to medicines.

As noted in last year's edition of the Index, in September 2017, **Malaysia** issued a government use license (the equivalent of a compulsory license) for sofosbuvir. In an accompanying statement to the decision, the Ministry of Health made clear that the purpose of the compulsory license was to lower the cost of treatment.[12] The Ministry made the announcement despite the fact that the manufacturer of the drug had already announced plans to include the country in its voluntary license scheme.[13] Similarly, over the past several years, the IP environment in Colombia has become much more challenging for the research-based biopharmaceutical sector, as a drive toward lowering health spending lead to the curtailment of IP rights. In 2016, the Colombian Ministry of Health actively considered issuing a compulsory license on the oncology drug Glivec on the grounds of high prices. Subsequently, the Colombian government issued a "Declaration of Public Interest" via Resolution 2475 and committed to unilaterally reducing the price of Glivec by about 45%. In effect, this practice all but nullifies any existing IP protection and is highly questionable under Colombia's obligations under Trade-Related Aspects of Intellectual Property Rights Agreement and the U.S.-Colombia Trade Promotion Agreement.

In March 2018, **Chilean** Minister of Health announced support for the issuing of a compulsory license for hepatitis C drugs for public health reasons.[14] The determination of a public health justification (Resolution No. 339[15]) followed a second vote by the Chamber of Deputies in January 2018 requesting the government use a compulsory license for drugs formulated with sofosbuvir.



Similarly, in **Peru**, the proposal to issue a compulsory license for the HIV drug atazanavir currently sits before the Peruvian Congress, having received approval by the Congressional Health Commission.[16]

Most recently, in **Russia**, the use of compulsory licenses for biopharmaceuticals has fused with localization requirements and wider industrial policy. Key policy initiatives include the Strategy for Innovative Development of the Russian Federation 2020, the State Coordination Program for the Development of Biotechnology (BIO 2020), the Strategy of Development of the Pharmaceutical and Medical Industries, the New Digital Society Strategy 201730, and the National Economic Security Strategy 2017. Localization and import substitution policies that actively discriminate against foreign entities and favor domestic Russian companies have been a major part of these efforts. While covering most parts of the economy, there has been a sustained focus on high-tech sectors such as aerospace and nuclear energy, nanotechnology, medical technologies, information and communications technology (ICT), and alternative fuels.

The requirements and intensity of these policies have varied from sector to sector, with the government targeting both the ICT and biopharmaceutical sectors. Data localization requirements for technology companies have been in place for a long time and have intensified over the past few years. For biopharmaceuticals, these localization policies have intersected with IP policy and broader health policy on the pricing and procurement of medicines. This has created a highly challenging environment for industry as it is difficult to meet industry-specific requirements for local manufacturing; procurement preferences for locally produced products; local clinical trials and R&D requirements; and, increasingly, the use and threat of compulsory licenses as public health policy. Members of the Russian Parliament (the Duma), the federal government, and the judiciary are increasingly viewing compulsory licensing as a legitimate policy for achieving industrial and public finance goals. The Russian Federal Antimonopoly Service (FAS) has been particularly active. In 2016, the FAS proposed utilizing a compulsory license scheme to reduce prices of certain high-cost specialty medicines. According to the proposed amendments to the Competition Act and the Civil Code, "threats to the individual and the rights of citizens to health protection and medical care" would justify the overriding of IP rights and the issuing of compulsory licenses. In 2017, the head of FAS, Igor Artemyev, stated it was only a matter of time before the government would formally begin to use this tool. Subsequently, in 2018, a Russian court issued the first court-ordered biopharmaceutical compulsory license. In July, the Moscow Arbitration Court granted a compulsory license to local manufacturer Nativa for Celgene's Revlimid. The compulsory license required Celgene to license one of its patents for the production of a product in which a dependent patent was to be used by Nativa. Without a license the use of this patent would constitute infringement of Celgene's patent. Critically, the court considered the lower cost of the product by Nativa to be economically advantageous. Nativa also has a number of other pending lawsuits involving similar dependent patents against originator products, and so with this decision the scope for the issuing of further licenses has now been heightened significantly.

Unfortunately, the net effect of these policies is to undermine the economic conditions that facilitate innovation, R&D, and investment. Using compulsory licensing, in particular, as an industrial and health policy tool is not only outside international norms but ultimately self-defeating: over time it will hollow out the IP environment and reduce the opportunities for future innovation—biopharmaceutical or otherwise—in a given economy. Critically, the negative effect will be the same on domestic as on foreign innovators. As the accompanying Annex demonstrates, there is a

clear and direct correlation between the strength of IP protection and rates of biopharmaceutical innovation, including clinical research. Economies that wish to develop a high-tech biopharmaceutical capacity are unlikely to reach this goal through policies that curtail, weaken, or eliminate IP protection for biopharmaceuticals.

International trade agreements and IP protection in 2018: One step forward, one step back

Historically, trade agreements have been fundamental in setting international standards for the protection and enforcement of IP rights. TRIPS, the North American Free Trade Agreement and numerous U.S.- and EU-led bilateral agreements have helped improve the global IP environment and set a floor for rights holders around the world.

It has been almost a quarter of a century since the conclusion of the Uruguay Round. While the Doha Round had the potential to become a truly global trade agreement, it has been effectively shelved since 2015. Thus, new bi- and pluri-lateral agreements become increasingly important in setting international IP standards. Several international trade agreements have been concluded, or are currently being negotiated, that contain substantial IP provisions. The Trans-Pacific Partnership (TPP) as agreed to in 2015 contained a high-standard IP chapter, which was equivalent to many of the standards as captured in the indicators used in the Index. Similarly, the EU-Canada Comprehensive Economic and Trade Agreement (CETA) provided the promise of finally bringing much of Canada's national IP environment into the modern era and aligning it with international best practices and other developed OECD economies. More recently, the United States-Mexico-Canada Agreement (USMCA), the EU-Japan Economic Partnership Agreement, and the Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP) have all included IP chapters.

Unfortunately, not all these treaties have lived up to their expectations or contain the same high standards of IP protection. For example, with the withdrawal of the U.S. as a contracting party to the TPP in early 2017, there has been considerable uncertainty about the future of the agreement. In November 2017, the remaining contracting parties confirmed in an inter-ministerial statement that the governments planned to substantively renegotiate the TPP agreement and rebrand it as the CPTPP. In March 2018, the final agreement was signed and the full text released. And while the text of the CPTPP retains important aspects of the TPP's IP provisions, including, for example, provisions relating to trade secrets and border enforcement, numerous critical provisions have been suspended. They include provisions relating to patentable subject matter, biopharmaceutical-specific IP rights such as regulatory data protection, and copyright protection and enforcement, as well as protections relating to satellite and cable signals. The result is that the CPTPP is substantively weaker than the TPP and does not conform to the modern standards of other post-TRIPS international trade agreements. Similarly, rights holders have expressed concerns over the implementation of critical aspects of the CETA pertaining to the enforcement of biopharmaceutical patents and effective restoration of patent exclusivity lost during market authorization proceedings for which the Canadian government has already devised an export waiver.

On the other hand, the USMCA offers a compelling alternative, improving on what was negotiated in the TPP to truly set a new global floor for the protection and enforcement of IP rights.

Setting a new standard: How the United States-Mexico-Canada Agreement could set a global benchmark for IP protection

NAFTA entered into force on January 1, 1994. At the time, it was widely considered as the first international

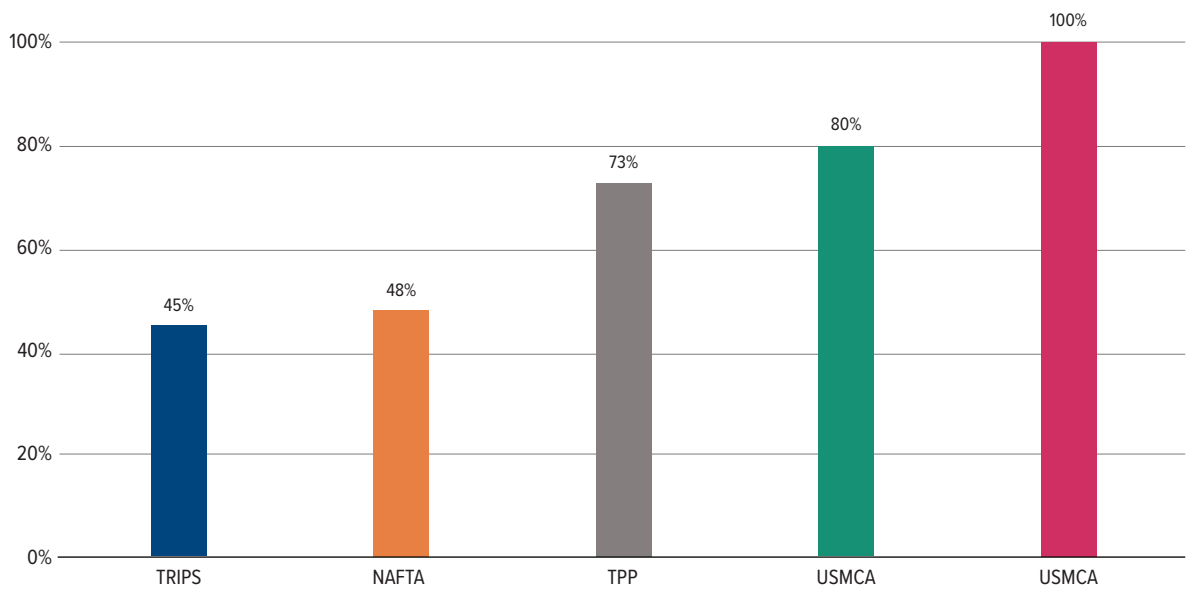
trade agreement that included specific obligations to protect IP rights.[17] Indeed, the NAFTA IP chapter was the precursor to the TRIPS Agreement—considered by many to be the most comprehensive and ambitious multilateral agreement ever reached in the IP domain[18] which was signed in 1995 and has been ratified by 164 economies. For a quarter of a century, NAFTA has stood as a model for a regional trade agreement. However, the economic relationships between nation-states are fundamentally different today than they were in the early and mid-1990s. 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 trade agreements.

Chapter 20 of the USMCA has the potential to set a new global IP standard. It includes 21st century IP provisions, such as the following:

- Stronger pharmaceutical-related IP protection, including regulatory data protection terms 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 in-transit goods
- Some strengthened copyright provisions, including a longer term of protection, digital rights management (DRM)/technological protection measures (TPM), and exceptions and limitations limited to the long-standing, internationally recognized three-step test

To illustrate the strength of the USMCA's IP chapter, we have benchmarked the agreement against relevant indicators from the Index, similar to how we benchmarked TRIPS and TPP treaties vis-à-vis the Index in 2016.[19] It is worth noting that the purpose of this exercise is to ***approximate*** the strength of the USMCA relative to the Index. The discussion is not intended to provide a ***definitive*** score, as there are methodological challenges that make such conclusions difficult. Nevertheless, it is useful to assess how the provisions of the USMCA compare to the indicators included in the Index and calculate an approximate Index score. To generate an Index approximation for the USMCA (with the Index constituting a full 100% score), it is assumed for methodological purposes that the USMCA will be the minimum IP law in force and that the contracting parties have implemented the principles and rules in the USMCA 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 related 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. In June 2017, the Canadian Supreme Court rejected 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 the provisions in the USMCA that may be considered equivalent to the indicators in the Index have been isolated and translated into scores. The research reveals that the USMCA's IP-related provisions are a significant improvement over NAFTA, TRIPS, and the original TPP agreement. Figure 5 shows the results of this exercise.

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

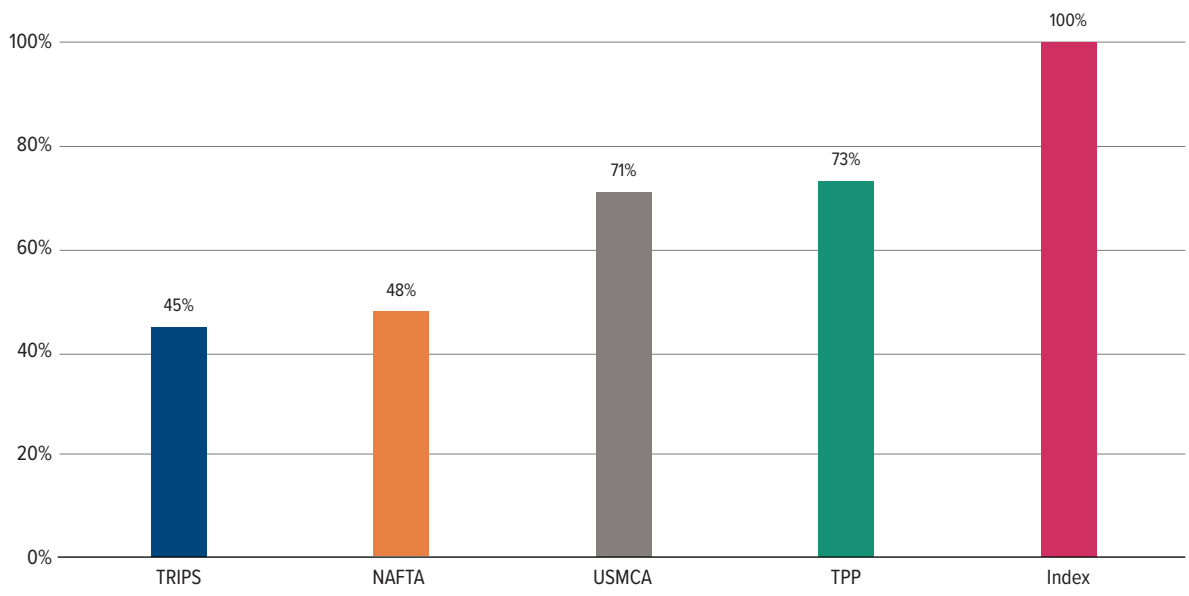


As this comparison shows, the USMCA comes the closest in achieving an IP standard that is comparable to the Index.

Nevertheless, some elements are still missing. Specific areas of the Agreement that could be strengthened include: online copyright protection; a defined term of patent term restoration for biopharmaceutical products (the Index uses a term of 5 years); and rules relating to online trademark protection, including clear requirements and standards for the expeditious removal of trademark-infringing material by online service providers.

However, 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. The article states, "This Agreement does not apply to a measure adopted or maintained by Canada with respect to a cultural industry." What this will mean in practice remains unclear. As is illustrated in Figure 6, if this cultural exception is utilized, this would result in a nearly 10% drop in the USMCA's Index score and would make the USMCA a weaker agreement than the TPP.

Figure 6: Canadian cultural industries exception drags the USMCA below the TPP



From the descriptive to the prescriptive: Why the strength of a national IP environment matters

Why do the results of the Index matter? What difference does it make if a given economy has a weak, medium, or strong national IP environment? Critics allege that the protection of IP is not as important to incentivizing innovation and economic development as R&D spending or rates of human capital. Simply put, the protection of IP matters a great deal.

Since 2015, the Index has included a *Statistical Annex* that illustrates the strong correlation between the strength of the national IP environment and different types of economic activity, including rates of R&D spending, innovation, technology creation, and creativity. The most up-to-date data on the benefits of IP protection reveal that IP rights are 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 related to innovation and development.

The following section provides a snapshot of some of this work and its application to three different areas: (1) readiness for the fourth industrial revolution, (2) the creative economy, and (3) licensing and technology transfer.