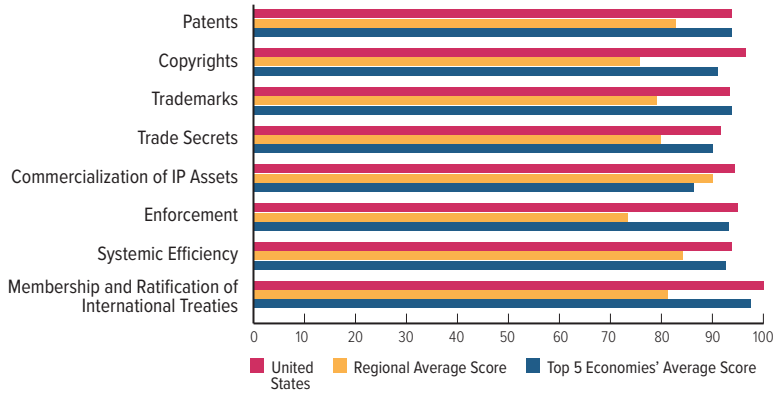
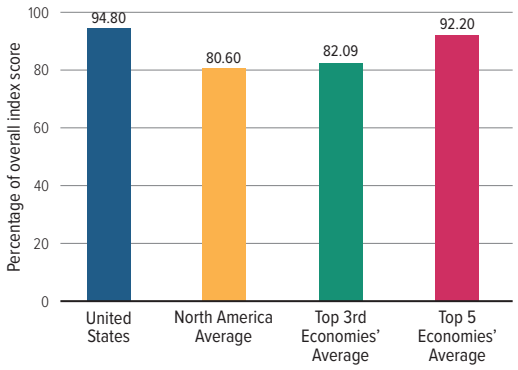
UNITED STATES RANK 1/50

Category Scores



Overall Score in Comparison



Strengths and Weaknesses

KEY AREAS OF STRENGTH

- ✓ Global leader and standard setter for the protection and enforcement of IP rights
- ✓ USMCA sets new standard for IP protection internationally and potential model for future FTAs
- ✓ Sector-specific rights and protections in place across all categories of the Index
- ✓ 2018 reform efforts to patent opposition proceedings by the USPTO should provide a greater balance and address concerns over unpredictability and uncertainty

KEY AREAS OF WEAKNESS

- ✗ 2018 congressional proposal for compulsory licensing as a pharmaceutical cost containment policy
- ✗ Continued uncertainty over patentability for high-tech sectors
- ✗ Lack of a targeted legal basis for addressing online piracy in line with other global leaders

Indicator Scores

INDICATOR	SCORE
Category 1: Patents, Related Rights, and Limitations	**7.50**
1. Patent term of protection	1.00
2. Patentability requirements	0.75
3. Patentability of computer-implemented inventions (CIIs)	1.00
4. Pharmaceutical-related patent enforcement and resolution mechanism	1.00
5. Legislative criteria and active use of compulsory licensing of patented products and technologies	1.00
6. Patent term restoration for pharmaceutical products	1.00
7. Membership in Patent Prosecution Highways (PPHs)	1.00
8. Patent opposition	0.75
Category 2: Copyrights, Related Rights, and Limitations	**6.75**
9. Copyright (and related rights) term of protection	1.00
10. Legal measures which provide necessary exclusive rights that prevent infringement of copyrights and related rights (including Web hosting, streaming, and linking)	1.00
11. Expeditious injunctive-style relief and disabling of infringing content online	0.75

INDICATOR	SCORE
12. Availability of frameworks that promote cooperative action against online piracy	1.00
13. Scope of limitations and exceptions to copyrights and related rights	1.00
14. Digital rights management (DRM) legislation	1.00
15. Clear implementation of policies and guidelines requiring that any proprietary software used on government ICT systems should be licensed software	1.00
Category 3: Trademarks, Related Rights, and Limitations	**5.60**
16. Trademarks term of protection (renewal periods)	1.00
17. Ability of trademark owners to protect their trademarks: requisites for protection	1.00
18. Legal measures available that provide necessary exclusive rights to redress unauthorized uses of trademarks	1.00
19. Availability of frameworks that promote cooperative private action against online sale of counterfeit goods	1.00
20. Industrial Design Term of Protection	0.60
21. Legal measures available that provide necessary exclusive rights to redress unauthorized use of industrial design rights	1.00

INDICATOR	SCORE
Category 4: Trade Secrets and Related Rights	**2.75**
22. Protection of trade secrets, civil remedies	1.00
23. Protection of trade secrets, criminal standards	1.00
24. Regulatory data protection (RDP) term	0.75
Category 5: Commercialization of IP Assets	**5.66**
25. Barriers to market access	1.00
26. Existence of technology transfer framework with clear and defined IP provisions	1.00
27. Registration and disclosure requirements of licensing deals	1.00
28. Direct Government intervention in setting licensing terms	1.00
29. IP as an economic asset	1.00
30. Tax incentives for the creation of IP assets	0.66
Category 6: Enforcement	**6.65**
31. Physical counterfeiting rates	0.80
32. Digital/online piracy rates	0.85
33. Civil and procedural remedies	1.00
34. Pre-established damages and/or mechanisms for determining the amount of damages generated by copyright infringement	1.00
35. Criminal standards including minimum imprisonment and minimum fines	1.00
36. Effective border measures	1.00
37. Transparency and public reporting by Customs authorities of trade-related IP infringement	1.00
Category 7: Systemic Efficiency	**3.75**
38. Inter-governmental coordination of IP rights enforcement efforts	1.00
39. Consultation with stakeholders during IP policy formation	1.00
40. Educational campaigns and awareness raising	1.00
41. Targeted incentives for the creation and use of IP assets for SMEs	0.75
Category 8: Membership and Ratification of International Treaties	**4.00**
42. WIPO Internet Treaties	1.00
43. Singapore Treaty on the Law of Trademarks	1.00
44. Patent Law Treaty	1.00
45. At least one free trade agreement (FTA) with substantive and/or specific IP provisions such as chapters on IP and separate provisions on IP rights provided it was signed after WTO/TRIPS membership	1.00
TOTAL 42.66	

Spotlight on the National IP Environment

Past Editions versus Current Scores

The United States' overall score has decreased marginally from 94.95% (scoring 37.98 out of 40) in the 6th edition to 94.80% (scoring 42.66 out of 45) in the 7th edition. On the one hand, the U.S. saw its score increase on indicator 8 and performed strongly on the majority of new indicators added to the Index. On the other hand, the U.S. underperformed its average Index score on 2 of the new indicators added this year, indicators 30 and 41.

Patents, Related Rights, and Limitations

5. Legislative criteria and use of compulsory licensing of patented products and technologies: In July 2018, Democratic Rep. Lloyd Doggett introduced bill H.R. 6505 *Medicare Negotiation and Competitive Licensing Act of 2018* to the House of Representatives. The bill proposes to provide the U.S. Secretary of Health and Human Services the power to directly negotiate the price of medicines purchased and covered under Medicare Part D. If such negotiations are deemed to be unsuccessful, the proposed legislation also grants the secretary the power to allow the "use of any patent, clinical trial data, or other exclusivity granted by the Federal government" under a "competitive license." In effect the bill would grant the United States government the power to override any granted form of exclusivity in the event the price of a given medicine was not to the government's liking. The passing of the proposed bill or similar legislation would be a strange and unexpected policy departure for the U.S. Not only would such legislation undermine the basic idea of the protection and sanctity of property rights generally, but on a sector-specific level it would threaten the very foundation of America's position as the undisputed global leader in biopharmaceutical innovation. Biopharmaceutical breakthroughs by American firms are improving health treatment for patients globally, providing a steady stream of new drugs and health technologies. Since 2000, American companies have developed more than 550 new medicines; roughly half of all drugs launched globally. American research-based biopharmaceutical firms spent an estimated USD58.8 billion in 2015 on R&D, more than 80% of which was spent domestically in the U.S. This leadership

in global biopharmaceutical research and manufacturing also translates into large economic dividends for Americans. Revenues generated by a new blockbuster drug are comparable to the export of 1 million cars. The sector also accounts for and supports 4.5 million jobs. With an average annual wage of more than USD117,000, jobs in the drugs and pharmaceuticals sector pay, on average, 85% more than the private sector average. The basic economics of the biopharmaceutical industry show how critical IP rights are to incentivizing and supporting the development of new medical technologies and products. 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 to have rocketed to USD802 million. Research from Tufts University in 2016 suggests that it costs USD2.6 billion to develop a new drug. On average, only 1–2 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. Patents and other forms of exclusivity for biopharmaceuticals, such as regulatory data protection and special exclusivity incentives for the protection and production of orphan drugs, enable research-based companies to invest these vast sums in R&D and the discovery of new drugs, products, and therapies. American taxpayers and patients are concerned with the cost of prescription medicines and want their elected representatives to take appropriate action. However, the cost of drugs is a complex subject that does not lend itself to generalizing. It involves many different factors, such as health system infrastructure, health financing, and how the American health system itself is organized, financed, and accessed by patients. Within this cost equation the protection of IP plays a relatively small role. Instead of achieving the goal of lowering costs, proposals like Rep. Doggett's risk killing the proverbial goose and model of innovation that since the mid-1980s have been providing Americans—and patients around the world—with new and better health technologies and medicines. The passing of bill H.R. 6505 or similar legislation into law would result in a score decrease from 1 to 0 on this indicator. Notably, a federal inter-agency task force convened under the National Institute for Standards and Technology (NIST) released a December 20918 Draft Green Paper, "Unleashing American Innovation," (NIST Special Publication 1234), which stated unambiguously that "[compulsory license] rights should not be used as a mechanism to control or regulate the market price of goods and services." The Index will continue to monitor these developments in 2019.

8. Patent opposition: In 2018, the U.S. Patent and Trademark Office (USPTO) introduced several significant changes to the administration of patent opposition proceedings under the Patent Trial and Appeal Board (PTAB). In April, USPTO Director Andrei Iancu stated that the reform of IPR proceedings was one of the agency's "highest priorities," and it was considering "how and when we institute proceedings, the standards we employ during the proceedings, and how we conduct the overall proceedings. The goal, with whatever action we take, is to increase predictability of appropriately-scoped claims." Following these remarks, important reforms at the USPTO were undertaken that collectively should improve the predictability of the review process. Specifically, these include (1) changing the patent claim construction standard used, moving away from the broadest reasonable interpretation (BRI) standard to the so-called Phillips standard, which is the claim construction standard used by federal courts since the mid-2000s; (2) a new Trial Practice Guide; and (3) Standard Operating Procedure (SOP) changes. Using the Phillips standard will align IPR proceedings with the same claim construction standards that are used in patent infringement proceedings at U.S. district courts. There will thus no longer be a discrepancy and difference in the claim construction standard used within the PTAB proceedings and that used in the judiciary. The new Trial Practice Guide provides greater clarity on the grounds on which a review may be initiated. And the changes to both SOP 1 and SOP 2 seek to streamline how judges are assigned, the composition of panels, and the way precedent-setting opinions are set. Specifically, SOP 2 sets up a Precedential Opinion Panel, headed by the USPTO director. SOP 2 states that this panel "will be used to establish binding agency authority concerning major policy or procedural issues, or other issues of exceptional importance in the limited situations where it is appropriate to create such binding agency authority through adjudication before the Board." These are meaningful reforms that go a considerable way to address concerns about unpredictability and uncertainty in the U.S.

patent opposition system. As a result of these changes, the score for this indicator has increased by 0.25. On the legislative front Senator Orrin Hatch introduced the Hatch-Waxman Integrity Act of 2018, a set of amendments to the Drug Price Competition and Patent Term Restoration Act (the Hatch-Waxman Act). The purpose of these amendments is to address the challenges that the biopharmaceutical sector has faced within the IPR proceedings. As Senator Hatch explained it, these amendments would "preserve Hatch-Waxman as the standard path for generic companies to challenge brand patents, while keeping IPR as an option in situations where other interests come into play." The proposed law would require all drug applicants (innovators as well as follow-on manufacturers) to certify they have not "filed, or will file, a petition to institute an IPR or PGR challenge of any patent claiming the reference listed drug." If enacted, this measure would improve predictability of patent opposition in the bio-pharmaceutical space.

Trade Secrets and the Protection of Confidential Information

23. Protection of trade secrets (criminal sanctions): U.S. law provides clear and strong criminal sanctions relating to the theft and misappropriation of trade secrets. The 1996 Economic Espionage Act (Chapter 90 of Title 18 of the U.S. Code, "Protection of Trade Secrets") provides criminal sanctions for the theft and misappropriation of trade secrets. The law provides for prison terms of up to 10 years and fines up to USD5 million or 3 times the value of the stolen trade secret to the organization; these fines were strengthened by the 2016 Defend Trade Secrets Act. There is also strong evidence that federal prosecution of trade secret theft under the Economic Espionage Act has increased substantially under both the Obama and Trump administrations. Domestic legal analysis estimates that under the Obama administration prosecution of criminal violation of trade secret law grew by approximately 20%, from 7.2 cases per year in 1996–2009 to 8.6 cases per year in 2009–2016. Given increasing rates of global economic integration and the growth of both direct and indirect state-sponsored economic and industrial espionage, cases have become more focused on corporate malfeasance involving corporate defenders as well as foreign nationals. The growth in prosecution rates seems to have held steady under the first half of the Trump administration's first electoral term, with an estimated 9 new cases prosecuted in 2017.

Commercialization of IP Assets and Market Access

30. Tax incentives for the creation of IP assets: R&D tax incentives are provided at both the federal and state levels, but there is no IP-specific tax incentive, such as a patent box, in place. The federal Research and Experimentation Tax Credit allows companies to claim a tax credit of between 14% and 20% of qualifying amounts. After 30 years of uncertainties, during which time the credit lapsed 6 times and was extended 17 times, it was made permanent in December 2015 and expanded to cover R&D investments by small businesses. In addition, 39 U.S. states offer R&D tax credits at varying rates. For example, California offers a research credit of 15% of qualifying supplemental research activity conducted within the state, Maryland provides a credit of up to 13% of qualifying expenditure, and Massachusetts offers a credit of 10% on R&D expenses and 15% for donations to universities for basic research. Many states also offer additional incentives and tax credits such as seed capital tax credits, state venture capital investments, and state sales tax exemptions for R&D equipment.

Systemic Efficiency

41. Targeted incentives for the creation and use of IP assets for SMEs: Reduced fees for patent applications are available for small and micro entities. The USPTO also provides a range of educational programs and direct technical assistance through, for example, the Inventors Assistance Center as well as numerous events and workshops targeting SMEs and micro entities. Expedited review is primarily offered under two USPTO programs: Accelerated Examination and Track One. Track One is open to all applicants. The Accelerated Examination program has eligibility rules and applications are treated on a case-by-case basis. Biotechnology applications filed by small entities qualify for Accelerated Examination, but there is no general qualification for SMEs.