



Reaffirm and Refine: A Government Agenda for Intellectual Property

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Introduction

For the United States to maintain its competitive edge on the global stage, we must lead in innovation. This is only achievable by committing to protect the intellectual property that underlies game-changing inventions and brings about transformative change for patients, consumers, and businesses. A strong innovation economy is inextricably linked to a strong intellectual property (IP) system. Now is the time for bipartisan majorities to gather in support of this essential linchpin of U.S. prosperity and economic growth.

Robust protection for patents, copyrights, trademarks, and other forms of intellectual property has long been an area of bipartisan consensus in the United States. When the Founders gathered for the Constitutional Convention in 1787, they understood that IP rights were so fundamental to the new nation's economic success that they enshrined them in the Constitution with a unanimous vote.¹ As they foresaw, intellectual property provided a stable foundation that allowed creative individuals to take a chance on their ideas and to attract investment in them.

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Since then, Republicans and Democrats have regularly joined together to reaffirm the need for strong IP protection and refine IP rights to align with changing times. As a result, in a virtuous cycle, IP rights have led to investment in, and the development of, previously unimagined technologies, which have, in turn, required the further modernization of IP protection.

Advancements in video technology, for example, have brought about unique challenges in the realm of content piracy. The emergence of influential brands, including those crafted by a new generation of creators, has sparked considerable incentives for counterfeiting. Meanwhile,

[1] Constitutional Rights Foundation, *The Origins of Patent and Copyright Law*, BILL OF RIGHTS IN ACTION (2008), <https://www.crf-usa.org/bill-of-rights-in-action/bria-23-4-a-the-origins-of-patent-and-copyright-law>.

ever-more sophisticated computing capabilities have led to striking developments in the field of artificial intelligence, which may someday have the capacity to generate inventions of its own. Will IP protection keep pace?

Yet America’s IP system has constantly confronted threats from opportunistic actors seeking to reap the benefits of others’ innovative efforts. Such actors range from individual thieves operating at the local level to organized adversaries with a global reach. Some may aim to rig IP protection in favor of their private interests, often the interests of big players seeking to preclude new competition. Others claim to target IP under the guise of “fairness” without considering the cumulative damage of such precedent-setting interventions to innovation.

Recent years have seen unprecedented attacks on IP rights along all these lines. As a result, careful observers are already calculating how much margin for error the U.S. innovation economy has before stagnation creeps in and paralyzes us. Of course, some countries, such as China, may see this working to their short-term advantage. But the global economy can ill-afford to see a decline in U.S. innovation. Nor does it seem likely that Americans will tolerate such a decline for long.

Avoiding innovation stagnation requires a robust bipartisan recommitment to the IP protection that underlies innovation. Accordingly, as the 118th Congress, federal agencies, and the Biden Administration weigh policy priorities for 2023 and 2024, the Council for Innovation Promotion (C4IP) urges consideration of the following IP agenda.

Reform Agenda for the 118th Congress

Section 1: Congress should reaffirm the property-right nature of patents by restoring the right to exclude

The Constitution provides that inventors should have “the exclusive right” to their discoveries.² This has historically always been enforced with injunctive relief—court orders that require patent infringers to stop stealing IP or selling the infringing technology.³ This is critical to maintaining the basic rules of the road that create a marketplace for patents

[2] U.S. CONST., art. I, § 8, cl. 8.

[3] Christopher B. Seaman, *Permanent Injunctions in Patent Litigation After eBay: An Empirical Study*, 101 IOWA L. REV 1949, 1959-62 (2016), <https://ilr.law.uiowa.edu/sites/ilr.law.uiowa.edu/files/2023-02/ILR-101-5-Seaman.pdf>.

and inventions. After all, if the worst that happens after someone uses another’s invention without permission is that they *eventually* have to pay, that person has no real incentive to take a license upfront.

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But the courts, through a series of rulings in recent years, have made it virtually impossible for many patent holders to obtain injunctive relief for patents ruled valid and infringed.⁴ This essentially turns into a compulsory license, forcing patent owners to share their technology.

That contradicts the purpose of patents, which provides inventors with exclusivity so that they have the ability to control who gets to use their invention and how—they can bring it to the market themselves or choose to license to another to do so. Allowing someone to infringe, with no ability for the patent owner to stop them, robs the inventor of their invention and their hard-won right to steer the direction of the invention’s development.

That this is the current rule was affirmed in *Robert Bosch LLC v. Pylon Manufacturing Corp.*, where the U.S. Court of Appeals for the Federal Circuit confirmed that the U.S. Supreme Court’s 2006 *eBay* decision “jettisoned the presumption of irreparable harm as it applies to determining the appropriateness of injunctive relief.”⁵

That means anyone who has had a valid patent infringed must *prove* they’ve been irreparably harmed before the court issues a permanent order for the infringer to stop stealing the IP, rather than acknowledging that this harm is implicit in the patent owner’s future inability to control their invention.⁶ This allows thieves to continue using stolen property regardless of the wishes of their rightful owner. Moreover, it has created a system akin to compulsory licensing in the domestic market, which diminishes the ability of patent owners to compete, recoup their investments, and grow.

[4] *Id.* at 2002.

[5] *Robert Bosch LLC v. Pylon Manufacturing Corp.*, 659 F.3d 1142, 1149 (2011); *see also eBay, Inc. v. MercExchange LLC*, 547 U.S. 388 (2006).

[6] *See Robert Bosch*, 659 F.3d at 1150-51.

The difficulty of obtaining injunctions over nearly two decades is already having an alarming impact on the innovation economy. This change, in addition to others discussed in this paper, has caused venture capitalists to shift the nature of their investments, away from products that require significant R&D expenditures to those that do not. In other words, this means they are choosing to invest in social media apps instead of the next generation of wireless communication technology,⁷ or in biomedical devices that improve quality of life (which often are not the type that need expensive regulatory approval) instead of ones that save lives (which do).⁸ As one VC commented, “[H]igh-impact types of diseases are not being addressed like they would have been previously. Everybody is less well off.”⁹

The owner of a property right should have the right to exclude others from that property. This applies to patents also. Therefore, Congress should introduce a bill to rectify this by returning to a *presumption* of irreparable harm when a valid patent is infringed. In 2020, Congress passed the Trademark Modernization Act, which ensures that trademark owners have the right to exclude others from using it.¹⁰ The same should be true for patent owners.

Section 2: Congress should pass the Patent Eligibility Restoration Act

The Patent Eligibility Restoration Act, recently reintroduced by Senators Thom Tillis, R-N.C., and Chris Coons, D-D.E., aims to eliminate confusion about whether certain categories of inventions are eligible for patent protection. This uncertainty stems from Supreme Court rulings in a series of cases:

- ✓ *Bilski v. Kappos*¹¹ in 2010
- ✓ *Mayo Collaborative Services v. Prometheus Laboratories*¹² in 2012

[7] *Competition and Consumer Protection in the 21st Century: Innovation and Intellectual Property Policy*, hearing before the Federal Trade Commission 111-115 (2018) (Testimony of Greg Raleigh), https://www.ftc.gov/system/files/documents/public_events/1415062/ftc_hearings_session_4_transcript_day_1_10-23-18_0.pdf.

[8] Mark F. Schultz, *The Importance of an Effective and Reliable Patent System to Investment in Critical Technologies*, THE ALLIANCE OF U.S. STARTUPS AND INVENTORS FOR JOBS (USIJ) 40 (interview with Eb Bright, VC specializing in medical devices companies), https://www.usij.org/s/USIJ-Full-Report_Final_2020.pdf.

[9] *Id.*

[10] Consolidated Appropriations Act, 2021, Pub. L. No. 116-260 § 221, 134 Stat. 1182, 2200-2210 (2020).

[11] 561 U.S. 593 (2010).

[12] 566 U.S. 66 (2012).

✓ *Association for Molecular Pathology v. Myriad Genetics*¹³ in 2013

✓ *Alice Corp. v. CLS Bank International*¹⁴ in 2014

Under the plain text of the statute, 35 U.S.C. § 101, virtually any man-made invention should be patentable.¹⁵ The courts, however, have created three exceptions for abstract ideas, laws of nature, and natural phenomena. The Supreme Court’s recent decisions have significantly expanded the scope of these exceptions and effectively excluded inventions in key sectors, such as the biotechnology and software industries, from being eligible for patent protection.¹⁶

The precedents set by these cases have made many inventors and enterprises question whether to research and invest in ineligible technologies at all. For example, one study of a survey of 475 investors found that, among those familiar with the case law, “patent eligibility is an important factor in investment decision-making, and that reduced eligibility has had a negative impact in every industry, but particularly in the biotechnology, medical device, and pharmaceutical industries.”¹⁷ The Executive Director of the Cleveland Clinic, a world-renowned leader in health care, explained that when assessing what research the clinic prioritizes trying to commercialize, “[i]f an invention can’t get intellectual property protection, usually that is a fatal flaw and the invention is abandoned at that point.”¹⁸

Investment is not the only casualty. An executive at IBM explained that without clear patent protection, the company is less likely to enter into collaborations (out of concern that their technology might be copied without recourse to patent litigation). And it is more likely to move away from seeking patent protection in favor of trade secret protection where

[13] 569 U.S. 576 (2013).

[14] 573 U.S. 208 (2014).

[15] 35 U.S.C. § 101, <https://www.law.cornell.edu/uscode/text/35/101>.

[16] Kevin C. Myhre, *Patent Eligibility Restoration Act Proposed to Address Longstanding Uncertainty*, BARLEY SNYDER NEWS ALERT (Aug. 4, 2022), <https://www.barley.com/patent-eligibility-restoration-act-proposed-to-address-longstanding-uncertainty/>; A. Sasha Hoyt, *The Impact of Uncertainty Regarding Patent Eligible Subject Matter for Investment in U.S. Medical Diagnostic Technologies*, 79 WASH. & LEE L. REV. 397 (2022), <https://scholarlycommons.law.wlu.edu/cgi/viewcontent.cgi?article=4762&context=wlulr>.

[17] David O. Taylor, *Patent Eligibility and Investment*, 41 CARDOZO L. REV. 2019, 2053 (2020), <http://cardozolawreview.com/wp-content/uploads/2020/10/6.-Taylor.41.5.3.FINAL-1.pdf>.

[18] *The State of Patent Eligibility in America: Part III*, hearing before the S. Comm. on the Judiciary, Subcomm. on Intellectual Property, 116th Cong. (2019) (Testimony of Peter O’Neill), <https://www.judiciary.senate.gov/imo/media/doc/O%27Neill%20Testimony.pdf>.

feasible—which means that the public will not have the benefit of the disclosures that come with seeking patent protection.¹⁹ In sum, this uncertainty has seriously hurt the U.S. diagnostics industry and harmed technology sectors in which our country faces stiff global competition, including 5G, blockchain, and artificial intelligence (AI).

The Patent Eligibility Restoration Act will return clarity to this area of law, ensure patentability in key categories of inventions—including diagnostics and computer-implemented inventions—and resolve questions regarding the scope of patent eligibility more generally.²⁰

Opponents of the bill assert that it would permit patents on laws of nature, products of nature, and abstract ideas. Some critics have even claimed that the legislation would permit patents on human genes. This is categorically untrue. Unmodified human genes, along with mathematical formulas, mental processes, and natural processes, would remain ineligible for patent protection.²¹ With American competitiveness at stake, such misinformation has no place in legislative debates.

Section 3: Congress should fix the Patent Trial and Appeal Board by passing the PREVAIL Act

The value of intellectual property rests, in considerable measure, on the certainty and predictability of its protection. Patents are a quintessential example of the need for this certainty, given the investment often needed to bring a new product or service to market.

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The U.S. Patent and Trademark Office (USPTO) takes its responsibilities in evaluating patent applications seriously. Nonetheless, having a review process to consider challenges to issued patents is a reasonable check on the initial examination. However, it is not reasonable for the challenges to be endless, as this robs the patent owner of the ability to predictably rely on the patent grant for business purposes.

[19] *Id.* (Manny Schecter, IBM Chief Patent Counsel, Responses to Questions for the Record), <https://www.judiciary.senate.gov/imo/media/doc/Schecter%20Responses%20to%20Questions%20for%20the%20Record.pdf>.

[20] Samantha Handler & Riddhi Setty, *New Patent Eligibility Bill Takes Aim at High Court Inaction*, BLOOMBERG LAW (Aug. 3, 2022), <https://news.bloomberglaw.com/ip-law/new-patent-eligibility-bill-takes-aim-at-high-court-inaction>.

[21] *Id.*

In 2011, Congress, through the passage of the America Invents Act (AIA), established the Patent Trial and Appeal Board (PTAB) and a corresponding review system within the USPTO to consider challenges to issued patents. The aim of this new adjudicative body was to offer a less expensive, more efficient alternative to challenging the validity of a patent in court.²²

When the PTAB takes up a patent challenge, it may determine that the patent should not have been granted in the first place despite the USPTO’s best efforts when it initially examined the patent application. As a result, the patents that should not have been granted can be found unpatentable, while owners of patentable inventions can be assured of their well-earned rights.

For the system to work, however, at some point a patent owner must achieve a measure of “quiet title,” or the certainty that the scope of their grant from the USPTO is final and established—akin to established boundaries associated with real estate and other property.²³ Otherwise, the patent owner cannot rely on, build a business around, or meaningfully enforce these rights.

Some large companies have become adept at ensuring their smaller rivals never achieve such certainty. These behemoths routinely steal small inventors’ IP and then, if the smaller inventor sues for patent infringement, repeatedly challenge the patent’s validity at the PTAB—effectively casting a permanent cloud over the patent.²⁴ After all, a patent cannot be infringed if the PTAB ultimately concludes that the patent should never have been issued.

Patent owners often find themselves in the midst of a well-funded and well-lawyered attack on two fronts: in the courts and at the PTAB. Tremendous financial pressure is put on

[22] The Michelson Institute for Intellectual Property, *Navigating the PTAB: A Primer on The Patent Trial and Appeal Board* (Dec. 8, 2021), <https://michelsonip.com/navigating-the-ptab-patent-trial-and-appeal-board/>.

[23] Brian O’Shaughnessy, *On the Next USPTO Director, Patents as a Private Property Right*, IPWATCHDOG (Jun. 13, 2017), <https://ipwatchdog.com/2017/06/13/next-uspto-director-patent-private-property-right/id=84440>.

[24] Zoe Thomas, *Apple Partnership was “Kiss of Death” Smaller Rivals Claim*, TECH NEWS BRIEFING, WSJ PODCASTS (May 1, 2023) (interview with reporter Aaron Tilley) (discussing Masimo’s patent litigation against Apple after Masimo alleged Apple stole its technology during their partnership and Apple’s challenges to their patents at PTAB), <https://www.wsj.com/podcasts/tech-news-briefing/apple-partnership-was-kiss-of-death-smaller-rivals-claim/82a80713-210f-4a8e-af89-6038ad1c8113>; *The Patent Trial and Appeal Board After 10 Years: Impact on Innovation and Small Businesses*, hearing before the H. Comm. On the Judiciary, Subcomm. on Courts, Intellectual Property, and the Internet, 117th Cong. (2022) (written testimony of Jonathan Rogers, COO of Centripetal Networks) (describing Centripetal’s patent litigation against larger rival Cisco after failed partnership and licensing negotiations where Centripetal alleged Cisco stole its technology and the PTAB challenges it faced from Cisco and Palo Alto Networks), <https://docs.house.gov/meetings/JU/JU03/20220623/114937/HHRG-117-JU03-Wstate-RogersJ-20220623.pdf>.

small companies who are forced to defend themselves.²⁵ As a result, many may not choose to fight in the first instance.²⁶ The strategy has proven remarkably successful for certain big companies. That is why the top 10 petitioners at the PTAB include the largest companies, such as Google, Samsung, Microsoft, and Apple.²⁷

The USPTO has taken steps to combat this abuse of the system, but future Directors can always undo those changes. Our decade-plus experience with the PTAB makes it clear that it is incumbent upon Congress to improve the laws governing the body’s operations. To that end, C4IP applauds Senators Chris Coons, D-D.E., and Thom Tillis, R-N.C., for recently-introducing the Promoting and Respecting Economically Vital American Innovation Leadership Act, or the “PREVAIL Act,” which would secure the much-needed stability of the patent system by introducing a series of reforms that would promote certainty and restore balance.

Some highlights of the PREVAIL Act include:

- ✓ *Ensuring that a given challenger has the ability to contest the validity of a patent only once and in only one forum.*

Challengers should be able to choose the forum in which they contest patent validity, whether in court or at the PTAB. But a given challenger should not be allowed to contest a patent in more than one forum. Instead, challengers (and entities related to them) should pick their preferred forum and make their best arguments only once.²⁸

[25] See, e.g., USPTO, *Request for Comments on Discretion to Institute Trials Before the Patent Trial and Appeal Board*, 85 Fed. Reg. 66502 (Oct. 20, 2020) [hereinafter, *Institution Comments Request*] (Comments of Roller Clutch Tools LLC) (“Rather than pay the agreed settlement amount, Lowes . . . filed 2 IPR’s in order to challenge the validity of our patents. My company could not pay the incredible amount required to process the IPR’s so instead we elected to reduce the settlement amount by 50%.”), <https://www.uspto.gov/sites/default/files/documents/11302020RollerClutchToolsLLC.pdf>; (Comments of e-Watch, Inc.) (“Defending these IPR’s adequately was economically impossible for e-Watch, and many patent rights were lost while e-Watch spent what it could ill afford.”), <https://www.uspto.gov/sites/default/files/documents/11192020EWWatchInc.pdf>; (Comments of Zaxcom, Inc.) (describing the expense of fighting a larger rival at PTAB), <https://www.uspto.gov/sites/default/files/documents/11162020ZaxcomInc.pdf>.

[26] See, e.g., *Institution Comments Request* (Comments of Zugara, Inc.) (“[W]e have had to sit by and watch as larger tech companies and competitors have replicated our patented inventions and technology and we have had no recourse to stop this ongoing infringement. Due to the PTAB, lawyers who once proudly helped defend smaller startups and inventors such as ourselves, now will not take on these cases.”), <https://www.uspto.gov/sites/default/files/documents/11102020ZugaraInc.pdf>.

[27] Unified Patents, *Analytics* (last visited, May 11, 2023), https://portal.unifiedpatents.com/ptab/analytics/case-level/top-parties?sort=-filing_date.

[28] 35 U.S.C. §§ 316(e), 326(e).

- ✓ Ensuring that issued patents are entitled to a presumption of validity at the PTAB, just as they are in district courts.

Currently, a challenger at the PTAB must prove a patent is invalid based on the standard of “a preponderance of evidence,” meaning the challenger’s contentions are slightly more convincing than not.²⁹ This is a much easier standard to meet than the “clear and convincing evidence” standard, in which a court presumes a patent is valid until a challenger proves his contentions to the contrary by clear and convincing evidence. Congress should pass the PREVAIL Act to mandate the “clear and convincing evidence” standard of proof to invalidate a patent at the PTAB, ensuring that powerful challengers cannot strike down a rival’s patent without a legitimate reason to do so. In other words, the USPTO should give the same deference to its initial examination as the courts do.

- ✓ Codifying the Phillips standard for claim construction, again aligning with district courts.

In 2018, the USPTO established the *Phillips* standard as the rule for the interpretation of a patent in challenges before the PTAB.³⁰ This means that the PTAB interprets the meaning and scope of a patent based on what the language would mean to a person of ordinary skill in the field in question. That is an improvement over the “broadest reasonable interpretation” standard, which proved too ambiguous and allowed challengers to invalidate patents easily.³¹ But what one USPTO Administration does, another can undo. Therefore, Congress should pass the PREVAIL Act and codify the *Phillips* standard for claim construction at the PTAB to avoid having it whipsaw from one Administration to another. Plus, this would align the standard used in the PTAB to that used in district courts.

Section 4: Congress should step in to address the FTC’s non-compete prohibition

President Biden recently heralded a Federal Trade Commission (FTC) proposal that would deal a heavy blow to the U.S. economy. The proposed rule would ban all non-compete

[29] *American Hoist & Derrick Co. v. Sowa & Sons*, 725 F. 2d 1350, 1360 (1984); 35 U.S.C. § 282.

[30] U.S. Patent and Trademark Office, *Changes to the Claim Construction Standard for Interpreting Claims in Trial Proceedings Before the Patent Trial and Appeal Board*, 83 Fed. Reg. 51340 (Oct. 11, 2018), <https://www.govinfo.gov/content/pkg/FR-2018-10-11/pdf/2018-22006.pdf>.

[31] Robert Van Arnam & Andrew R. “Drew” Shores, *PTAB Adopts Phillips Claim Construction Standard for AIA Challenges*, WILLIAMS MULLEN NEWS (Oct. 15, 2018), <https://www.williamsmullen.com/news/ptab-adopts-phillips-claim-construction-standard-aia-challenges>.

agreements, which prevent, for a limited time, employees who leave their jobs from taking up the same work at rival firms.³²

Non-compete agreements have existed for centuries. They are common in high-tech industries, where senior employees are privy to highly confidential data, formulas, techniques, processes, and other trade secrets that provide their companies a competitive edge.³³ That insider knowledge drives innovation and economic growth.

“[Non-compete agreements] are common in high-tech industries, where senior employees are privy to highly confidential data, formulas, techniques, processes, and other trade secrets that provide their companies a competitive edge.”

Quite rationally, a company wants to prevent its employees from jumping ship and sharing secrets with competitors or using proprietary information to start their own businesses. Once divulged, the harm is done and the competitive edge may be erased forever. In the absence of measures to deter such conduct, companies will exhibit reluctance towards investing in high-risk trade secrets and sharing such secrets with employees, which is bad for investment and workforce development.

Some argue that non-competes are unnecessary because of our robust trade secret laws. But such laws alone are not enough. When applied to highly skilled, highly compensated executives, enforcement of trade secret laws is tantamount to closing the barn door after the livestock has run off. Non-competes prevent running off to direct competitors in the first place.

Hundreds of years of case law on non-competes equip the courts to deal with occasional cases of overreach, thereby restoring the proper balance between the interests of the employer and the employee. Courts routinely strike down overly broad non-competes, especially those that apply to hourly wage workers, last longer than two years, or attempt to protect “trade secrets” that are not really secrets.³⁴

[32] Federal Trade Commission, *FTC Proposes Rule to Ban Noncompete Clauses, Which Hurt Workers and Harm Competition* (Jan. 5, 2023), <https://www.ftc.gov/news-events/news/press-releases/2023/01/ftc-proposes-rule-ban-noncompete-clauses-which-hurt-workers-harm-competition>; Federal Trade Commission, *Non-Compete Clause Rule*, 88 Fed. Reg. 3482 (Jan. 19, 2023), <https://www.govinfo.gov/content/pkg/FR-2023-01-19/pdf/2023-00414.pdf>; see also Thompson Reuters, *5 Things You Need to Know About Non-compete Agreements* (Mar. 11, 2022), <https://legal.thomsonreuters.com/en/insights/articles/the-basics-of-non-compete-agreements>.

[33] *A Non-Compete Law Roadmap for Tech Start-Ups in Key Jurisdictions*, GREENBERGTRAUER (Aug. 14, 2019), <https://www.gtlaw.com/en/insights/2019/8/a-non-compete-law-roadmap-for-tech-start-ups-in-key-jurisdictions>.

[34] *Id.*; *5 Things You Need to Know About Non-compete Agreements*, *supra* n.33.

If finalized by the FTC in its current form—which unfortunately seems to be a foregone conclusion—the staggeringly broad proposal would stunt job growth, curb investment in U.S. research and development, and send a terrible message to other countries that America is walking away from robust IP protections.

The courts may ultimately determine the legality of the FTC’s broad prohibition. But Congress should not wait to use its legislative pen and reverse the destructive overreach by the FTC.

Section 5: Congress should modernize 17 U.S.C. § 512, enacted by the DMCA

The Digital Millennium Copyright Act (DMCA) brought copyright law into the digital age, a trailblazing achievement when Congress passed the legislation in 1998, including establishing a way for copyright owners to request that their works be removed from online platforms if they are used without permission under 17 U.S.C. § 512.³⁵ But the internet of today is vastly different than in 1998, and Section 512 is not equipped to meet the needs of current copyright owners, independent creators, and content users.

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The proliferation of online piracy, in particular, hinders content creators’ incentives to innovate and poses a security threat to unsuspecting consumers of pirated content. A report from Muso, a research firm, found that global illegal streaming of films increased by nearly 40% between 2021 and 2022. Meanwhile, global traffic to websites that pirate TV content grew nearly 10% over the same period.³⁶

It is nearly impossible for content creators to continually identify and request the takedown of copyrighted material, as Section 512 contemplates, and they end up playing an endless game of whack-a-mole when taken-down content just gets reposted. As the U.S. Copyright Office concluded after its years-long study of the issue, “Congress’ original intended balance has been tilted askew” in favor of online platforms, to the detriment of content creators.³⁷

[35] Pub. L. No. 105-304, 112 Stat. 2860 (Oct. 28, 1998); see also U.S. Copyright Office, *The Digital Millennium Copyright Act of 1998: U.S. Copyright Office Summary* (1998), <https://www.copyright.gov/legislation/dmca.pdf>.

[36] Muso, *Piracy Data and Audience Demand in the Film and TV Industries* (last visited May 11, 2023), <https://www.muso.com/magazine/piracy-data-and-audience-demand-in-the-film-and-tv-industries>.

[37] U.S. Copyright Office, *Section 512 of Title 17* (2020), <https://www.copyright.gov/policy/section512/section-512-full-report.pdf>.

It is time for Congress to reform this framework after seeking input from stakeholders across the creative ecosystem, especially regarding online infringement and piracy.

Section 6: Congress should return user fees to the USPTO

The USPTO is 100% funded by fees collected from users who file patent applications. Its operations do not depend on government appropriations of tax dollars.³⁸

But between FY1990 to FY2011, and before the USPTO gained fee-setting and collection authority through the America Invents Act, collected user fees were frequently intentionally withheld from the Office to balance proposed budgets. During some of those years, congressional estimates proved incorrect (in particular, when the use of the system unexpectedly surged and more applications were filed on a specific technology or brand). As a result, the U.S. Treasury currently holds approximately \$1 billion in prior year “offsetting fee collections” in its USPTO accounts. The Office requires Congressional approval to access these funds.

Diverting funds from the USPTO has real-world consequences. For example, until recently, the USPTO was still relying on computer mainframe systems from the 1980s, leading to a single point of failure that brought down the whole system for a week in August 2018.³⁹ Applicants who had deadlines during that time had to switch to paper or fax filing—a procedure many attorneys had to learn for the first time. The USPTO also ended up refunding the extra fee normally charged for paper and fax filings, further hurting the USPTO’s finances. The productivity of the entire patent community was impacted—in large part because the USPTO had been deprived of the funds paid by its users for so long that important IT upgrades had to be continually postponed.

And this was just the cost of a prolonged failure to replace old systems—it does not account for the efficiencies *not* realized by the failure to upgrade to new systems with better and faster technology.

Congress should return use of these funds to the USPTO for use to manage its operations and to invest in essential modernization efforts.

[38] Patent Public Advisory Committee, *Fee Setting Report 1* (2018), https://www.uspto.gov/sites/default/files/documents/PPAC_Fee_Setting_Report_Oct2018_1.pdf.

[39] Ryan Davis, *Prolonged Outage Sparks Concern About USPTO’s Aging Tech*, LAW360 (Aug. 28, 2018), <https://www.law360.com/articles/1077556/prolonged-outage-sparks-concern-about-uspto-s-aging-tech>.

Section 7: Congress should not regulate the standard-essential patents (SEPs) marketplace and devalue American IP

Standardization plays a fundamental role in developing and implementing the foundational technologies at the core of critical global infrastructure, such as 5G and Wi-Fi. The standard-setting process generally includes a commitment from innovators whose new technology is included in the standard to license any applicable patents on fair, reasonable, and non-discriminatory (FRAND) terms.⁴⁰ This process enables those innovators to collect royalties to invest in further research and development. It also rewards the innovators for the risk they take in creating new technologies without knowing whether it will be included in the standard.

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SEP licensing involves complex incentives, highly sophisticated markets, and worldwide portfolio considerations. Critics of the system suggest that it is not working, pointing to the few licensing disputes that end up in court. But the fact that there is some litigation does not mean the system is broken. And in any case, data shows that SEP-related litigation has decreased when normalized to account for the growth of industries implementing SEPs.⁴¹

Purported solutions to this non-existent problem, such as the European Union’s recent release of a draft proposal to create a court to set a non-binding royalty rate⁴² or a similar proposal being informally circulated in the United States to have a single SEPs rate court, will most likely lead to the devaluation of innovator companies’ intellectual property. It will also signal to countries whose domestic industry is dominated by implementors of technology (rather than innovators of it) to create their own system that is explicitly designed to depress royalty

[40] See generally Justus Baron and Kirti Gupta, *Unpacking 3GPP Standards*, JOURNAL OF ECONOMICS AND MANAGEMENT STRATEGY, forthcoming, (Northwestern Law & Econ Research Paper No. 18-09) (Jan. 31, 2018), <https://ssrn.com/abstract=3119112>.

[41] David Kappos & Kirti Gupta, *Smartphone Standard Essential Patents Aren’t Driving Litigation*, BLOOMBERG LAW (Dec. 14, 2022) (showing that U.S. smartphone patent litigation drastically decreased during the period from 2005 to 2020 when normalized by the total dollar volume of U.S. smartphone sales and that SEPs are asserted in a small fraction of smartphone patent litigations despite the smartphone industry being heavily dependent on SEPs), <https://news.bloomberglaw.com/us-law-week/smartphone-standard-essential-patents-arent-driving-litigation>.

[42] See Ryan Davis, *Questions Abound on EU Plan for New Essential Patent Rules*, LAW360 (May 1, 2023), <https://www.law360.com/ip/articles/1602559>.

rates. This is already occurring in a less systematic form in countries like China, and would predictably be accelerated if the United States signals that significant regulatory intervention in this space is needed.⁴³ In other words, attempting to regulate these markets at home will almost surely guarantee that American IP is devalued abroad. Congress should avoid heavy-handed legislation targeting standard essential patents and their licensing environment. The industry is working well on its own, and efforts to undercut it will stifle innovation.

Section 8: Congress should not advance other short-sighted, anti-IP legislation

Good policy requires planning for the long term. In this spirit, Congress should stop advancing short-sighted bills that undermine IP rights, disincentivize innovation investments, and sacrifice the long-term pay-offs these investments provide.

For example, consider the Affordable Prescriptions for Patients Act currently under consideration in Congress.⁴⁴ The legislation takes aim at so-called “product hopping” and “patent thickets.” Some lawmakers claim drugmakers nefariously make small changes to a medicine and file for a new patent to avoid generic competition.⁴⁵

It is a baseless and dangerous assertion. Pharmaceutical companies, like companies in any other industry, routinely make incremental changes to their products that represent real improvements in the function of those products. Such changes should be encouraged and protected.

For instance, Allergan altered the formula of its glaucoma drug, Lumigan, to reduce side effects and increase patent compliance. The innovation made “the difference between an effective and safe drug and one with significant side effects that caused many patients to discontinue treatment,” as the Court of Appeals for the Federal Circuit Court noted.⁴⁶ That innovation is certainly worthy of a new patent—and must meet the statutory requirements to receive one.

[43] See Jonathan Barnett, *Antitrust Mercantilism: The Strategic Devaluation of Intellectual Property Rights in Wireless Markets*, BERKELEY TECHNOLOGY LAW JOURNAL, forthcoming (USC CLASS Research Paper No. CLASS23-2) (Apr. 20, 2023), <https://ssrn.com/abstract=4427937>.

[44] Affordable Prescriptions for Patients Act of 2023, S. 150, 118th Cong. (2023).

[45] Eileen McDermott, *Reviewing the Five Bipartisan Senate Bills Aimed at Lowering Drug Prices*, IPWATCHDOG (Feb. 10, 2023), <https://ipwatchdog.com/2023/02/10/reviewing-five-bipartisan-senate-bills-aimed-lowering-drug-prices/id=156420/>; see also Cornyn, *Blumenthal Introduce Bill to Lower Drug Costs by Preventing Patent System Abuse* (Jan. 31, 2023), <https://www.cornyn.senate.gov/news/cornyn-blumenthal-introduce-bill-to-lower-drug-costs-by-preventing-patent-system-abuse/>.

[46] Allergan, Inc. v. Sandoz, Inc., 796 F.3d 1293, 1307 (Fed. Cir. 2015).

Demonizing these improvements and punishing their inventors will deter innovation and result in degraded patient outcomes.

Congress would also be wise not to single out a particular industry for discriminatory policymaking—either overtly or by implication—as it has recently done with bills targeting the pharmaceutical industry. Doing so risks distorting the market, diverting investment from life-saving products to other, “safer” areas of investment. It sounds alarm bells for the broader innovation ecosystem and works to our nation’s competitive detriment.

Reform agenda for the Biden Administration and federal agencies

Section 9: The Biden Administration should continue rejecting efforts to misuse the Bayh-Dole Act and Section 1498

The landmark Bayh-Dole Act—considered one of the most important pieces of legislation of the 20th century—revolutionized scientific research in the United States.⁴⁷

Prior to this 1980 law, the government retained ownership of the patents on discoveries made at university labs that received federal funding. But it did a poor job of licensing those patents to companies interested in developing them into commercial products.

The Bayh-Dole Act changed this. It allowed universities, research institutions, and businesses to retain the IP rights to inventions made using federal dollars. Today, those entities can license their IP to startups and others that turn the research into valuable products, ranging from firefighting drones to airport scanners that monitor for explosives, among thousands of other examples.⁴⁸

The law has been a tremendous catalyst for innovation. It has helped launch over 15,000 startups, contributed over \$1 trillion to the U.S. economy, and supported millions of jobs.⁴⁹

[47] An Act to Amend the Patent and Trademark Laws, Pub. L. No. 96-517 (1980) (commonly referred to as the Bayh-Dole Act), <https://www.congress.gov/96/statute/STATUTE-94/STATUTE-94-Pg3015.pdf>.

[48] AUTM, *Bayh-Dole Innovations* (last visited May 11, 2023), <https://autm.net/about-tech-transfer/advocacy/legislation/bayh-dole-act/bayh-dole-innovations>.

[49] The Bayh-Dole Coalition, *Driving the Innovation Economy: Academic Technology Transfer in Numbers* (presenting data from between 1996-2017), <https://bayhdolecoalition.org/wp-content/uploads/2021/08/FY20-Infographic.pdf>.

But over the past few years, activists and lawmakers have repeatedly petitioned federal officials to misuse Bayh-Dole.⁵⁰ They say the federal government can use the law’s “march-in” provision—which allows the government to relicense patents resulting from federally-funded research under limited circumstances—in a putative attempt to lower drug prices.⁵¹

The Bayh-Dole Act’s march-in provision was never intended to be exploited as a basis for price regulation. Doing so now, as some politicians recently called for in the case of the prostate cancer drug Xtandi, would have dire consequences.⁵²

Investment in innovation depends on stable patent rights. Threats to take away these rights to enforce price controls will result in reduced investment in research and development and fewer new treatments. The Biden administration has denied the Xtandi request. But this most recent march-in petition likely will not be the last. The government must reject all efforts to misuse the Bayh-Dole Act going forward, as all previous administrations have done.

Some activists and lawmakers also wrongly believe that the government has the power to lower drug prices by invoking a century-old statutory provision known as 28 U.S.C. § 1498.⁵³ There is no legal precedent to support this.⁵⁴

Section 1498 permits the government to infringe patents under very limited circumstances and entitles patent holders to reasonable and entire compensation if the government takes that unusual step. It has been successfully invoked only infrequently in the past, most often in cases of national security.⁵⁵ The provision was designed to limit the government’s immunity from infringement lawsuits, not to act as a price control mechanism.⁵⁶

[50] Knowledge Ecology International, *Timeline Regard [sic] March-in Right Requests* (last visited May 11, 2023), <https://www.keionline.org/march-in-rights-timeline>.

[51] See, e.g., *Using March-in Rights as a Strategy for Reducing Drug Prices*, PATIENTS RISING NOW (Sept. 2, 2022), <https://patientsrisingnow.org/using-march-in-rights-as-a-strategy-for-reducing-drug-prices/>.

[52] Letter from Elizabeth Warren, U.S. Senator, et al. to Xavier Becerra, Secretary, Department of Health and Human Services (Jan. 10, 2023), <https://www.warren.senate.gov/imo/media/doc/Bicameral%20Xtandi%20Petition%20Follow-up%201.10.23%20FINAL.pdf>.

[53] Susan G. Braden & Joshua A. Kresh, *Section 1498(a) Is No Rx for Drug Prices*, WASHINGTON LEGAL FOUNDATION (2022), <https://www.wlf.org/2022/05/19/publishing/legal-backgrounders/section-1498a-is-no-rx-for-lowering-drug-prices/>

[54] Adam Mossoff et al., *Proposal for Drug Price Controls is Legally Unprecedented and Threatens Medical Innovation*, CENTER FOR INTELLECTUAL PROPERTY X INNOVATION LAW (Nov. 5, 2018), <https://cip2.gmu.edu/2018/11/05/proposal-for-drug-price-controls-is-legally-unprecedented-and-threatens-medical-innovation/>.

[55] Braden, *supra* n.54.

[56] *Id.*; Mossoff, *supra* n.55.

Yet activists have implored the government to use Section 1498 to “break” patents on high-cost drugs, manufacture them at a lower cost, and offer them to at least Medicaid and Medicare enrollees.⁵⁷ If the government sets that sort of precedent, patent holders will lose confidence in the protection of their IP and hesitate to take a risk on future research and development. This issue goes beyond pharmaceuticals, as the same reasoning can be applied to other industries.

The Biden administration must oppose the misuse of Section 1498.

Section 10: The Office of the United States Trade Representative should oppose further expanding the World Trade Organization’s TRIPS waiver related to COVID-19

On Dec. 6, the Office of the U.S. Trade Representative (USTR) urged the World Trade Organization (WTO) to postpone “the deadline to decide whether there should be an extension” of the current patent waiver for COVID-19 vaccines under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement)—an agreement governing minimal standards of intellectual property protection member countries must provide in their national laws.⁵⁸ Citing the need for more information, USTR also requested the U.S. International Trade Commission to investigate the “market dynamics” for COVID-19 diagnostics and therapeutics.⁵⁹

After months of consultations with relevant experts and stakeholders—and access to a wealth of data on “market dynamics” for COVID-19 diagnostics and therapeutics—the basis for providing this additional flexibility under TRIPS is unclear.⁶⁰ What problems are being caused by IP that a waiver would solve? There are no grounds for an expansion.

No IP-induced shortages of COVID-19 tests and treatments exist. Indeed, diagnostics

[57] Braden, *supra* n.54.

[58] USTR, *U.S. to Support Extension of Deadline on WTO TRIPS Ministerial Decision; Requests USITC Investigation to Provide More Data on COVID-19 Diagnostics and Therapeutics* (Dec. 6, 2022), <https://ustr.gov/about-us/policy-offices/press-office/press-releases/2022/december/us-support-extension-deadline-wto-trips-ministerial-decision-requests-usitc-investigation-provide-0>; WTO, *Ministerial Decision on the TRIPS Agreement* (Jun. 17, 2022), <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:WT/MIN22/W15R2.pdf&Open=True>.

[59] Letter from Katherine Tai, USTR, to David S. Johanson, Chair, U.S. International Trade Commission (Dec. 16, 2022), <https://infojustice.org/wp-content/uploads/2023/01/ustr12162022.pdf>.

[60] Communication from Mexico and Switzerland, *TRIPS Council Discussions on COVID-19 Therapeutics and Diagnostics: Evidence and Questions on Intellectual Property Challenges Experienced by Members* (Nov. 1, 2022), <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:IP/C/W693.pdf&Open=True>.

manufacturers have reported large surpluses of tests available for order.⁶¹ Meanwhile, governments and NGOs have large stockpiles of treatments going unused.⁶² Companies have already bolstered access through more than 400 voluntary licensing agreements, partnerships with multilateral organizations, and tiered pricing policies.⁶³

“Suspending global commitments to protect IP for COVID-19 diagnostics and therapeutics will do nothing to improve access to these products.”

Suspending global commitments to protect IP for COVID-19 diagnostics and therapeutics will do nothing to improve access to these products. Yet ongoing uncertainty regarding the world’s commitment to protect IP on existing and future therapies for COVID-19,

many of which will potentially treat diseases beyond COVID-19, will jeopardize American innovators’ willingness to continue these risky investments. In addition, it may create additional problems related to counterfeit goods and the safety of the diagnostics and therapeutics that patients rely on to manage the disease effectively.

Diagnostics, therapeutics, and vaccines manufactured for COVID-19 may be the first impacted, but they will not be the last. UN Secretary-General António Guterres has indicated as much. He recently suggested, for example, that “removing obstacles to knowledge sharing and technological transfer—including IP constraints—is crucial for a rapid and fair renewable energy transition.”⁶⁴

This sort of disregard for IP leaves inventors unsure of whether they can trust global leaders to protect their IP rights, and thus makes them less likely to invest in innovating in the future. Of equal concern, the waiver expansion would hamper U.S. competitiveness and manufacturing by allowing adversaries to appropriate U.S.-developed technologies.

The United States erroneously backed the original waiver for vaccines, even though no IP-related shortage existed. We should not make the same mistake twice.

[61] *Id.*

[62] *Id.*

[63] *Id.*; International Federation of Pharmaceutical Manufacturers and Associations, *Statement at the Human Rights Council 52 Regular Session: Interactive dialogue on access to COVID-19 vaccines* (Mar. 17, 2023), <https://ifpma.org/news/statement-at-the-human-rights-council-52-regular-session-interactive-dialogue-on-access-to-covid-19-vaccines/>.

[64] António Guterres, *Time to Jump-Start the Renewable Energy Transition*, UNITED NATIONS CLIMATE CHANGE (May 18, 2022), <https://unfccc.int/news/antonio-guterres-time-to-jump-start-the-renewable-energy-transition>.

Section 11: The USPTO and U.S. Copyright Office should lead on Providing AI Guidance

The intersection between IP and emerging technologies—specifically Artificial Intelligence (AI)—has become a subject of significant discussion.⁶⁵ Specifically, recent debate has centered on whether an AI algorithm should be able to claim inventorship status in a patent application.⁶⁶ Existing U.S. law says it cannot.⁶⁷

It is essential that IP experts and policymakers not get bogged down with this single question at the expense of a well-rounded, long-term view of the AI-IP landscape. Prolonged uncertainty over IP protections creates hesitancy in this market and stifles access to investment.

Today, scientists and engineers at elite American universities are pursuing cutting-edge research in the field of AI. Consider the Massachusetts Institute of Technology (MIT), where scientists are using this technology to reduce the environmental impact of all sorts of processes, ranging from machine learning to the production of industrial materials.⁶⁸

Incentivizing these pursuits should be a top priority given that AI is the future—of the digital economy, satellites, cancer treatments, environmental protection, and much more.

But the private sector will be hesitant to pour capital into these transformative ventures if the underlying research lacks IP protection or if that protection is uncertain. AI is a product of expensive and risky investments in computing technology, algorithms, and data.

America’s global competitors are forging ahead with significant investments in AI, and we can only rival their effort if private capital is brought to bear. That will not happen without the strong investment incentive provided by robust, clear, and reliable IP rights.

[65] Kathi Vidal, *Incentivizing and Protecting Innovation in Artificial Intelligence and Emerging Technologies*, USPTO DIRECTOR’S BLOG (Jun. 6, 2022), <https://www.uspto.gov/blog/director/entry/incentivizing-and-protecting-innovation-in>.

[66] Franklin Graves, *AI Year in Review: A Busy 2022 for AI and IP Promises Even More in 2023*, IPWATCHDOG (Dec. 18, 2022), <https://ipwatchdog.com/2022/12/18/ai-year-in-review-a-busy-2022-for-ai-and-ip-promises-even-more-in-2023/id=154005/>.

[67] *Thaler v. Vidal*, 43 F.4th 1207, 1210-11 (2022), https://cafc.uscourts.gov/opinions-orders/21-2347.OPINION.8-5-2022_1988142.pdf.

[68] Adam Zewe, *Learning to Grow Machine-learning Models*, MIT NEWS (Mar. 22, 2023), <https://news.mit.edu/2023/new-technique-machine-learning-models-0322>; *MIT-led Teams Win National Science Foundation Grants to Research Sustainable Materials*, MIT NEWS (Mar. 21, 2023), <https://news.mit.edu/2023/mit-affiliates-win-nsf-grants-research-sustainable-materials-0321>; Poornima Apte, *Helping the Cause of Environmental Resilience*, MIT NEWS (Mar. 22, 2023), <https://news.mit.edu/2023/helping-cause-environmental-resilience-haruko-wainwright-0322>.

To this end, the USPTO and U.S. Copyright Office must strike the right balance around our IP laws as related to AI. For example, clear policy statements are needed with respect to patent eligibility under 35 U.S.C. § 101; whether AI machines can be named as “inventors,” or “authors,” respectively; protection for data used by AI systems; and more.

The USPTO and U.S. Copyright Office are the expert agencies in this space and are the ones that must take the lead in ensuring our IP law keeps the United States at the global forefront of AI breakthroughs.

Conclusion

When U.S. policymakers take concrete steps to protect our IP system, the benefits are far-reaching and extend to every American. This has been true since the founding of the United States, fueling successful U.S.-born innovation as countries around the world model their laws on our system.

By creating an environment characterized by robust and reliable IP protections, talented scientists and engineers are incentivized to push the boundaries of innovation. Meanwhile, skilled entrepreneurs and investors are encouraged to invest in the development of new products and technologies. This, in turn, drives economic growth and job creation, bolstering America’s overall prosperity.

As we move forward, it is incumbent upon Congress, federal agencies, and the Administration to take decisive action to issue sound policies that optimally incent innovation by strengthening our primary means for incentivizing innovation—our IP systems.