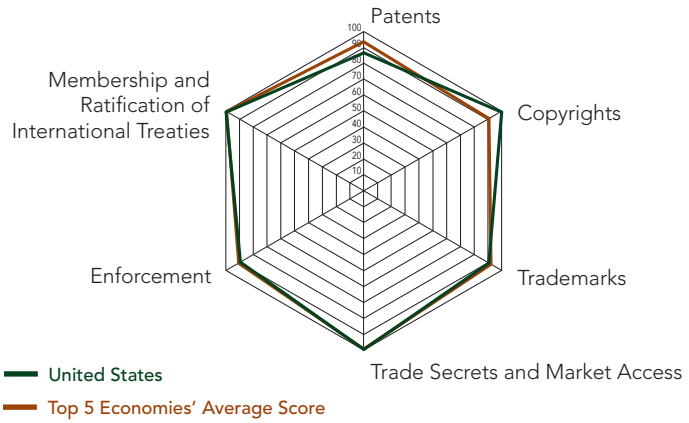
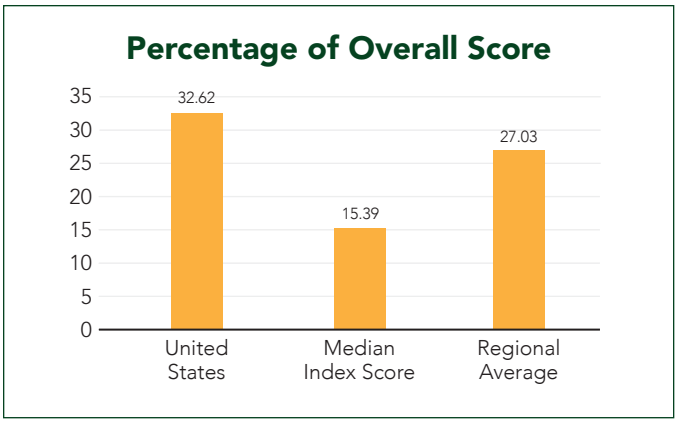
UNITED STATES

Rank: 1/45





Strengths and Weaknesses

Key Areas of Strength

- ✓ Key IP rights, including sector-specific rights, in place
- ✓ Largely supportive technology transfer and licensing environment
- ✓ Generally deterrent civil and criminal remedies
- ✓ Commitment to and implementation of international treaties

Key Areas of Weakness

- ✗ Patent opposition system adds substantial costs and uncertainty
- ✗ Somewhat narrow interpretation of patentability of biotech and computer-related inventions compared with international standards
- ✗ Inconsistent enforcement against counterfeit and pirated goods, especially goods sold online

INDICATOR	SCORE	INDICATOR	SCORE
Category 1: Patents, Related Rights, and Limitations			
1. Term of protection	1	19. Frameworks against online sale of counterfeit goods	0.75
2. Patentability requirements	0.75	20. Industrial design term of protection	0.6
3. Patentability of CIIs	1	21. Exclusive rights, industrial design rights	1
4. Pharmaceutical-related enforcement	1	**Category 4: Trade Secrets and Market Access**	
5. Legislative criteria and active use of compulsory licensing	1	22. Protection of trade secrets	1
6. Pharmaceutical patent term restoration	1	23. Non-barriers to market access	1
7. Regulatory data protection term	0.75	24. Regulatory and administrative barriers to commercialization	1
8. Patent opposition	0.5	**Category 5: Enforcement**	
Category 2: Copyrights, Related Rights, and Limitations		25. Physical counterfeiting rates	0.69
9. Term of protection	1	26. Software piracy rates	0.83
10. Exclusive rights	1	27. Civil and procedural remedies	1
11. Cooperative action against online piracy	1	28. Pre-established damages	1
12. Limitations and exceptions	1	29. Criminal standards	1
13. Digital rights management	1	30. Effective border measures	0.75
14. Government use of licensed software	1	31. Transparency and public reporting by customs	1
Category 3: Trademarks, Related Rights, and Limitations		**Category 6: Membership and Ratification of International Treaties**	
15. Term of protection	1	32. WIPO Internet Treaties	1
16. Limitations on use of brands	1	33. Singapore Treaty on the Law of Trademarks	1
17. Protection of well-known marks	1	34. Patent Law Treaty	1
18. Exclusive rights	1	35. Post-TRIPS FTA	1
TOTAL: 32.62			

Spotlight on the National IP Environment

Past Editions versus Current Scores

The United States' overall score has dropped slightly from 95% (with a score of 28.61 out of 30) to 93% (with a score of 32.62 out of 35). This decrease in score is mainly due to challenges, additional cost, and uncertainty in the patent opposition system in place since 2011, compared with other post-grant opposition systems (discussed below in relation to the new indicator on patent opposition).

Patents, Related Rights, and Limitations

2. **Patentability requirements:** In 2016, as part of its ongoing effort to develop guidance on recent key Supreme Court decisions in *Myriad, Mayo,* and *Alice*, the USPTO issued new guidelines on eligibility for patentable subject matter for naturally occurring substances. Although greater clarity is still needed, the guidance thus far appears to indicate that certain biologic claims and diagnostic methods are patentable, particularly where they involve something "significantly more" than an underlying "law of nature." A number of court cases in 2016 appear to mirror this approach. In *Rapid Litigation Management Ltd. v. Cellzdirect Inc.*, a Federal Circuit decision reversed an earlier decision limiting patentability of diagnostic claims, finding that biologic processes and diagnostic claims applying laws of nature (beyond merely observing or identifying such laws) and leading to a "new and useful" result are patentable. In *Vanda Pharmaceuticals Inc. v. Roxane Labs, Inc.*, claims on a personalized medicine method were upheld on the basis that both diagnostic and treatment methods included an additional step that went beyond merely depending on the laws of nature. Nevertheless, the patenting environment in the U.S. continues to be affected by uncertainty as to how to interpret Myriad and other key decisions, and greater clarity, consistency, and closing of gaps with international best practices is crucial to upholding a supportive innovation environment.

3. **Patentability of computer-implemented inventions (CIIs):** The USPTO has also issued updated guidance on software patenting in relation to a number of court decisions in 2016 (such as *McRO v. Bandai Namco, BASCOM v. AT&T Mobility,* and *Amdocs v. Openet Telecom*) that suggests that software patents that otherwise meet patentability criteria may be considered patent-eligible and clarifies that claims directed to software are not automatically considered to be patent-ineligible abstract subject matter.

8. **Patent opposition:** The U.S. provides for various types of post-grant opposition proceedings, including 2 introduced as part of the 2011 America Invents Act (AIA) in an effort to provide a more cost-effective, efficient alternative to judicial proceedings for challenging bad faith actors. The first is the post-grant review, available during a 9-month period following the grant of a patent, a mechanism that shares many similarities to the opposition regime available at the EPO. The second and most commonly used mechanism since the AIA is the *inter partes* review, available after the above window for a post-grant review; requests that are accepted for an IPR review must be issued within 18 months. Both proceedings occur before a specialized Patent Trial and Appeals Board (PTAB) within the USPTO and composed of administrative patent judges. Despite the intention of the new opposition mechanisms, the ease of challenging patents during the post-grant period, particularly via *inter partes* review, has led to a high rate of trials (particularly for life sciences claims) and of rejections (between 40% and 65% depending on the type of technology), with challenges considered by some experts to be disproportionately funded by bad faith actors. In addition, evidence suggests that there is a reduced opportunity to amend claims in opposition proceedings, with USPTO data indicating that only about 5% of requests to amend claims are granted by PTAB, and a lower burden of proof for opposing parties than in district court proceedings. Also, the rate of appeals to PTAB decisions is beginning to rise, with backlogs noticeable. As such, the opposition system in the U.S. still represents a potential channel for bad faith actors and can involve a great deal of cost and uncertainty for patent owners compared to other post-grant opposition systems.

Trade Secrets and Market Access

22. **Protection of trade secrets:** The Defend Trade Secrets Act was signed into law in 2016. The new law introduces a federal right of action against the misappropriation of trade secrets (on top of existing state-level rights of action). Available remedies include damages for actual losses, with higher damages for willful infringement, injunctive relief, and seizures (in extreme situations). Relief is also provided for threatened misappropriation if clear evidence of a threat exists. The new framework aids in enhancing the protection of trade secrets across the U.S.

Enforcement

30. **Effective border measures:** In 2016, the Trade Facilitation and Trade Enforcement Act was signed into law. Among other elements, the new measure aims to close existing gaps in the fight against trade in counterfeit goods. The law includes requirements for customs authorities to disclose information to rights holders based on suspected infringing goods and earlier in the process than previously existed in law. These requirements are intended to shore up the ability to identify and speedily address potential counterfeits. The measure also formally establishes the new National IPR Coordination Center, with authority to coordinate investigations with other agencies, improve communication with rights holders, and support criminal prosecution. Depending on the application of the law in practice, the U.S.'s score may rise for this indicator in future editions of the Index.