

Total research spending at American universities reached nearly \$90 billion in 2021,^{1 2} and university licensing revenue has climbed to almost \$3 billion a year.³ From robotics to agriculture to medicine, useful discoveries constantly emerge from academic labs. Yet policymakers often fail to recognize the critical role of intellectual property in driving all that spending, income, and innovation. Standing up for strong IP rights must be a priority for American universities.

Drug Price Controls

The Issue:

Some lawmakers claim that IP rights are responsible for high prescription drug prices.^{4 5} They offered their two-fold “solution” to this misdiagnosed problem in a 2022 letter to Health and Human Services Secretary Xavier Becerra.⁶ Both proposals offer faulty interpretations of existing law.

- Congress passed the Bayh-Dole Act in 1980 to enable universities to patent discoveries based on government-funded research. Today, the Bayh-Dole framework underpins billions of dollars’ worth of funding and licensing opportunities at U.S. institutions.⁷ The letter writers incorrectly say that the law authorizes the government to “march in” on drug patent rights and relicense them to generic manufacturers as a form of price control.^{8 9}
- The same letter calls on the administration to use Section 1498 of the U.S. code for a similar purpose. Section 1498 is a wartime procurement law dating to the early 20th century, which permits the government to relicense intellectual property to generic manufacturers to meet emergency needs.¹⁰ The letter writers wrongly assert that the law authorizes patent seizure as a means of price control.

Impact on Universities:

Patents and other IP rights enable universities to license out breakthroughs for further development by private companies. Those companies need secure IP in order to justify their investments. If patents can be voided based on misguided legal reasoning or political whim, investors will lose the incentive to license new discoveries. This will destroy a major source of revenue for universities and cut off funds for groundbreaking research.¹¹

1 <https://nces.nsf.gov/pubs/nsf23304>

2 <https://www.forbes.com/sites/michaelnietzel/2022/12/17/the-top-25-american-universities-based-on-r-and-d-spending-johns-hopkins-again-heads-the-list/?sh=6cdd61aa47a0>

3 <https://ipwatchdog.com/2020/04/07/evolution-university-technology-transfer/id=120451/>

4 <https://news.bloomberglaw.com/health-law-and-business/biden-drug-price-pressure-on-patent-office-draws-skeptics>

5 <https://news.bloomberglaw.com/health-law-and-business/warren-bid-to-grab-pfizer-cancer-drug-patents-gets-stern-rebuke>

6 <https://doggett.house.gov/sites/evo-subsites/doggett.house.gov/files/evo-media-document/Bicameral%20Letter%20Urging%20HHS%20to%20Lower%20Drug%20Prices.pdf>

7 <https://catalyst.phrma.org/ip-explained-four-things-to-know-about-the-bayh-dole-act>

8 <https://www.warren.senate.gov/imo/media/doc/Bicameral%20Letter%20Urging%20HHS%20to%20Lower%20Drug%20Prices%20FINAL1.pdf>

9 <https://www.washingtonpost.com/politics/2021/09/08/claim-that-us-government-already-has-power-lower-drug-prices/>

10 <https://www.warren.senate.gov/imo/media/doc/2022.4.20%20Letter%20to%20Warren%20on%20Drug%20Pricing%20Executive%20Authorities.pdf>

11 <https://www.warf.org/about-warf/impact-on-uw-madison/> (note: WARF represents the upper bound of potential operating revenue from TTOs)

Impact on Innovation Ecosystem:

Both proposals would destroy confidence in U.S. patent rights and thoroughly discourage the kind of risky, long-term private investment required to bring new discoveries to market. Academic tech transfer — which is enabled by Bayh-Dole — has contributed up to \$1.7 trillion to the U.S. economy and supported millions jobs.¹² Gutting our IP framework would threaten these jobs, shrink the tech clusters that have grown up around top universities, and hurt our economy nationwide.¹³

The Patent Eligibility Restoration Act

The Issue:

Over the past decade, confusing and contradictory jurisprudence from the Supreme Court has introduced a cloud of uncertainty over which inventions and ideas are patentable.¹⁴ This has hurt the U.S. diagnostics industry and chilled high-tech sectors like artificial intelligence, 5G, and biotechnology. The bipartisan Patent Eligibility Restoration Act would clarify patent eligibility.¹⁵

Impact on Universities:

Patent uncertainty in critical sectors discourages investment and dampens private-sector enthusiasm for licensing new discoveries from universities.

Impact on Innovation Ecosystem:

America's research and development system runs on patents, and patents depend on clear, predictable rules. Passing the Patent Eligibility Restoration Act will strengthen the U.S. economy and national security by encouraging new research and development in critical industries.

Upholding Fintiv Precedent

The Issue:

The U.S. Patent and Trade Office (USPTO) recently established the “Fintiv rule,” which lets the Patent Trial and Appeal Board decline to review a patent case if it's already being litigated elsewhere. This protects inventors from having to defend their intellectual property in multiple courts.¹⁶ Named for a 2020 case between Apple and mobile commerce platform Fintiv,¹⁷ the rule helped level a playing field in which Big Tech firms strategically mounted the same legal battle in more than one court at once, with the intention of beating smaller rivals by outspending them.

Impact on Universities:

As patent holders, university tech-transfer offices may face IP-related legal challenges in multiple forums. The Fintiv rule helps protect them from costly and frivolous lawsuits.

12 <https://bayhdolecoalition.org/wp-content/uploads/2021/08/FY20-Infographic.pdf>

13 <https://www.bostonherald.com/2022/08/17/nelsen-help-americas-universities-keep-transforming-the-world/>

14 <https://c4ip.org/wp-content/uploads/2022/10/C4IP-Letter-on-Patent-Eligibility-Restoration-Act.pdf> pg 2

15 <https://www.tillis.senate.gov/2022/8/tillis-introduces-landmark-legislation-to-restore-american-innovation>

16 <https://news.bloomberglaw.com/ip-law/turning-away-a-patent-challenge-the-nhk-fintiv-rule-explained>

17 [https://www.uspto.gov/sites/default/files/documents/IPR2020-00019,%20Apple%20v.%20Fintiv,%20Paper%2011%20\(3.20.20\).pdf](https://www.uspto.gov/sites/default/files/documents/IPR2020-00019,%20Apple%20v.%20Fintiv,%20Paper%2011%20(3.20.20).pdf)

Impact on Innovation Ecosystem:

The Fintiv precedent helps protect entrepreneurs and startups from unfounded legal attacks.¹⁸ Unraveling it would chill innovation across many sectors of the American economy.

TRIPS Waiver Extension

The Issue:

The World Trade Organization is deciding whether to extend an international patent waiver so that it applies to tests and treatments for Covid-19. Some U.S. lawmakers have encouraged this extension. The waiver nullifies rights normally protected by the Trade-Related Aspects of Intellectual Property Rights agreement, known as TRIPS. By making it legal under international law for some foreign companies to appropriate U.S. IP without permission or compensation, the waiver extension would hurt the U.S. economy and national security.

Impact on Universities:

University research underlies many Covid-19 technologies, including the mRNA vaccine platform pioneered at the University of Pennsylvania and the anti-viral molnupiravir, which was developed at Emory University. Suspending the IP rights that enabled these and other discoveries would destroy confidence in the university licensing system, cut off university revenue, and undermine research that could save us from the next pandemic.

Impact on Innovation Ecosystem:

The proposed TRIPS waiver extension would decimate innovation incentives and hamstring the private sector's ability to respond to future pandemics. This wholly unnecessary suspension of a landmark global agreement — TRIPS — would jeopardize intellectual property worldwide.

¹⁸ https://www.realclearpolicy.com/articles/2022/08/11/does_our_patent_system_really_need_a_revamp_847336.html