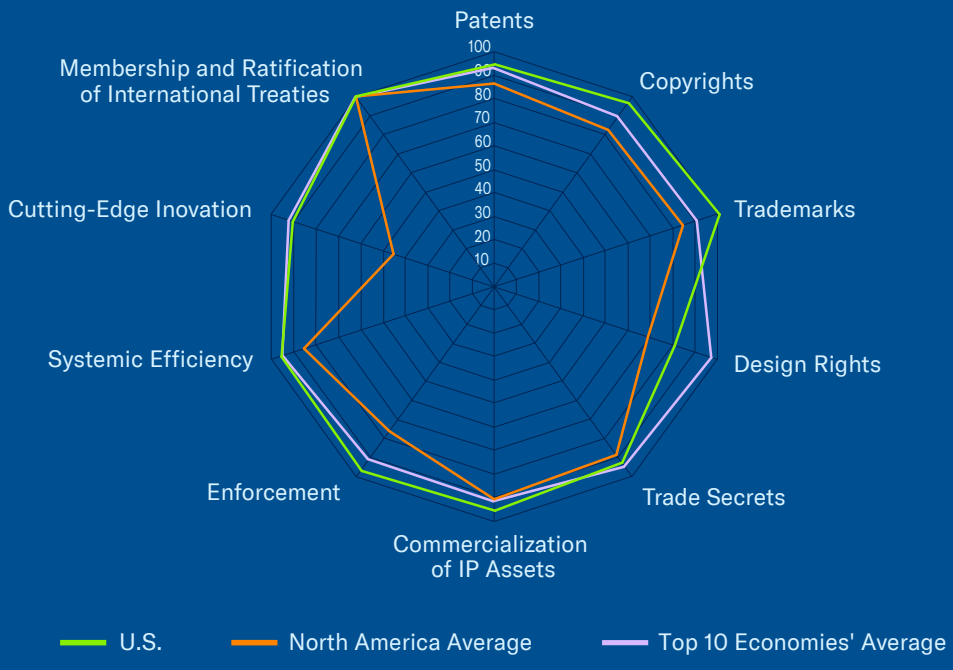
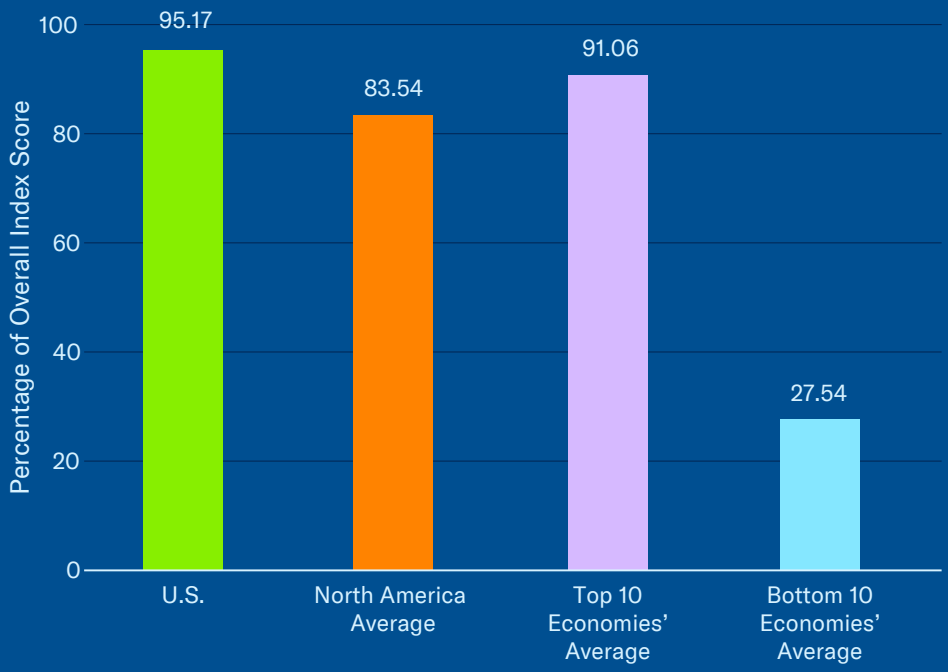
United States

Rank
1/55

Category Scores



Overall Score in Comparison



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Key Areas of Strength

- Since the mid-1980s, the Orphan Drugs Act has provided a world leading seven-year term of orphan market exclusivity resulting in new biopharmaceutical R&D and the development of new treatments and medicines for rare diseases
- The U.S. national IP system continues to provide international leadership
- Sector-specific rights and protections are in place across all Index categories
- Congressional efforts to address long-standing challenges and uncertainty over patentable subject matter and PTAB proceedings
- Continued efforts made to reform patent nullity and opposition proceedings in 2024; USPTO should be commended for efforts to provide a greater balance and to address concerns over unpredictability and uncertainty within the PTAB process

Key Areas of Weakness

- 2024 FTC blanket banning of noncompete agreements puts IP assets at risk
- 2024 bills S150, HR6986, and S3583 all fundamentally seek to limit the number of patents a rightsholder may assert in an infringement action
- 2025 NIH changes to the Intramural Research Program puts U.S. innovation and economic growth at risk
- 2023 NIST proposals for exerting “march-in rights” fundamentally undermine patent rights
- Long-standing uncertainty about patentability standards for high-tech sectors
- Long-standing uncertainty about PTAB proceedings
- USPTO administrative efforts to undermine patent examination practices for the life sciences industry
- Past administration pushed “collaboration” efforts between USPTO and FDA
- No targeted legal basis for addressing online piracy along the lines of other global leaders

Indicator	Score
Category 1: Patents Rights and Limitations	**8.50**
1. Term of protection	1.00
2. Patentability requirements	0.75
3. Patentability of CIIs	1.00
4. Plant variety protection	1.00
5. Pharmaceutical-related enforcement	1.00
6. Legislative criteria and use of compulsory licensing	1.00
7. Pharmaceutical patent term restoration	1.00
8. Membership of a Patent Prosecution Highway	1.00
9. Patent opposition	0.75
Category 2: Copyrights and Limitations	**6.75**
10. Term of protection	1.00
11. Exclusive rights	1.00
12. Expeditious legal remedies disabling access to infringing content online	0.75
13. Cooperative action against online piracy	1.00
14. Limitations and exceptions	1.00
15. TPM and DRM	1.00
16. Government use of licensed software	1.00
Category 3: Trademarks Rights and Limitations	**4.00**
17. Term of protection	1.00
18. Protection of well-known marks	1.00
19. Exclusive rights, trademarks	1.00
20. Frameworks against online sale of counterfeit goods	1.00
Category 4: Design Rights and Limitations	**1.60**
21. Industrial design term of protection	0.60
22. Exclusive rights, industrial design rights	1.00
Category 5: Trade Secrets and the Protection of Confidential Information	**2.75**
23. Protection of trade secrets (civil remedies)	1.00
24. Protection of trade secrets (criminal sanctions)	1.00
25. Regulatory data protection term	0.75
Category 6: Commercialization of IP Assets	**5.67**
26. Barriers to market access	1.00
27. Barriers to technology transfer	1.00
28. Registration and disclosure requirements of licensing deals	1.00
29. Direct government intervention in setting licensing terms	1.00
30. IP as an economic asset	1.00
31. Tax incentives for the creation of IP assets	0.67
Category 7: Enforcement	**6.72**
32. Physical counterfeiting rates	0.87
33. Software piracy rates	0.85
34. Civil and precedural remedies	1.00
35. Pre-established damages	1.00
36. Criminal standards	1.00
37. Effective border measures	1.00
38. Transparency and public reporting by customs	1.00
Category 8: Systemic Efficiency	**4.75**
39. Coordination of IP rights enforcement	1.00
40. Consultation with stakeholders during IP policy formation	1.00
41. Educational campaigns and awareness raising	1.00
42. Targeted incentives for the creation and use of IP assets for SMEs	0.75
43. IP-intensive industries, national economic impact analysis	1.00
Category 9: Cutting-Edge Innovation	**2.70**
44. IP incentives for orphan medicinal product development	1.00
45. IP incentives for orphan medicinal product development, term of protection	0.70
46. Restrictions on the effective use of existing IP incentives for orphan medicinal product development	1.00
Category 10: Membership and Ratification of International Treaties	**7.00**
47. WIPO Internet Treaties	1.00
48. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	1.00
49. Patent Law Treaty and Patent Cooperation Treaty	1.00
50. Membership of the International Convention for the Protection of New Varieties of Plants, act of 1991	1.00
51. Membership of the Convention on Cybercrime, 2001	1.00
52. The Hague Agreement Concerning the International Registration of Industrial Designs	1.00
53. Post-TRIPS FTA	1.00

Percentage of Overall Score: 95.17% • **Total Score: 50.44**

Spotlight on the National IP Environment

Past Editions versus Current Score

The United States' overall Index score has increased from 47.74 out of 50 indicators in the twelfth edition to 50.44 out of 53 indicators. This reflects a strong performance for the new indicators added under Category 9: Incentives for Cutting-Edge Innovation.

Patent Rights and Limitations

2. Patentability requirements:
As noted over the course of the Index, since the Supreme Court decisions in the *Bilski, Myriad, Mayo,* and *Alice* cases, uncertainty surrounds what constitutes patentable subject matter in the United States. Since 2014, the USPTO has issued and updated patent examination guidelines almost on an annual basis. Lower and circuit court decisions in patent infringement proceedings have not always been consistent. The net result is that rightsholders are left without a clear sense of how decisions on patent eligibility will be made, or, when granted patents are subsequently challenged or reviewed either through the courts or through the *inter partes* proceedings within the USPTO, which patent claims will be upheld. The USPTO has recognized this dilemma and has sought to reformulate its position and the approach to be taken by its examiners. In 2019, the office released new guidance covering Section 101, Patentability, and Section 112, Claims, related to computer inventions, the "2019 Revised Patent Subject Matter Eligibility Guidance," and "Examining Computer-Implemented Functional Claim Limitations for Compliance With 35 U.S.C. 112." With respect to Section 101, Patentability, the guidance provided more of a principle-based analysis of how patentability would be judged, and it described the stepwise approach examiners should follow to understand and apply the Supreme Court's Alice/Mayo test.

As the guidance rightly pointed out, the key challenge for USPTO examiners and courts has been to "consistently distinguish between patent-eligible subject matter and subject matter falling within a judicial exception." The guidance recognized this and sought, to the extent possible without further statutory changes, to clear this up with a revised procedure and process for examiners to follow.

In 2020, the USPTO's Office of the Chief Economist published *Adjusting to Alice USPTO Patent Examination Outcomes after Alice Corp. v. CLS Bank International*. This report examined the effect of the 2019 guidance on rates of first office rejections for Alice-related technologies, that is, technologies and applications that the USPTO and the U.S. Patent Classifications have defined as containing "abstract ideas." The report found that, overall, since the introduction of the guidance, a measurable and statistically significant decrease has occurred in the number of first office rejections for *Alice*-related technologies. Specifically, the likelihood of receiving a first office rejection decreased by 25% in the 12 months after the introduction of the guidance. As the USPTO rightly noted at the time of publication, this is positive news.

Unfortunately, as noted repeatedly by the Index, uncertainty about what constitutes patentable subject matter has crept into all facets of the American patent system, from initial application and examination to standards of review and invalidity proceedings, whether administratively through PTAB or through the judiciary. For instance, with respect to the influence and use of the USPTO's guidance, the U.S. Court of Appeals for the Federal Circuit has expressly, and repeatedly, stated that the guidance does not carry the force of statutory law or relevant case law and is therefore not a controlling factor in any patentability analysis carried out by the court.

Efforts to address this long-standing problem continued in 2024. The Patent Eligibility Restoration Act—introduced into the Senate in 2023 by Senators Tillis and Coons—marks a significant breakthrough on the legislative front. As noted in the Index last year, the draft legislation addresses many of the long-standing areas of concern and uncertainty about what constitutes patentable subject matter in the United States. In another positive development in Congress, Senators Coons and Cottons introduced the Realizing Engineering, Science, and Technology Opportunities by Restoring Exclusive (RESTORE) Patent Rights Act in 2024. The RESTORE Act seeks to address the difficulty rightsholders have had since in getting permanent injunctions in infringement proceedings since the 2006 Supreme Court decision in *eBay v. MercExchange*.

On the other end of the spectrum, in 2024, several developments occurred that would negatively affect the patenting environment and curtail existing patent rights. First, in May, the USPTO proposed to change the practice of terminal disclaimers. The agency requires these disclaimers in relation to nonstatutory double patenting. The USPTO wants to include a new requirement whereby applicants also agree to limit the number of claims that could be referred to in future infringement action. The agency argues that the proposed rule change would lower "the cost of challenging groups of patents tied by terminal disclaimers, resulting in reduced barriers to market entry and lower costs for consumers." In other words, the USPTO seeks to limit and reduce existing IP rights because the agency—not Congress or existing patent statute—believes that doing so would achieve a perceived policy good.

In Congress, several bills—S150, HR6986, and S3583—were introduced that all seek to limit the number of patents a rightsholder may assert in an infringement action.

Not only do these bills discriminate and selectively target the life sciences sector with these restrictions, but they also embrace a fundamentally anti-IP and anti-innovation logic whereby the restriction of IP rights will lead to lower prices and greater access to a given product, in this case, biopharmaceutical treatments.

As detailed across numerous editions of the Index and most clearly illustrated by the life-saving innovation and product development witnessed during the COVID-19 pandemic, 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. The latest *Annual Membership Survey* from the Pharmaceutical Research and Manufacturers of America (PhRMA) shows that in 2024, American research-based biopharmaceutical firms spent an estimated $71.3 billion in 2023 on R&D domestically in the United States and over $96 billion globally.[17] This leadership in global biopharmaceutical research and manufacturing also translates into large economic dividends for Americans. In 2022, the research-based industry directly employed over 1 million workers and supported an additional 3.8 million jobs, bringing the total number of jobs supported in the U.S. economy to 4.9 million.[18] In terms of added value and contributions to national economic output, these were estimated at 3.4% and 3.6% of the GDP, respectively.[19] The basic economics of the biopharmaceutical industry show how critical IP rights are to incentivize and support the development of new medical technologies and products.

In 1979, the total cost of developing and approving a new drug stood at approximately $138 million. Today, the most recent research from Tufts University suggests that it costs $2.6 billion, on average, to develop a new drug.

Only one to two 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 RDP 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. Instead of achieving the goal of lowering costs, proposals that undermine these IP rights and incentives that make biopharmaceutical R&D and investment possible risk the very model of innovation that since the mid-1980s has provided Americans, and patients around the world, with new and better health technologies and medicines. The Index will continue to monitor these developments in 2025.

9. Patent opposition:
To provide a more cost-effective, efficient alternative to judicial proceedings, the 2011 America Invents Act (AIA) introduced new postgrant opposition and patent nullity proceedings. As has been detailed in previous editions of the Index, despite the intentions of these new AIA mechanisms, the result has been a sustained level of uncertainty and unpredictability for many patent owners. This has been especially the case with the *inter partes* review, which occurs before the specialized PTAB within the USPTO. As noted over the course of the Index, the U.S. government (chiefly through the USPTO) has recognized the unintended effects of the PTAB system and has publicly pledged to work with all stakeholders to address and remedy them. As a result, many important changes have since been introduced, including changes to claim construction standards, trial practices, and standard operating procedures. These efforts continued in 2024 with several USPTO rule changes coming into effect. These include changes to Standard Operating Procedure 4 and the internal review of PTAB decisions, the Director Review process and replacement of the Precedential Opinion Panel, and legal representation rules before the USPTO. At the time of research, the USPTO had not finalized additional proposed rules related to serial and parallel petitions. In 2024, Congress continued reviewing the Promoting and Respecting Economically Vital American Innovation Leadership Act (PREVAIL Act). As discussed last year, the PREVAIL Act would address much of the uncertainty and unpredictability caused by PTAB. At the time of research, no legislative proposals had been passed by Congress or signed into law. The Index will continue to monitor these developments in 2025.

Copyrights and Limitations

14. Scope of limitations and exceptions to copyrights and related rights:
Like many other Index economies, the United States has identified the application of AI and machine learning as important areas of technological development and future economic activity. Both the federal government and Congress have worked on policy reforms related to AI and machine learning over the past two years. The Copyright Office issued a "notice of inquiry request for comments" on the interaction between AI and copyright. In 2024, the Copyright Office published the first in a series of reports on AI and copyright. This report addresses the issue of digital replicas, that is, the use of computer software technologies, including AI and machine learning applications, to replicate human beings' voice and appearance. The office has already announced that future reports will examine copyright within the context of the development and application of AI and machine learning tools.

Separately, Congress introduced several bills related to AI and copyright. These include the NO FAKES Act, the Generative AI Copyright Disclosure Act, the Transparency and Responsibility for Artificial Intelligence Networks Act, and several others. Many of these bills would address the issue of digital replicas identified by the Copyright Office and would put in place new transparency requirements on developers of generative AI and machine learning technologies.

In 2024, lawsuits related to the potential use of copyright protected material in the development of generative AI increased. At the time of research, these suits remained pending. The use and application of AI and machine learning is an important area of future economic activity as advances in computational power and new technological breakthroughs allow for scientific advances and innovation to take place through the analysis of large volumes of data and information. However, given the existing dynamics of the internet and the volume of infringing content available online—much of it made available without rightsholders' permission or even their knowledge—as well as the ability of scraping technologies to access rightsholders' content without their permission, it is essential that traditional safeguards enshrined in decades of copyright law and legal practice be strictly adhered to and that rightsholders can enforce their rights, both in the United States and around the world. The Index will continue to monitor these developments in 2025.

Trade Secrets and the Protection of Confidential Information

In April 2024, the Federal Trade Commission (FTC) issued a rule banning the effective use of noncompete agreements. Historically, these agreements have been an important component in an organization's ability to protect its trade secrets and confidential information.

Noncompete agreements prevent employees from potentially using any trade secrets or confidential information acquired over the course of their employment. Ultimately , the FTC's rule was vacated in court. Given the rise in trade secret theft and the misappropriation of confidential information, if rightsholders are unable to protect their IP assets with the support of noncompete agreements, this would pose a new and unnecessary risk to the United States' national IP environment and national security. The Index will continue to monitor these developments in 2025.

Commercialization of IP Assets and Market Access

27. Barriers to technology transfer:
In the early and mid-1980s, the U.S. Congress passed several groundbreaking pieces of legislation establishing the basis for our modern-day technology transfer and commercialization framework. Chief among these was the University and Small Business Patent Procedures Act, (the Bayh-Dole Act) of 1980. Over the past 40 years, this legislative framework has supplied federal laboratories, small businesses, universities, and other entities using federal funds with the incentives needed to work with the private sector for the purpose of translating early-stage research into usable products in the marketplace for the benefit of the wider public. This framework—together with subsequent changes and legal amendments—secured these goals through four major changes to the U.S. IP system. First, they allowed universities and federally funded bodies to retain ownership of the proprietary knowledge stemming from the research and daily activities of these institutions, including the ability to own patents on their inventions.

Second, they encouraged these institutions to become much more proactive and professional in the management and use of their IP rights by creating professional technology transfer offices. Third, the legislation sought to stimulate the commercial and financial aspects of public-private collaboration, with the intention of creating new businesses (such as spin-off companies) and generating income for institutions and researchers. Finally, by codifying under what specific and highly unique circumstances the federal government has the power to use march-in-rights, the Bayh-Dole framework provided relevant institutions and rightsholders legal certainty on their ownership rights and title to developed IP assets. The importance of the Bayh-Dole framework to U.S. innovation cannot be overstated.

In 2002, *Economist* magazine called the law the "most inspired piece of legislation to be enacted in America in the last half-century." This statement aptly sums up the positive impact the legislation has had on U.S. innovation. To begin with, research into the effects of the Bayh-Dole framework has found a significant correlation between increased patenting activities at U.S. universities and the Act. In 1981, the number of Bayh-Dole patents granted in the United States totaled 1,635. Over the next four decades, this has increased by over 400% with over 7,000 patents issued per year. Indeed, a 2004 academic study found that university share of total patenting in the United States increased from 0.69% of total patents at the time of legislation to just under 5% in 1996. More broadly, this positive impact can also be seen in terms of the direct and significant contributions to U.S. economic output and employment. For instance, using 25 years of data from the annual Association of University Technology Managers survey, a 2022 study estimating the economic contribution of licensing activity by academic institutions found that in the United States, the contribution of academic licensing to gross industry output ranged from $631 billion to $1.9 trillion (measured in 2012 U.S. dollars). Contributions to GDP were equally significant and estimated at between $333 billion and $1 trillion (measured in 2012 U.S. dollars). And at the micro level, the Bayh-Dole framework has led to the invention and commercialization of thousands of products and technologies on which consumers, patients, and businesses today rely. This innovation has not been concentrated in any one industry or economic sector but has been broad-based across all industries and the entire U.S. economy. For example, this positive impact can be seen in the ICT and semiconductor industry, manufacturing, and venture capital (including investments in biotechnology).

Over the past two years, the federal government has put forth proposals that would undermine the Bayh-Dole framework and all the innovation and socioeconomic gains of the past 40 years. In late 2023, the National Institute of Standards and Technology (NIST) published a "Request for Information" on a Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights. A primary focus of the draft is the extent to which the price of a relevant invention can be considered as justifying the federal government's ability to override any existing IP exclusivity. This follows a similar discussion in 2021 when the Department of Commerce and NIST requested comments for potential changes to the way federally funded or supported technologies developed are transferred and licensed. Part of the discussion around the proposed rule changes in 2021 related to the issue of so-called "march-in rights." Such rights grant the federal government a mechanism to access a given technology under specific circumstances. These march-in-rights are not—and have never been—meant to be used as a way for the federal government to insert itself in the innovation and commercialization process of a technology or product.

These rights were also not intended to allow the government to impose price, access, or production/manufacturing controls on a technology or the abrogation of an existing licensing agreement to reduce public expenditure or achieve any other stated federal policy goal. This was never the intention of the underlying legislation, and it would be counter to the legislation's stated policies and objectives. Until now, this has also been acknowledged by federal agencies through their actions and public statements. For example, then NIH Director Francis Collins in 2017 stated, in public testimony before Congress, that march-in rights do not apply within the context of the price of medicine.

In a separate development, in May 2024, NIH issued a Request for Comment on a new policy within its Intramural Research Program. Under the proposed policy, NIH would require licensees who successfully develop and commercialize a medicinal product (defined by NIH as "drugs, biologics, vaccines, or devices") to submit a "plan outlining steps they intend to take to promote patient access to those products." In January, NIH announced a finalized policy largely mirroring this proposal. The finalized policy only applies to patents wholly owned by NIH and not to any IP developed and owned by a third party through an NIH grant. Unfortunately, the policy is unlikely to achieve NIH's objectives. Instead of achieving greater patient access, the new policy will simply act as a disincentive to partner with NIH. This will, in turn, lead to fewer partnerships and fewer new products and technologies developed. Fundamentally, NIH seems to have misunderstood its role and that of the private sector in the technology transfer process. The overwhelming majority of publicly funded research—whether through the NIH, academic institutions or other parts of the federal government—does not result in or even seek to result in a finalized, commercially available product.

The translation of basic research into new products, services, and technologies is done through the partnership of the private sector, which invests the resources and shoulders all of the accompanying financial risk of the commercialization process. In this respect, although critical, basic research, no matter how pathbreaking, is almost never in itself enough to lead to a final product or service. The commercialization process for each licensed technology and invention is unique, and the exact amount of expenditure and commercialization spending ratio between licensee and licensor varies from technology to technology and from transaction to transaction. However, practical experience and research suggests that most investment needed in the development and commercialization of a product is done by the private sector entity to which the invention has been licensed. For example, in a 2012 study, the Congressional Research Service stated, "Although research is often important to innovation, it appears that, on average, it constitutes approximately 25% of the cost of commercializing a new technology or technique, thus requiring the expenditure of a substantial amount of additional resources to bring most products or processes to the marketplace [emphasis added]." The new administration has the opportunity to move in a different direction. Instead of adopting a more expansionist and interventionist view of march-in rights and the public-private licensing process, it could revert to a more traditional understanding of both the Bayh-Dole Act and the role of the federal government in the licensing process. Such a change of direction could help ensure that the Bayh-Dole framework continues to stimulate innovation, economic growth, and prosperity for another 50 years.

Incentives for Cutting-Edge Innovation

44. Special market exclusivity incentives for orphan medicinal product development; 45. Special market exclusivity incentives for orphan medicinal product development, term of protection; and 46. Restrictions on the effective use of existing market exclusivity incentives for orphan medicinal product development:

The United States was the first economy to introduce dedicated incentives for the development and commercialization of medicinal orphan products. The 1983 Orphan Drug Act and subsequent regulations and rules issued by the U.S. FDA provides the legislative basis for the designation of orphan drugs in the United States.

Under this framework, the U.S. provides several dedicated incentive programs related to both the financing of drug development and support in the acceleration and facilitation of regulatory and administrative procedures. Specific programs include a seven-year orphan market exclusivity period, grants, tax credits and fee waivers, and fast-track approval.