Reaffirm and Refine: A Government Agenda for Intellectual Property

Edition 2

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The Constitution gives Congress the power "To promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries."[1] Acting on this authority, Congress passed the first patent and copyright acts shortly after the nation's founding, laying the foundation for a robust intellectual property (IP) system.[2] This system has driven American prosperity and improved the quality of life worldwide.

Today, the United States relies on its strong IP system to sustain innovation, economic growth, and national security. As technological and global challenges evolve, bipartisan leadership is essential to protect this cornerstone of American success.

IP faces ongoing threats from opportunistic actors who seek to profit from innovation without contributing to its creation. These actors include counterfeiters who use sophisticated tools to infiltrate online marketplaces, large companies exploiting small startups, and foreign adversaries like China seeking unfair global advantages. Some challenges also arise from well-meaning but misguided efforts to lower costs in the short term, which can undermine incentives to develop new and groundbreaking products and services.

> "IP faces ongoing threats from opportunistic actors who seek to profit from innovation without contributing to its creation."

Rapid technological advancements, such as artificial intelligence (AI), present new challenges. For instance, while AI holds enormous potential to drive innovation, it raises critical questions about the fair use of copyrighted works and the acceptable computer replication of voices or images.

These challenges demand renewed, bipartisan support for the IP protections that fuel creativity, innovation, and entrepreneurship. As the 119th Congress and the Trump administration set priorities for 2025 and 2026, the Council for Innovation Promotion (C4IP) urges the adoption of the following agenda to fortify America's IP system.

[1] U.S. Const., Art. I, Sec. 8, cl. 8.

[2] *Patent Act of 1790*, ch. 7, 1 Stat. 109; *Copyright Act of 1790*, ch. 15, 1 Stat. 214.

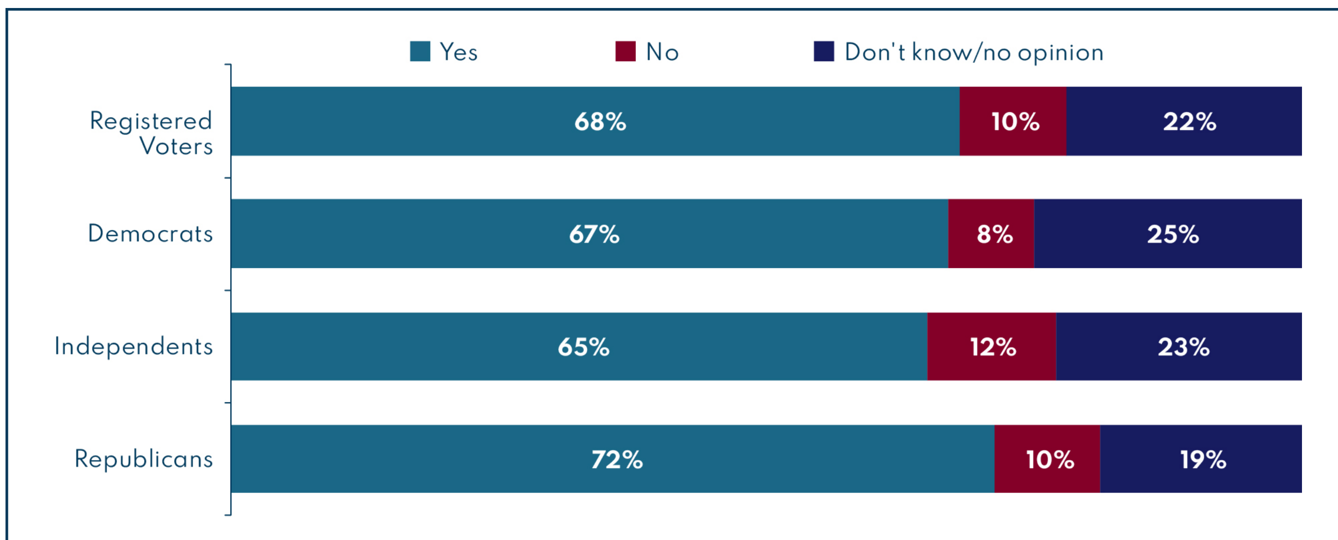

Figure 1: At least two in three voters say that, yes, lawmakers need to continue protecting IP standards to promote future innovation and competition, this includes strong majorities of both Democrats and Republicans *(Source: Morning Consult and the Bayh-Dole Coalition).*[3]

[3] Morning Consult and the Bayh-Dole Coalition, *Intellectual Property Protections and March In Rights* 8 (2024), https://bayhdolecoalition.org/wp-content/uploads/2024/12/Winter-2024-Poll-on-IP-Protections-and-March-In-Rights.pdf.

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Congress

1. Pass an established package of pro-innovation legislation.

The most immediate action Congress can take to strengthen America's innovation economy is to pass a package of three key bills developed by leaders on the Senate and House Intellectual Property Subcommittees. These bipartisan measures—the RESTORE Patent Rights Act, the Patent Eligibility Restoration Act (PERA), and the Promoting and Respecting Economically Vital American Innovation Leadership (PREVAIL) Act—address critical challenges to the U.S. patent system.

C4IP recommends the swift introduction and advancement of:

- **The RESTORE Patent Rights Act**,[4] which would strengthen the value of patents by reestablishing an inventor's right to stop unauthorized use of their invention following a successful lawsuit.

- **The Patent Eligibility Restoration Act (PERA)**,[5] which would resolve uncertainty created by recent Supreme Court cases regarding which innovations can be protected by the patent system. PERA would modernize the Patent Act to make clear that critical new technologies—such as computer-implemented systems and medical diagnostics—can be eligible for patenting, ensuring the U.S. patent system remains competitive internationally.

- **The Promoting and Respecting Economically Vital American Innovation Leadership (PREVAIL) Act**,[6] which would improve the Patent Trial and Appeal Board (PTAB), established under the 2011 Leahy-Smith America Invents Act, by ensuring it fulfills its purpose: providing faster, more efficient reviews of issued patents. The bill would close loopholes that enable duplicative proceedings and align PTAB and district court standards, among other reforms.

[4] *RESTORE Patent Rights Act of 2024*, H.R. 9221, 118th Congress (July 30, 2024), https://www.congress.gov/118/bills/hr9221/BILLS-118hr9221ih.pdf; *RESTORE Patent Rights Act of 2024,* S. 4840, 118th Congress (July 30, 2024), https://www.congress.gov/118/bills/s4840/BILLS-118s4840is.pdf.

[5] *Patent Eligibility Restoration Act of 2023*, S. 2140, 118th Congress (June 22, 2023), https://www.congress.gov/118/bills/s2140/BILLS-118s2140is.pdf; *Patent Eligibility Restoration Act of 2024*, H.R. 9474, 118th Congress (Sep. 6, 2024), https://www.congress.gov/118/bills/hr9474/BILLS-118hr9474ih.pdf.

[6] *Promoting and Respecting Economically Vital American Innovation Leadership (PREVAIL) Act*, H.R. 4370, 118th Congress (June 27, 2023), https://www.congress.gov/118/bills/hr4370/BILLS-118hr4370ih.pdf; *PREVAIL Act*, S. 2220, 118th Congress (July 10, 2023), https://www.congress.gov/118/bills/s2220/BILLS-118s2220rs.pdf.

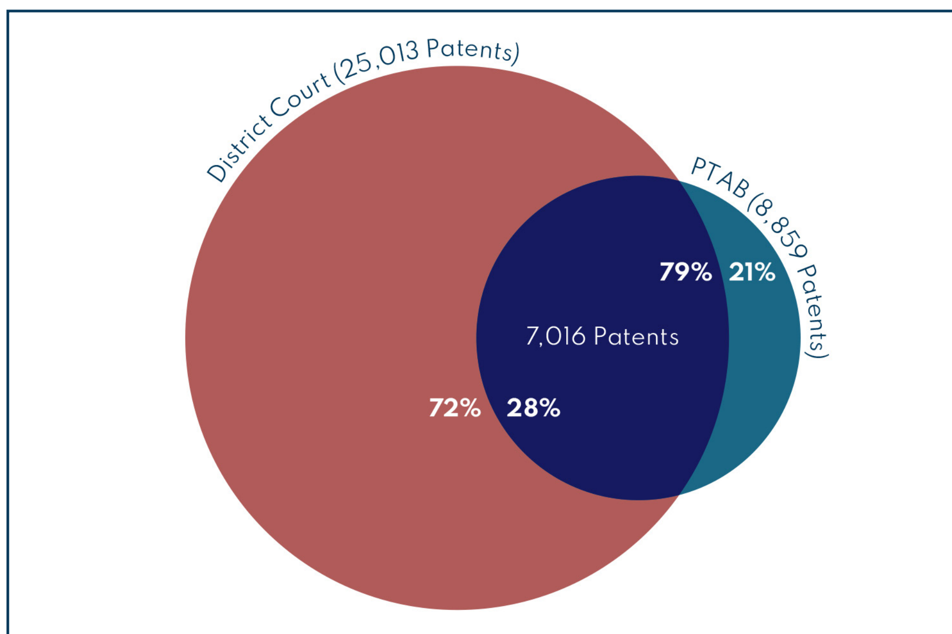

Figure 2: The PTAB has led to significant duplication with district court, which the PREVAIL Act would help streamline. *Note: Excludes declaratory judgment (DJ) actions and biopharma litigation (Source: RPX).*[7]

The new Congress should build on the momentum of the 118th Congress, during which the Senate Judiciary Committee held hearings on all three bills and advanced the PREVAIL Act favorably out of committee. All three bills have bipartisan, bicameral support and address well-documented issues. C4IP has compiled extensive resources on these bills, available on our website.[8]

2. Forge a leading role for the United States in vital areas of interoperable technology through pro-innovation standard essential patents (SEPs) policy.

Shared standards like 5G and WiFi are vital to the tech sector, ensuring device interoperability while fostering ongoing innovation. These advancements depend on patents, which enable companies to invest in R&D to build future generations of these standards because patents allow for fair compensation through market-based licensing. This system has driven remarkable innovation and growth.

Despite the system's success, critics point to isolated cases of litigation and the increasing use of standards by new participants to justify heavy-handed government regulation. Both the EU and China have proposed establishing centralized bureaucracies to oversee SEPs and set

[7] RPX, *The Overlap Between Patents Asserted in District Court and Challenged at the PTAB* (June 1, 2023), https://www.rpxcorp.com/data-byte/the-overlap-between-patents-asserted-in-district-court-and-challenged-at-the-ptab.

[8] C4IP, *Key Issues*, https://c4ip.org/key-issues.

licensing rates.[9] However, the EU withdrew its misguided proposal earlier this year.[10] These top-down schemes risk undervaluing innovation, oversimplifying the complexities of these technologies, and introducing inefficiencies—ultimately discouraging future improvement of the standards.

The United States should reject these misguided approaches and instead champion the free-market system that has underpinned standards development so far.

To this end, Congress should:

> "Congress should legislatively affirm that all patents, including standard-essential patents, are exclusive rights, as intended by the Constitution, which foster a dynamic, competitive marketplace."

- **Legislatively affirm that all patents, including standard-essential patents, are exclusive rights, as intended by the Constitution, which foster a dynamic, competitive marketplace. Such legislation should also clarify that antitrust authorities are limited to addressing threats to static competition.**
- **Grant federal courts the right to enforce fair, reasonable, and non-discriminatory (FRAND) SEP licensing terms, ensuring consistency and clarity compared to current state court processes.**
- **Reject attempts to create centralized rate-setting bodies for SEPs in the United States or abroad.**
- **Affirm SEP owners' ability to enforce their rights via litigation if market-based negotiations fail.**
- **Coordinate internationally to resist unilateral jurisdictional efforts to impose globally applicable royalty rates, safeguarding the integrity of the free market-based SEP licensing system.**

3. Ensure that patent legislation is based on accurate, reputable data.

In recent years, misinformation about the patent system has proliferated. For example, certain organizations have falsely linked perceived high prescription drug prices to alleged

[9] James Lewis & Julie Brock, *The European Commission's Proposed Ruling on Standard Essential Patents*, Ctr. for Strategic & Int'l Stud. (July 26, 2023), https://www.csis.org/analysis/european-commissions-proposed-ruling-standard-essential-patents.

[10] C4IP, *Council for Innovation Promotion Applauds the EU's Withdrawal of a Standard-Essential Patents Proposal*, https://c4ip.org/c4ip-applauds-the-eus-withdrawal-of-a-standard-essential-patents-proposal/.

abuses of the patent system, repeatedly using incorrect and long-disproven data.[11] These misleading claims have fueled policy proposals that would weaken the patent system, risking innovation, economic growth, and America's competitive edge.

Some of this disproven "data" misleadingly points to the patent system as a supposedly easy target to lower drug prices when more accurate data would show that such reforms are unnecessary and more likely to have a harmful effect on the development of new treatments and cures.[12] For example, in response to a letter from Sen. Thom Tillis raising questions about patent data allegedly related to drug prices, the USPTO produced a report showing that there is no clear correlation between the number of patents listed in the FDA's "Orange Book" as covering a particular drug and when a generic version of the drug enters the market. This data stands in contrast to claims that multiple patents associated with prescription drug products unduly block generic competition, so-called "patent thicketing."[13]

Product	Orange Book-listed Patents	Total Exclusivity (Years)
AMBIEN tablet	1	14.4
AMBIEN CR	2	5.1
NORVASC	2	14.7
MIRAPEX ER	3	5.8
LYRICA	3	14.6
LYRICA solution	3	9.6
LYRICA CR	5	3.5
INTERMEZZO	4	4.3
MIRAPEX	4	12.5
LIPITOR	5	15
KALETRA solution	14	16.4
KALETRA tablet	20	15.6
REVLIMID	27	16.2

Figure 3: USPTO data shows that there is no clear correlation between the number of Orange Book patents covering a particular prescription drug and when a generic version of that drug enters the market *(Source: United States Patent and Trademark Office).*[14]

[11] Adam Mossoff, *USPTO Confirms Unreliable Patent Numbers by I-MAK in Drug Pricing Debate*, Hudson Inst. (Dec. 10, 2024) [hereinafter "Mossoff on I-MAK and USPTO"], https://www.hudson.org/drug-policy/uspto-confirms-unreliable-patent-numbers-i-mak-drug-pricing-debate-adam-mossoff.

[12] C4IP, *Debunking Patent Disinformation: Insights from the USPTO's Drug Patent and Exclusivity Study* (Jan. 28, 2025), https://c4ip.org/debunking-patent-disinformation-insights-from-the-usptos-drug-patent-and-exclusivity-study/.

[13] Letter from Senator Thom Tillis Re: False Narratives in Drug Pricing (Jan. 31, 2022) (available in *Drug Patent and Exclusivity Study*, United States Patent and Trademark Office (app. 1) (2024)) [hereinafter "USPTO Study"], https://www.uspto.gov/sites/default/files/documents/USPTO_Drug_Patent_and_Exclusivity_Study_Report.pdf; Mossoff on I-MAK and USPTO, *supra* note 11.

[14] USPTO Study, *supra* note 13.

Because bad data can lead to ineffective laws and regulations, C4IP urges Congress to ensure that its actions are grounded in a well-sourced factual record.

4. Pass reforms to prevent future overregulation, promote efficiency, and ensure the USPTO's future stability.

a. Limit future executive overreach in the patent marketplace.

i. Codify that the government cannot reclaim licenses to federally-funded patents based on second-guessing market pricing.

The federal government funds significant research, including at universities. Some of this research results in patented inventions. Under the 1980 Bayh-Dole Act, universities and other federal funding recipients can own these patents and exclusively license them to private entities.[15] However, the federal government retains nonexclusive rights to the patents and the right to "march in" and revoke an entity's exclusive license under narrowly defined statutory circumstances.[16]

The framework of the Bayh-Dole Act has been celebrated as a success, fostering countless public-private partnerships.[17] This success largely stems from the certainty of exclusive licenses, which encourage private entities to take on the risks of turning federally funded inventions into viable commercial products. Such risks are significant since many early-stage federally funded discoveries may not have practical applications. Many other countries have adopted Bayh-Dole's approach.[18]

> "The framework of the Bayh-Dole Act has been celebrated as a success, fostering countless public-private partnerships."

Despite its success, Bayh-Dole has been a target of harmful reform efforts. The Biden administration proposed expanding the government's march-in rights to challenge the pricing

[15] *See* David S. Levine, *What Can the Uniform Trade Secrets Act Learn from the Bayh-Dole Act*, 33 Hamline L. Rev. 615, 623-28 (2010); Patent and Trademark Law Amendments Act, Pub. L. 96-517 (Dec. 12, 1980) (commonly referred to as the "Bayh-Dole Act"); Mossoff on I-MAK and USPTO, *supra* note 11.

[16] 35 U.S.C. § 202(c)(4) (federal government retains a nonexclusive license); 35 U.S.C. § 203(a)(1)-(4) (setting forth the circumstances under which the federal government is authorized to exercise march-in rights).

[17] *Innovation's Golden Goose*, The Economist (2002), https://www.economist.com/technology-quarterly/2002/12/14/innovations-golden-goose; *Preserve the Bayh-Dole Act and University Technology Transfer*, Ass'n of Am. Univ. (Mar. 28, 2024), https://www.aau.edu/key-issues/preserve-bayh-dole-act-and-university-technology-transfer.

[18] Thorsten Gores & Albert N. Link, *The Globalization of the Bayh-Dole Act*, 5 Annals of Sci. and Tech. Pol'y 1, 10 (2022) (discussing various countries that have adopted Bayh-Dole like university technology policy, including Spain, the United Kingdom, Denmark, France, Germany, Finland, China, Japan, and many others).

of products derived from federally funded inventions.[19] [20] Though it was not finalized, and should be formally withdrawn, this proposal would have undermined the Act's incentives by penalizing entities that took on the financial risks of product development. It would also have allowed companies that took no risk and invested nothing in development to petition the government, claiming they could offer lower prices—a claim easily made by larger companies with extensive lobbying resources.

This proposal conflicted with the Act's clear statutory limits, which do not include the consideration of pricing as a basis for march-in rights. Previous administrations consistently declined to invoke march-in rights on pricing grounds, even when petitioned to do so. No administration has ever exercised march-in rights since the Act's passage.[21]

The proposal is seen as harmful to innovation as it may have signaled to private entities that the federal government is an untrustworthy R&D partner, deterring future collaboration.

To safeguard the commercialization of government-funded innovations, Congress should:

- **Pass legislation explicitly clarifying and reaffirming that the government cannot revoke a license due to disagreements over a licensee's pricing decisions.**

The executive branch is often urged to use its eminent domain power under 28 U.S.C. § 1498—intended for emergencies like wartime—to ignore the intellectual property rights on privately funded patents, particularly to lower prescription drug costs.[22] Similar to the misuse of march-in rights, such proposals would undermine the investments made by private companies in R&D by allowing others to successfully copy products without bearing the costs of development. While these measures may aim to reduce drug prices now, they risk depriving future patients of better treatments or cures.

[19] Request for Information Regarding the Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights, 88 Fed. Reg. 85593 (Dec. 8, 2023), https://www.federalregister.gov/documents/2023/12/08/2023-26930/request-for-information-regarding-the-draft-interagency-guidance-framework-for-considering-the.

[20] *See* Comments from C4IP to NIST Director Locascio on NIST RFI for Exercise of Patent March-In Rights (Feb. 6, 2024), https://c4ip.org/wp-content/uploads/2024/02/C4IP-Comments-RE_-Draft-Interagency-Guidance-Framework-for-Considering-the-Exercise-of-March-In-Rights.docx.pdf.

[21] *See* 35 U.S.C. § 203(a)(1)-(4); Alexander Kersten & Gabrielle Athanasia, *March-In Rights and U.S. Global Competitiveness*, Center for Strategic & International Studies (Mar. 24, 2022), https://www.csis.org/analysis/march-rights-and-us-global-competitiveness.

[22] *See* Letter from C4IP to the Senate Judiciary Committee (May 20, 2024) (describing efforts by others to urge the executive branch use section 1498 improperly), https://c4ip.org/wp-content/uploads/2024/05/C4IP-Letter-RE_-5_21-Hearing-on-Drug-Prices.pdf.

Accordingly, Congress should:

- **Reject proposals permitting the executive branch to force licensing of privately-held patents based on subjective assessments of product pricing.**

ii. **Codify that the President cannot allow other countries to ignore intellectual property rights without Congressional approval.**

As a World Trade Organization (WTO) member, the United States adheres to the Agreement on Trade-Related Aspects of Intellectual Property (TRIPS). This agreement establishes minimum standards for IP systems among member countries, accounting for varying levels of economic development by providing more lenient requirements for less-developed nations.

TRIPS permits members to waive these standards—beyond their tiered normal implementation—under exigent circumstances. Such waivers are often pushed by ideological opponents of the patent system, who cite crises as a pretext without evidence that IP protections hinder crisis responses.

The global response to Covid-19 highlights this abuse of the waiver process. Patent rights enabled the unprecedented development of vaccines and treatments, yet delays in distributing these interventions stemmed from issues like inadequate infrastructure—not IP barriers.[23] Despite this, a pressure campaign succeeded in convincing WTO members to waive patent protections for Covid-19 vaccines, accompanied by calls for even broader waivers.

"Patent rights enabled the unprecedented development of vaccines and treatments, yet delays in distributing these interventions stemmed from issues like inadequate infrastructure—not IP barriers."

These Covid-19 waiver measures effectively penalized companies that made critical R&D investments while doing nothing to address the actual causes of delays or shortages. Unsurprisingly, since IP protections did not cause delays or shortages in the first place, waivers did not improve patient access to vaccines, treatments, or other countermeasures.[24]

Allowing unfettered use of American-developed technology during the Covid-19 pandemic harmed U.S. innovators without any demonstrable benefits. Similar actions in the future would only erode global crisis response capabilities and U.S. competitiveness.

[23] *See* Testimony of Frank Cullen, Executive Director of C4IP on ITC Inv. No. 332-596 (Mar. 29, 2023), https://c4ip.org/wp-content/uploads/2023/04/C4IP-Testimony-ITC-332-596.pdf [hereinafter "C4IP Testimony"]; Letter from C4IP to the commissioners of the ITC in regards to Inv. No. 332-596 (Apr. 10, 2023), https://c4ip.org/wp-content/uploads/2023/04/C4IP-Post-Hearing-Brief-Submission-ITC-332-596.pdf [hereinafter "C4IP Post-Hearing Brief"].

[24] C4IP Testimony, *supra* note 23, at 2 (for example, there were at least 400 voluntary licenses for Covid-19 technology transfer); see also C4IP Post-Hearing Brief, *supra* note 23, at 3-4 (voluntary licenses outperform compulsory licenses).

To prevent future crises from being used as a pretext to undermine IP rights, Congress should:

- **Pass legislation requiring Congressional approval for any presidential waivers of TRIPS requirements, safeguarding innovation incentives and reinforcing efforts initiated in the last Congress.**[25]

b. **Promote efficiency by consolidating the position of the Intellectual Property Enforcement Coordinator (IPEC) into the USPTO.**

The USPTO Director is charged with advising the President on IP matters, administering the USPTO, issuing patents and registering trademarks.[26] However, government-related enforcement of these rights involves multiple agencies, including the Department of Justice and the National Intellectual Property Rights Center.

To coordinate these efforts and strengthen international IP enforcement, Congress established the Intellectual Property Enforcement Coordinator (IPEC) in 2008.[27] IPEC, a Presidentially appointed and Senate-confirmed position within the Executive Office of the President (EOP), is tasked with producing a three-year strategic plan and annual report to Congress in addition to spearheading coordination among the different enforcement components of the executive branch.[28]

In practice, IPEC has largely focused on producing its required reports rather than addressing duplication or coordination across executive branch functions. Additionally, IPEC's responsibilities overlap significantly with those of the USPTO's Office of Policy and International Affairs (OPIA), which includes an enforcement section dedicated to promoting U.S. IP rights domestically and abroad.[29]

[25] *See e.g., No Free TRIPS Act*, H.R. 3858, 118th Congress (June 6, 2023), https://www.congress.gov/118/bills/hr3858/BILLS-118hr3858ih.pdf (a bill requiring the President to obtain explicit Congressional authorization before negotiating or implementing any changes, waivers, or modifications to the Agreement on Trade-Related Aspects of Intellectual Property Rights); *see also* Letter to U.S. Trade Representative Tai urging the Biden Administration to oppose the proposed waiver of portions of TRIPS, H. Comm on the Judiciary (Feb. 13, 2024), https://www.congress.gov/118/meeting/house/117252/documents/HHRG-118-JU03-20240507-SD005-U5.pdf.

[26] 35 U.S.C. § 2(b); 35 U.S.C. § 3(a)(1).

[27] *Prioritizing Resources and Organization for Intellectual Property Act of 2008*, Pub. L. 110-403, tit. III, 122 Stat. 4256 (2008) [hereinafter "*PRO-IP Act*"]; Off. of the Intell. Prop. Enf't Coordinator, White House, https://bidenwhitehouse.archives.gov/ipec/ (last visited Jan. 8, 2025).

[28] *See PRO-IP Act, supra* note 27.

[29] *Office of Policy and International Affairs Enforcement Policy*, USPTO, https://www.uspto.gov/ip-policy/enforcement-policy; *Office of Policy and International Affairs Enforcement Initiatives*, USPTO, https://www.uspto.gov/ip-policy/enforcement-policy/enforcement-initiatives; *Office of Policy and International Affairs Enforcement Resources*, USPTO, https://www.uspto.gov/ip-policy/enforcement-policy/enforcement-resources.

To enhance efficiency and reduce redundancy, C4IP recommends that Congress:

- **Amend the statute governing IPEC to move the position from the EOP to the USPTO and consolidate it with OPIA's enforcement section, which shares the same mission.**

c. **Ensure the USPTO's financial stability by renewing its fee-setting authority.**

For years, user fees intended to fund patent and trademark examinations were diverted to other parts of the federal government. The Leahy-Smith America Invents Act of 2011 largely resolved this issue by granting the USPTO authority to retain and adjust its own fees.[30] Initially granted for seven years, this authority was extended for another eight years in 2018 and is now set to expire in late 2026.[31]

The USPTO has responsibly adhered to the statutorily required public consultation requirements for fee changes. While some proposals have been controversial, this financial control has enabled critical, ongoing IT upgrades and allowed the USPTO to keep pace with rising costs, ensuring the delivery of essential patent and trademark examination services. These efforts directly support America's innovation economy.

C4IP accordingly urges Congress to:

- **Extend the USPTO's fee-setting authority—a prerequisite for the other improvements to the IP system outlined in this agenda.**

5. Create a legal environment that encourages the robust development of AI, including appropriate protection and support for human creators.

AI has emerged as a transformative technology with countless applications, and it continues to evolve. The global race to lead in AI development underscores its potential to shape the future, raising critical questions about which nation will dominate this space.

Unfortunately, public discourse around AI often overhypes its capabilities and fuels fears of a technology that has not yet—and may never—reach the envisioned levels of autonomy. The potential future risks of AI may be worth discussing, but we must not lose sight of AI's current usefulness as a tool that enhances human creativity and ingenuity.

> "The potential future risks of AI may be worth discussing, but we must not lose sight of AI's current usefulness as a tool that enhances human creativity and ingenuity."

[30] *Leahy-Smith America Invents Act*, Pub. L. 112-29, § 10 (2011).

[31] *The SUCCESS Act*, Pub. L. 115-273, § 4 (2018) (new expiration date set at Sept. 16, 2026).

These dynamics call for thoughtful congressional oversight.

First, C4IP urges Congress to:

- **Avoid overly prescriptive regulations that could stifle innovation, harm human creators, and undermine American competitiveness. For instance, the EU's AI Act risks limiting progress, and the United States should steer clear of similar approaches.[32] Congress should also avoid penalizing the use of AI in determining eligibility for IP protections.[33]**

Certain areas already demand legal clarity to support human creators and provide certainty for AI developers.

For these issues, C4IP recommends that Congress:

- **Establish a national standard for AI use of individuals' names, images, and likenesses. The NO FAKES Act is a useful starting point.[34]**
- **Develop a framework for AI developers' use of copyrighted materials in training models, potentially incorporating transparency-focused ideas from past legislative efforts.[35]**
- **Address the use of copyrighted materials already employed in training AI, determining appropriate compensation and penalties for unlicensed use.**

6. Ensure consumer safety on e-commerce platforms by modernizing trademark protection for the internet age.

Current IP laws place too much responsibility on consumers and brand owners to guard against counterfeits, while online platforms avoid accountability. Brand owners are expected to police platforms for

"Current IP laws place too much responsibility on consumers and brand owners to guard against counterfeits, while online platforms avoid accountability."

[32] *AI Act*, European Commission (last updated Feb. 17, 2025), https://digital-strategy.ec.europa.eu/en/policies/regulatory-framework-ai.

[33] *See infra* (discussing the USPTO's AI and inventorship guidance and the Copyright Office's AI and copyright guidance).

[34] *NO FAKES Act of 2024*, S. 4875, 118th Congress (2024), https://www.congress.gov/118/bills/s4875/BILLS-118s4875is.pdf; *NO FAKES Act of 2024*, H.R. 9551, 118th Congress (2024), https://www.congress.gov/118/bills/hr9551/BILLS-118hr9551ih.pdf; Statement by C4IP in support of the NO FAKES Act of 2024 (Sep. 12, 2024), https://c4ip.org/council-for-innovation-promotion-statement-on-house-introduction-of-the-nurture-originals-foster-art-and-keep-entertainment-safe-no-fakes-act-of-2024; *see also* Kathleen O'Malley, *The AI revolution is coming for artists—laws need to catch up*, World Intell. Prop. Rev. (Aug. 21, 2024), https://www.worldipreview.com/artificial-intelligence/the-ai-revolution-is-coming-for-artists-laws-need-to-catch-up.

[35] *Generative AI Copyright Disclosure Act of 2024*, H.R. 7913, 118th Congress (2024), https://www.congress.gov/118/bills/hr7913/BILLS-118hr7913ih.pdf.

counterfeit products, and consumers often have no clear way to identify who is selling goods. When issues arise, online marketplaces frequently shift the blame.

The solution is to extend long-established trademark protections from physical marketplaces to online platforms. The bipartisan, bicameral SHOP SAFE Act achieves this goal.[36] Previous congresses have held hearings and advanced this legislation through committee.[37]

Accordingly, C4IP recommends that the 119th Congress:

- **Reintroduce and swiftly pass the SHOP SAFE Act.**

7. Address CCP manipulation of the patent and trademark system by promoting greater transparency, not by undermining critical aspects of our IP engine.

America's global innovation leadership is rooted in openness to new ideas, which is supported and codified through strong IP laws and a robust rule-of-law system. While this foundation fosters domestic and international collaboration, it also makes the United States vulnerable to manipulation.[38] The Chinese Communist Party (CCP) has repeatedly disregarded international norms to advance its nationalist agenda, such as achieving technological dominance through its "China Standards 2035" initiative.

Experts have raised concerns that CCP-backed efforts may artificially inflate patent filings to exaggerate inventive activity.[39] Similarly, evidence suggests that Chinese government subsidies have fueled a surge in U.S. trademark filings, straining the American trademark examination system.[40]

The United States response should focus on transparency and accountability—the cornerstones of our world-leading IP system. Current law requires patent applicants to disclose U.S. government support for their research.[41] Expanding this requirement to include support from all governments for both patent and trademark applications would help identify manip-

[36] Letter from C4IP in support of SHOP SAFE Act of 2024 (June 13, 2024), https://c4ip.org/wp-content/uploads/2024/06/C4IP-Letter-RE-SHOP-SAFE-Act.pdf.

[37] *Back to School with the SHOP SAFE Act: Protecting Our Families from Unsafe Online Counterfeits: Hearing on S. 2934 Before the Subcomm. on Intell. Prop. of the S. Comm. on the Judiciary*, 118th Cong. (2023).

[38] Adam Mossoff, *A Protectionist Patent Bill Undermines the Patent System and Will Backfire*, Hudson (July 29, 2024), https://www.hudson.org/legal-affairs/protectionist-patent-bill-undermines-patent-system-will-backfire-adam-mossoff.

[39] *See* USPTO, *Patenting Activity by Companies Developing 5G* (Feb. 2022), https://www.uspto.gov/sites/default/files/documents/USPTO-5G-PatentActivityReport-Feb2022.pdf.

[40] USPTO, *USPTO report examines the impact of Chinese government subsidies and other non-market factors on the recent rise in patent and trademark filings in China* (Jan. 13, 2021), https://www.uspto.gov/about-us/news-updates/breaking-news-uspto-report-examines-impact-chinese-government-subsidies-and.

[41] 35 U.S.C. § 203 (Bayh-Dole Act provision requiring disclosure of U.S. government funding).

ulation and highlight where U.S. research funding may lag behind international competitors. Existing IP laws already provide penalties, such as losing IP rights, for nondisclosure or misrepresentation.[42] This transparency-based approach would minimize the risk of retaliatory measures to U.S. companies operating in China and allow for continued international collaboration where appropriate.[43]

C4IP recommends that Congress:

- **Introduce and pass legislation requiring disclosure of all governmental support for patent and trademark applications, building on existing U.S.-only disclosure requirements.**

A related concern is the growing opacity of Chinese courts, which increasingly handle high-value international patent disputes. Key decisions are often unavailable, cases are anonymized or hidden, and fewer rulings are published.[44] These practices, coupled with China's use of anti-suit injunctions to block other jurisdictions from adjudicating patent rights, undermine international norms. Recently, the European Union led a complaint at the World Trade Organization over China's use of these tactics.[45] The CCP's opaque legal system appears designed to advance national interests rather than resolve disputes impartially.

To address this issue and educate the public on the risks of doing business in China, C4IP recommends that Congress:

- **Pass legislation directing the USPTO to create an English-language repository of Chinese court patent decisions and key decisions in other IP areas if resources allow.**
- **Conduct oversight and hold hearings to investigate the CCP's manipulation of international legal norms and hold it accountable for deviations.**

8. Promote U.S. national prosperity and competitiveness by promoting greater awareness of the patent system and how it supports invention.

a. Ensure that there is a widespread understanding of how to obtain patent protection.

[42] Therasense, Inc. v. Becton, Dickinson & Co., 649 F.3d 1276 (Fed. Cir. 2011) (en banc).

[43] *See, e.g., Prohibiting Adversarial Patents Act of 2023*, H.R. 5475, 118th Cong. (2023), https://www.congress.gov/118/bills/hr5475/BILLS-118hr5475ih.pdf.

[44] *IP and Strategic Competition with China: Part IV – Patents, Standards, and Lawfare, Hearing before the Subcomm. on Courts, Intellectual Property, and the Internet of the House Comm. on the Judiciary*, 118th Cong. (2024) (testimony of Mark A. Cohen) [hereinafter "Cohen testimony"], https://www.congress.gov/118/meeting/house/117764/witnesses/HHRG-118-JU03-Wstate-CohenM-20241218-U9.pdf.

[45] *See id.*

Innovation is key to keeping the United States at the global forefront of economic competitiveness and national security. IP protection plays a critical role in the process of turning innovative concepts into real-world solutions.

Yet research shows that there are apparent gaps in awareness and utilization of the IP system—for example, there are clear geographic disparities in where patents are obtained, which markedly increase the likelihood that children raised in those areas will become inventors themselves.[46] This, along with a body of additional research, suggests the United States is not fully educating potential innovators on how to leverage the patent system to develop their ideas.

Collecting better data on where there are disparities would help policymakers design reforms to ensure all communities participate in America's innovation economy. The IDEA Act is a key step in doing this. It directs the USPTO to voluntarily collect demographic data from patent applicants. This data would be a significant improvement over current research techniques, which rely on techniques to infer such data rather than direct reporting.

The bipartisan, bicameral IDEA Act has been refined and favorably voted out of the Senate Judiciary Committee twice in prior congresses.[47]

C4IP supports this bill[48] and urges Congress to:

- **Quickly reintroduce and pass the IDEA Act in the 119th Congress.**

b. Pass legislation designating October as National Intellectual Property Month.

Intellectual property contributes $7.8 trillion annually to U.S. gross domestic product and supports 63 million jobs.[49] IP's impact is especially significant for small businesses and startups, which see 76% more venture capital funding and 55% higher employee growth over five years when their

"Intellectual property contributes $7.8 trillion annually to U.S. gross domestic product and supports 63 million jobs."

[46] Alex Bell, Raj Chetty, Xavier Jaravel, Neviana Petkova, John Van Reenen, *Who Becomes an Inventor in America? The Importance of Exposure to Innovation*, Quarterly J. of Ec. 647 (May 2019), https://doi.org/10.1093/qje/qjy028.

[47] *IDEA Act*, S. 632, 117th Cong. (2021), https://www.congress.gov/117/bills/s632/BILLS-117s632is.pdf (voted favorably out of Senate Judiciary Committee with amendment); *IDEA Act*, S. 4713, 118th Cong. (2024), https://www.congress.gov/118/bills/s4713/BILLS-118s4713rs.pdf (voted favorably out of Senate Judiciary Committee without amendment).

[48] *See* Letter from C4IP to Senate Judiciary Committee in support of PREVAIL, PERA, and IDEA Act (Sep. 18, 2024), https://c4ip.org/wp-content/uploads/2024/09/C4IP-Letter-RE_-PERA-PREVAIL-Act-and-IDEA-Act.pdf; Letter from C4IP to Senate Judiciary Committee in support of IDEA Act (Sep. 17, 2024), https://c4ip.org/wp-content/uploads/2024/09/C4IP-Letter-RE_-IDEA-Act.pdf.

[49] USPTO, *USPTO Marks IP Month with Expanded Tools for Entrepreneurs and Startups* (Oct. 24, 2024), https://www.uspto.gov/about-us/news-updates/uspto-marks-ip-month-expanded-tools-entrepreneurs-and-startups.

ideas are protected.[50] To recognize IP's essential role in driving innovation and economic growth, C4IP supports a growing movement aimed at designating October as National Intellectual Property Month.

This designation would raise awareness of IP's importance and educate individuals and small businesses on how they can benefit from its protection. Nine states and the District of Columbia already recognize October as Intellectual Property Month.[51]

C4IP urges Congress to:

- **Introduce and pass legislation declaring October as National Intellectual Property Month.**

9. Reject legislation premised on false narratives and facts.

a. "Poor quality" patents are not a major problem.

The claim that too many "poor quality" patents are issued is often used to justify weakening the IP system. However, this argument relies on flawed premises, as a recent study shows.[52] The study leverages three independent analyses to show that overall patent quality is high and that the U.S. patent system outperforms most other major global systems. In fact, the U.S. system may actually be biased against innovators; patent claims that should be approved are rejected over twice as often as invalid claims are mistakenly granted.

[50] *Id.*

[51] *October is IP Month*, United States Intellectual Property Alliance (last accessed Jan. 6, 2025), https://www.usipalliance.org/october-ip-month.

[52] The Sunwater Institute, *Patent Quality in the United States: Findings and Suggestions for Policymakers* 18 (2024) [hereinafter "SWI Study"], https://sunwater.org/wp-content/uploads/2024/09/SWI-Policy-Report-Patent-9-23-2024.pdf.

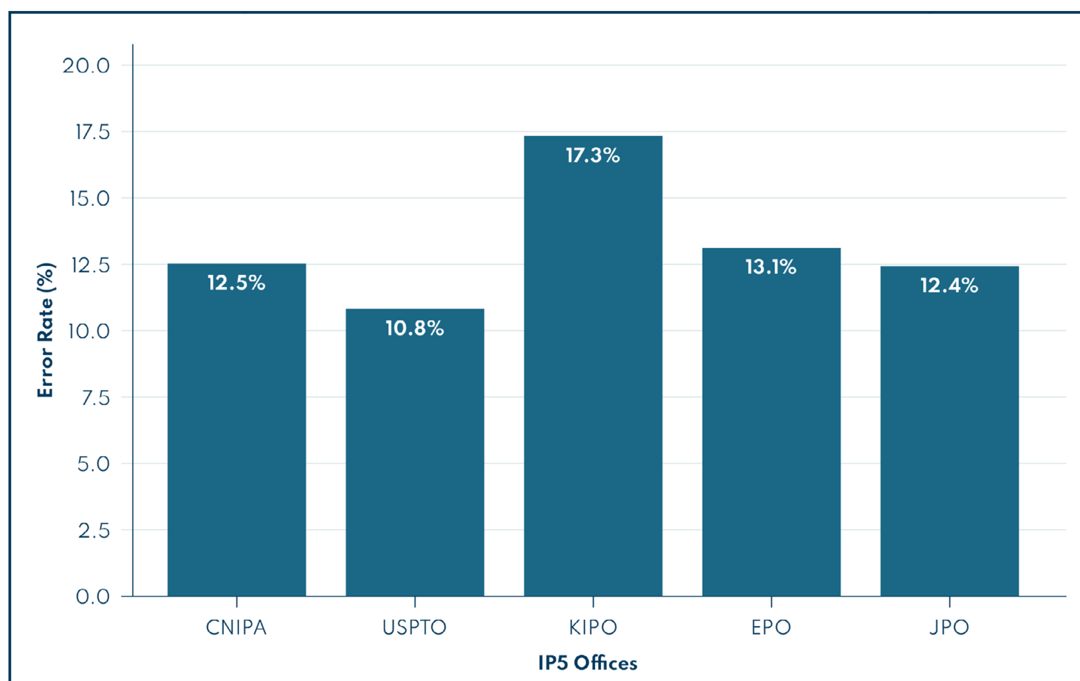

Figure 4: Estimated error rates across global patent offices *(Source: The Sunwater Institute)*.[53]

b. The patent system is not routinely abused to "extend monopolies" for prescription drugs.

Legislation targeting the patent system often rests on false claims linking prescription drug prices to alleged patent abuses. These narratives rely on demonstrably flawed data and a fundamental misunderstanding of how the patent system drives high-risk innovation, which has made the United States a global leader in key technologies.[54]

Two common misconceptions are "patent thicketing" and "patent evergreening." **Patent thicketing** is used by critics to suggest a practice of securing multiple patents on a single product, portrayed as a way to unfairly block competition. **Patent evergreening** suggests companies use trivial product improvements to extend exclusivity and prevent generic competition.

These characterizations are misleading. Complex products, like medicines or smartphones, often require numerous patents to protect distinct innovations. For instance, the original iPhone was estimated to be protected by hundreds of patents, each reflecting unique components or discoveries.

Similarly, allegations of patent evergreening overlook key facts. When a patent expires, anyone can freely use the invention. New patents are issued only for genuine improvements

[53] *Id.*

[54] Mossoff on I-MAK and USPTO, *supra* note 11.

that meet the USPTO's stringent requirements of being novel, useful, and non-obvious. Patents on innovations that go beyond the original product—such as better dosing flexibility or time-release mechanisms to reduce adverse reactions—reflect real, not trivial, advancements. But importantly, for a product that has "gone generic," a patent for new improvements does not block generic manufacturing of the original product—only the version of the product incorporating the newly patented component. This allows companies investing in ongoing innovation to be rewarded through the patent system. The public benefits from these new improvements as well as from the ability to freely use the technology disclosed in expired patents.

c. The authority of the International Trade Commission (ITC) to block imports of infringing products helps—rather than hinders—American prosperity.

The International Trade Commission (ITC) provides swift, effective relief for U.S. rights holders whose innovations are copied abroad and sold to the United States market. The ITC's 12-18 month investigative process can result in "exclusion orders," blocking imports of products found to infringe valid U.S. patents. This authority is essential for maintaining U.S. innovation leadership and protecting domestic innovation from foreign theft.[55]

Exclusion orders are particularly important for addressing infringement that occurs beyond the reach of U.S. courts. With rampant foreign IP theft, which can be state-sponsored, as seen with China, the ITC's role has never been more critical to safeguarding American innovation.

> "With rampant foreign IP theft, which can be state-sponsored, as seen with China, the ITC's role has never been more critical to safeguarding American innovation."

Critics argue that limiting the ITC's jurisdiction would "help" American companies, noting that some U.S. firms have faced exclusion orders for products manufactured abroad. However, these arguments fall short. American companies producing goods overseas should be held to the same standards as foreign-owned firms when they infringe on U.S. IP rights. In both cases, the manufacturing is happening overseas and attempting to compete with American-based manufacturing, which is subject to the jurisdiction of U.S. courts and our domestic patent laws. The ITC's exclusion power is necessary to ensure that U.S. manufacturers who respect and license U.S. patents are not forced to compete with infringing foreign-made products.

[55] *See* C4IP letter on IP Litigation and the U.S. I.T.C. (July 22, 2024), https://c4ip.org/wp-content/uploads/2024/07/C4IP-Letter-RE_-IP-Litigation-and-the-U.S.-International-Trade-Commission.pdf.

d. The USPTO does not need additional information from other parts of government, such as the FDA, to examine patents.

Some activists claim that the USPTO needs to work more closely with other government agencies, such as the FDA, to prevent abuses of the system. For instance, one proposal would require companies seeking FDA drug approvals to submit the same information to the USPTO during patent applications. These reform efforts misunderstand the distinct needs of each process and overlook existing safeguards that already protect the integrity of the patent system.[56]

Demands for more "cooperation" rest on a false assumption—that applicants systematically fail to disclose material information to the USPTO. While isolated misconduct may occur, there is no evidence of widespread deception. This is unsurprising, given the significant penalties for material misrepresentations or omissions during the patent application process.

Such proposals would harm the patent system in several ways. First, they would burden the USPTO with large volumes of FDA-related information, such as clinical data, much of which is irrelevant to determining patentability. With the USPTO already stretched thin, this would burden examination without any likely benefit. Second, adding more administrative requirements would increase costs, delays, and complexity for both patent applicants and innovators seeking regulatory approval for new medicines.

> "... adding more administrative requirements would increase costs, delays, and complexity for both patent applicants and innovators seeking regulatory approval for new medicines."

Finally, these new complex requirements could create new risks for innovators, especially given the need to comply with the USPTO's practice of making all submissions public, whereas the FDA routinely allows certain submissions to be confidential to protect trade secrets. Even though most innovators will comply in good faith with any new requirements, patent infringers could still use even minor discrepancies to undermine patent protection for groundbreaking developments.

[56] *See* Letter from C4IP to Senator Sanders & Senator Cassidy voicing concerns with S.2780 (Aug. 26, 2024), https://c4ip.org/wp-content/uploads/2024/08/C4IP-Letter-RE-The-Medication-Affordability-and-Patent-Integrity-Act.pdf.

Executive Branch

10. Actively support Congress in passing the RESTORE Patent Rights Act, PERA, and the PREVAIL Act into law.

These three bills are critical to strengthening the U.S. IP system—a cornerstone of American innovation, economic growth, and global competitiveness. Active support from the Trump administration could accelerate their passage by highlighting the national importance of these reforms.

To that end, the administration should:

- **Provide high-level leadership encouraging Congress to reintroduce and swiftly pass the RESTORE Patent Rights Act, PERA, and the PREVAIL Act.**
- **Provide expertise during legislative consideration, including participating in hearings and offering technical advice to lawmakers and staff.**

11. Reduce the backlogs of patent and trademark applications to increase the pace of innovation development and small business growth.

The backlog of unexamined patent and trademark applications has reached historic highs.[57] Backlogs harm inventors, entrepreneurs, and the public by delaying innovation and business growth.[58] Each year of delay at the USPTO, European, and Japanese patent offices is estimated to cost the global economy $10 billion, according to a 2010 study.[59]

[57] Eileen McDermott, *Vidal Addresses USPTO's 'Inherited Backlog', Which May Be at an All-Time High for Patents*, IPWatchdog (July 11, 2024), https://ipwatchdog.com/2024/07/11/vidal-addresses-usptos-inherited-backlog-may-time-high-patents/id=178793/#; Dennis Crouch, *USPTO Patent Grant Rate and Growing Backlog*, Patently-O (Nov. 29, 2024), https://patentlyo.com/patent/2024/11/uspto-patent-grant.html; *see also* Setting and Adjusting Patent Fees During Fiscal Year 2025, 89 Fed. Reg. 23226, 23229 tbl.2 (Jan. 20, 2024) (the patent application backlog is anticipated to increase to 820,200 by FY 2026 before decreasing to 780,000 by FY 2029).

[58] Mark Schultz & Kevin Madigan, *The Long Wait for Innovation: The Global Patent Pendency Problem*, Ctr. for the Prot. of Intell. Prop. (2016), https://sls.gmu.edu/cpip/wp-content/uploads/sites/31/2016/10/Schultz-Madigan-The-Long-Wait-for-Innovation-The-Global-Patent-Pendency-Problem.pdf; *see e.g.*, London Econ., *Patent Backlogs & Mutual Recognition: An Economic Study* viii (2010) [hereinafter "UK Study"], https://www.gov.uk/government/publications/patent-backlogs-and-mutual-recognition; Sean Tu, *Understanding the Backlog Problems Associated with Requests for Continued Examination Practice*, 13 Duke L. & Tech. Rev. 216 (2015).

[59] UK Study, *supra* note 58.

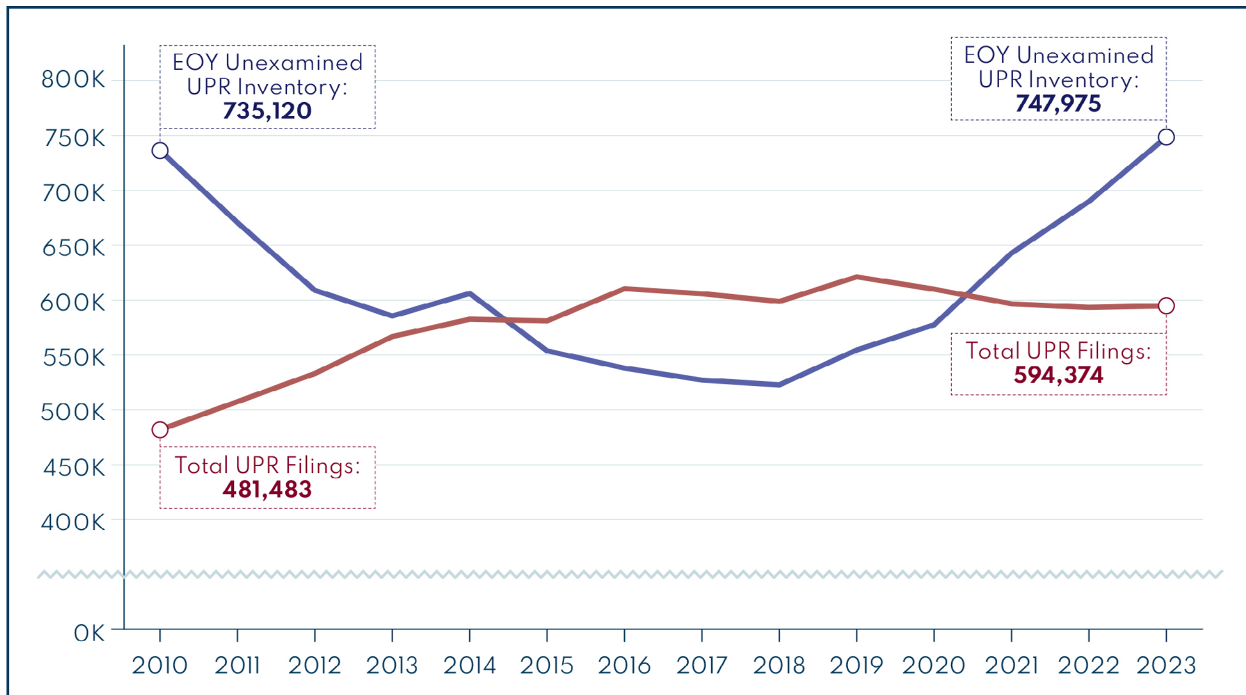

Figure 5: End of Year unexamined utility, plant, and reissue (UPR) inventory and UPR filings *(Source: PPAC Annual Report 2024).*[60]

Every year a patent grant is delayed reduces a startup's employment and sales growth by 21% and 25%, respectively, over five years.[61] Similarly, delays in trademark registration leave businesses uncertain about securing nationwide rights to their chosen identities. Together, these issues hinder companies' ability to plan for the future and attract investment, ultimately postponing consumer access to new products and services and slowing the engine of innovation.

> "Every year a patent grant is delayed reduces a startup's employment and sales growth by 21% and 25%, respectively, over five years."

Backlogs also create systemic issues and have second and third-order impacts. Delays in granting an original innovator's patent discourage potential competitors from investing in related research, as they remain uncertain about the scope of protection the innovator will ultimately receive. Prolonged wait times may also drive innovators to rely on trade secrets instead of patents, reducing the public disclosure of valuable knowledge over time. Finally,

[60] *Patent Public Advisory Committee 2024 Annual Report*, USPTO 22 (2024), https://www.uspto.gov/sites/default/files/documents/ppac-2024-annual-report.pdf.

[61] Joan Farre-Mensa et al., *The Bright Side of Patents*, Nat'l. Bureau of Econ. Rsch. 3 (2016), https://www.nber.org/system/files/working_papers/w21959/w21959.pdf; *see also* Deepak Hegde et al., *Quick or Broad Patents? Evidence from U.S. Startups 2021*, 35 The Rev. of Fin. Stud. 2705 (2022).

backlogs and delays hurt the USPTO's reputation and can lead to rushed hiring, which risks lowering the quality of its workforce.

To redress the patent and trademark backlogs, the administration should:

- **Establish target backlog and pendency levels with a clear plan to reduce current excesses and sustain manageable levels long-term.**
- **Take steps to address examiner attrition and obtain exemptions for patent and trademark examiners from any government-wide policies aimed at workforce reduction, given the unique fee-based nature of the USPTO, where the number of examiners directly correlates to productivity and revenue.**
- **Expand hiring while ensuring sufficient training time and rigorous candidate selection to maintain quality.**

12. Assert a strong defense of U.S. IP abroad, especially with respect to countries having a poor track record like China.

Intellectual property rights are a major strength for the United States, consistently contributing to a trade surplus.[62] However, this advantage faces significant threats from countries seeking shortcuts through theft or infringement. IP theft remains rampant—counterfeiting and piracy alone were estimated to cost $464 billion in 2019, or 2.5% of global trade.[63] In FY2022, the United States seized $3 billion in infringing goods, with China being the greatest source of violations.[64]

Many other nations fail to prioritize innovation as the United States does. In recent years, numerous countries have enacted burdensome regulations that strain innovators or devalue American-owned IP.

To safeguard this critical advantage, the administration should:

- **Support a strong International Trade Commission to block infringing products from entering the U.S. market.**

[62] Shayerah I. Akhtar & Liana Wong, *Intellectual Property Rights (IPR) and International Trade*, Cong. Rsch. Serv. (2025) [hereinafter "CRS Report"], https://www.congress.gov/crs-product/IF10033; *U.S. Trade in Charges for the Use of Intellectual Property: 2014-18*, U.S. Int'l Trade Comm. (last accessed Jan. 17, 2025), https://www.usitc.gov/publications/332/recent_trends_2020/intellectualproperty.htm.

[63] *See* CRS Report *supra* note 62; *see also* Frank Cullen, *Congress should investigate Chinese IP theft*, The Hill (Feb. 23, 2023), https://thehill.com/opinion/congress-blog/3871875-congress-should-investigate-chinese-ip-theft.

[64] *See* CRS Report *supra* note 62.

- **Restore the USTR's Special 301 Report to previous levels of vigorous analysis to advance U.S. intellectual property priorities in foreign markets.**
- **Push back against anti-innovation policies, such as the European Union's proposals on regulating SEPs (now withdrawn), compulsory licensing, as well as patent term restoration and other policies in China.**
- **Reverse the previous administration's willingness to waive international IP obligations under the TRIPS Agreement without solid justification.**
- **Encourage other nations to adopt robust IP policies that bolster their own innovation systems. This includes prioritizing IP protection in all U.S. trade agreements.**

Technology	Lead country	Technology monopoly risk
Advanced materials and manufacturing		
1. Nanoscale materials and manufacturing	China	high
2. Coatings	China	high
3. Smart materials	China	medium
4. Advanced composite materials	China	medium
5. Novel metamaterials	China	medium
6. High-specification machining processes	China	medium
7. Advanced explosives and energetic materials	China	medium
8. Critical minerals extraction and processing	China	low
9. Advanced magnets and superconductors	China	low
10. Advanced protection	China	low
11. Continuous flow chemical synthesis	China	low
12. Additive manufacturing (incl. 3D printing)	China	low
Artificial intelligence, computing and communications		
13. Advanced radiofrequency communications (incl. 5G and 6G)	China	high
14. Advanced optical communications	China	medium
15. Artificial intelligence (AI) algorithms and hardware accelerators	China	medium
16. Distributed ledgers	China	medium
17. Advanced data analytics	China	medium
18. Machine learning (incl. neural networks and deep learning)	China	low
19. Protective cybersecurity technologies	China	low
20. High performance computing	USA	low
21. Advanced integrated circuit design and fabrication	USA	low
22. Natural language processing (incl. speech and text recognition and analysis)	USA	low
Energy and environment		
23. Hydrogen and ammonia for power	China	high
24. Supercapacitors	China	high
25. Electric batteries	China	high
26. Photovoltaics	China	medium
27. Nuclear waste management and recycling	China	medium
28. Directed energy technologies	China	medium
29. Biofuels	China	low
30. Nuclear energy	China	low
Quantum		
31. Quantum computing	USA	medium
32. Post-quantum cryptography	China	low
33. Quantum communications (incl. quantum key distribution)	China	low
34. Quantum sensors	China	low
Biotechnology, gene technology and vaccines		
35. Synthetic biology	China	high
36. Biological manufacturing	China	medium
37. Vaccines and medical countermeasures	USA	medium
Sensing, timing and navigation		
38. Photonic sensors	China	high
Defence, space, robotics and transportation		
39. Advanced aircraft engines (incl. hypersonics)	China	medium
40. Drones, swarming and collaborative robots	China	medium
41. Small satellites	USA	low
42. Autonomous systems operation technology	China	low
43. Advanced robotics	China	low
44. Space launch systems	USA	low

Figure 6: Lead country and technology monopoly risk *(Source: Australian Strategic Policy Institute).*[65]

[65] Jamie Gaida, Jennifer Wong-Leung, Stephan Robin and Danielle Cave, *ASPI's Critical Technology Tracker: The global race for future power*, 60 (2023), https://ad-aspi.s3.ap-southeast-2.amazonaws.com/2023-03/ASPIs%20Critical%20Technology%20Tracker_0.pdf?VersionId=ndm5v4DRMfpLvu.x69Bi_VUdMVLp07jw#page=60.

13. Revise USPTO and USCO guidance on AI by not deterring its usage as a tool to enhance human ingenuity.

The USPTO and U.S. Copyright Office (USCO) play a critical role in shaping policies that influence the use of AI in developing inventions, creating expressive works, and advancing AI technology itself. While their policies are not legally binding on courts, they have immediate practical impacts.

Unfortunately, current guidance from both agencies risks discouraging the use of AI as a tool for innovation and creativity. Both agencies have adopted overly cautious policies that deny patent and copyright protection when AI is deemed to play "too much" of a role in the creative process.[66] This subjective line drawing, left to thousands of individual decision-makers, is likely to be enforced inconsistently and arbitrarily.

Even if applied uniformly and fairly, these policies would still harm human creators by irrationally denying IP protection to original works solely because they happened to benefit from AI. Disqualifying such inventions will prevent many promising ideas from becoming marketable products, ultimately limiting the societal benefits AI can offer.

Accordingly, C4IP encourages the administration to:

- **Revise USPTO and USCO guidance to ensure the use of AI as a tool by human inventors and creators is not discouraged.[67]**
- **Revise the USPTO's Section 101 and inventorship guidance to acknowledge AI's integral role in inventions, ensuring inventors are not automatically disqualified from patent rights simply for using AI as a tool.[68]**
- **Review public comments on the USPTO's inquiry into AI's impact on patentability and inventorship to craft guidance that supports the development of AI technology and AI-driven inventions.[69]**

[66] David Kappos & Andrei Iancu, *New Patent Guidance on AI Could Quash Innovation*, Wall St. J. (July 11, 2024), https://www.wsj.com/articles/new-patent-guidance-on-ai-could-quash-innovation-dd848ea4?mod=latest_headlines; Rama Elluru & Andrei Iancu, *When Inventors Get an AI Assist, Who Gets the Patent*, Reuters (Jan. 31, 2024), https://www.context.news/ai/opinion/when-inventors-get-an-ai-assist-who-gets-the-patent.

[67] *See* Letter from C4IP to USPTO Director Katherine Vidal regarding AI and inventorship (May 13, 2024), https://c4ip.org/wp-content/uploads/2024/05/C4IP-Public-Comment-RE-PTO-P-2023-0043.pdf.

[68] *See* Letter from C4IP to USPTO Director Katherine Vidal on the 2024 Guidance Update on Patent Subject Matter Eligibility, Including on AI (Sep. 16, 2024), https://c4ip.org/wp-content/uploads/2024/09/C4IP-Public-Comment-RE-PTO-P-2024-0026.pdf.

[69] *See* Letter from C4IP to USPTO Director Katherine Vidal regarding the impact of the proliferation of AI (July 29, 2024), https://c4ip.org/wp-content/uploads/2024/07/C4IP-Public-Comment-RE-PTO-P-2023-0044.pdf.

14. Establish proper parameters for exercising federal Bayh-Dole march-in rights and improve the tech transfer process for federally owned or federally funded patents.

The Trump administration should strengthen innovation by fostering public-private partnerships that drive technological progress. This requires reversing the previous administration's attempts to misinterpret the 1980 Bayh-Dole Act and taking proactive steps to safeguard the law against future efforts to undermine it.[70]

Accordingly, C4IP recommends that the administration:

- **Clarify that pricing is not a valid basis for the federal government to revoke patent licensing agreements under the Bayh-Dole Act's march-in provision and formally withdraw the proposal issued by the previous administration to do so.**
- **Work with federal agencies to review best practices and ensure no agency unilaterally adds pricing or other "access" requirements to commercialization licenses. This includes rescinding the recently finalized "NIH Intramural Research Program Access Planning Policy."[71]**

15. Ensure adequate protection for trade secrets by allowing non-competition agreements for employees having access to such information.

Trade secret laws are essential for protecting confidential business information, but they alone are not enough. Non-competition agreements provide a crucial safeguard by preventing employees with access to sensitive information from immediately transferring it to a competitor. These agreements are particularly important for addressing trade secret theft by foreign actors like China.[72]

"Non-competition agreements provide a crucial safeguard by preventing employees with access to sensitive information from immediately transferring it to a competitor."

[70] *See supra* Congress(4)(a)(i); *see also* Letter from C4IP to NIST Director Laurie Locascio responding to the RFI on March-In Rights (Feb. 6, 2024), https://c4ip.org/wp-content/uploads/2024/02/C4IP-Comments-RE_-Draft-Interagency-Guidance-Framework-for-Considering-the-Exercise-of-March-In-Rights.docx.pdf.

[71] Joseph Allen, *The Biden Administration Rolls the Dice on NIH Patent Licensing*, IPWatchdog (Jan. 13, 2025), https://ipwatchdog.com/2025/01/13/biden-administration-rolls-dice-nih-patent-licensing/id=185035; *and see* Nat'l. Inst. of Health, *NIH Intramural Research Program Access Planning Policy*, NOT-OD-25-062 (Jan. 10, 2025), https://grants.nih.gov/grants/guide/notice-files/NOT-OD-25-062.html.

[72] Mark Cohen, *The Federal Trade Commission's Notice of Proposed Rulemaking on a Non-Compete Clause Rule and Its International Impact* (Mar. 6, 2023), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4378931; *Rule of Law: China's Increasingly Global Reach: Hearing Before the U.S.-China Econ. & Sec. Rev. Comm'n*, 118th Cong. 11-12 (2023) (testimony of Mark A. Cohen), https://www.uscc.gov/sites/default/files/2023-05/Mark_Cohen_Testimony.pdf.

Non-competition agreements are commonly used in high-skilled, well-paid roles where employees handle proprietary information.[73] The previous administration's Federal Trade Commission (FTC) proposal to impose a blanket ban on all non-competition agreements threatened to weaken trade secret protections in the United States.[74]

Although courts have put the FTC proposal on hold due to pending litigation,[75] the Trump administration should:

- **Formally withdraw the FTC's non-competition ban pertaining to employees who have access to trade secrets, as it undermines companies' ability to protect core IP assets.**

16. Promulgate regulations codifying established Patent Trial and Appeal Board (PTAB) practices.

After more than a decade of experience, the USPTO's Patent Trial and Appeal Board (PTAB) has developed effective practices that help implement the vision of the Leahy-Smith America Invents Act of 2011 (AIA).[76] Post-grant proceedings were created to serve as quick, cost-effective alternatives to litigation—not as tools for harassment or obstacles to market entry. Misusing these proceedings undermines the AIA's purpose.[77]

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Codifying these proven practices is crucial to addressing duplicative proceedings and repeated challenges to the same patent. These measures, refined through extensive public input, are ready for finalization in the Federal Register. Formalizing these practices would ensure greater business certainty and stability for innovators.[78]

[73] Andrei Iancu & David Kappos, *Banning Non-compete Agreements Hurts U.S. Companies and Workers*, The Hill (Mar. 23, 2023), https://thehill.com/opinion/congress-blog/3914783-banning-non-compete-agreements-hurts-us-companies-and-workers.

[74] The one-size-fits-all nature of this ban was a particular problem: there may well be areas where non-competition agreement usage is abused that have nothing to do with trade secret protection, as with a notorious case involving fast-food workers.

[75] Fisher Phillips, *Breaking Down the FTC Non-Compete Ban Appeals: Heading to a Circuit Split and SCOTUS Intervention*, JD Supra (Oct. 23, 2024), https://www.jdsupra.com/legalnews/breaking-down-the-ftc-non-compete-ban-8080431; Lauren Berg, *FTC Asks 5th Circ. To Revive Noncompete Ban*, Law360 (Jan. 2, 2025), https://www.law360.com/articles/2279088/ftc-asks-5th-circ-to-revive-noncompete-ban.

[76] *Leahy-Smith America Invents Act*, Pub. L. 112–29 (2011).

[77] H.R. Rep. No. 112-98, at 48 (2011).

[78] *See* Letter from C4IP to USPTO Director Katherine Vidal commenting on the ANPRM Docket No. PTO-P-2020-0022 (June 20, 2023), https://c4ip.org/wp-content/uploads/2023/06/C4IP-Response-to-PTO-P-2020-0022.pdf; *see also* Letter from C4IP to USPTO Director Katherine Vidal commenting on Docket No. PTO-P-2023-0048 (June 18, 2024), https://c4ip.org/wp-content/uploads/2024/06/C4IP-Comment-RE-PTO-P-2023-0048.pdf.

The administration should enact rules to:

- **Prohibit repeat challenges to the same patent by the same or related parties.[79]**
- **Deny PTAB challenges when parallel district court or ITC cases exist unless the accused infringer agrees to resolve the invalidity issue exclusively through the PTAB.[80]**
- **Reinforce confidence in the original patent examination process by denying PTAB review of materials already considered by the examiner unless compelling evidence shows the examiner erred.[81]**

17. Safeguard the integrity of the patent system by removing the prospect of political interference from PTAB decisions.

In *United States v. Arthrex, Inc.*, the Supreme Court ruled that the USPTO Director—not a panel of administrative patent judges—must have final authority over decisions invalidating issued patents.[82] This ruling aligns PTAB decisions with other matters statutorily assigned to the Director, such as patent issuance and trademark-related decisions, which are typically delegated to career officials while the Director retains ultimate oversight.[83]

The USPTO's recently finalized rules go beyond what *Arthrex* requires by allowing for the Director to *personally* review every PTAB decision.[84] The Supreme Court and Federal Circuit

[79] This would involve codifying the approaches of *General Plastic and Valve Corp*. Gen. Plastic Co. v. Canon Kabushiki Kaisha, IPR2016-01357, Paper 19 (PTAB Sep. 6, 2017) (precedential as to Section II.B.4.i); Valve Corp. v. Elec. Scripting Products, Inc., IPR2019-00062, Paper 11 at 8 (PTAB Apr. 2, 2019) (designated precedential, May 7, 2019) ("Valve and HTC were co-defendants in the District Court litigation and were accused of infringing the '934 patent based on HTC's VIVE devices that incorporate technology licensed from Valve. Thus, there is a significant relationship between Valve and HTC with respect to Patent Owner's assertion of the '934 patent.").

[80] This would essentially codify the practice of *Sotera* stipulations, which can be used to obviate the Director's exercise of discretion to deny PTAB institution if there is a parallel district court proceeding following *Fintiv*. Sotera Wireless, Inc. v. Masimo Corp., IPR2020–01019, 2020 WL 7049373, at *7 (PTAB Dec. 1, 2020); Apple Inc. v. Fintiv, Inc., IPR2020-00019, Paper 11 at 9 (PTAB Mar. 20, 2020) (designated precedential May 5, 2020).

[81] This would involve codifying the two-part test of *Advanced Bionics and Becton, Dickinson*. Advanced Bionics, LLC v. Med-El Elektromedizinische Geräte GmbH, IPR2019-01469, Paper 6 (PTAB Feb. 13, 2020) (designated precedential, Feb. 24, 2020); Becton, Dickinson & Co. v. B. Braun Melsungen AG, IPR2017-01586, Paper 8 (Dec. 15, 2017) (precedential as to § III.C.5, first paragraph, Dec. 15, 2017).

[82] 594 U.S. 1, 23-25 (2021).

[83] 35 U.S.C. §§ 131 (patent examination) ("The Director shall cause an examination to be made of the application and the alleged new invention; and if on such examination it appears that the applicant is entitled to a patent under the law, the Director shall issue a patent therefor.") (emphasis added); 132(a) (rejections) ("Whenever, on examination, any claim for a patent is rejected, or any objection or requirement made, the Director shall notify the applicant thereof, stating the reasons for such rejection, or objection or requirement . . . . ") (emphasis added); 121 (divisional applications) ("If two or more independent and distinct inventions are claimed in one application, the Director may require the application to be restricted to one of the inventions.") (emphasis added); 154(b)(3)(B) (patent term adjustment); 156(e) (patent term extension); 15 U.S.C. § 1068; *see also Trademark Modernization Act of 2020*, Pub. L. 116-260 (2020), Div. Q, Title II, Subtitle B, § 288(a) (similarly amending 15 U.S.C. §§ 1070 and 1092 to give the Director clear authority to modify TTAB decisions).

[84] Rules Governing Director Review of Patent Trial and Appeal Board Decisions, 89 Fed. Reg. 79744 (Oct. 1, 2024), https://www.govinfo.gov/app/details/FR-2024-10-01/2024-22194.

made clear that the Director only needs to have the discretionary authority to review decisions. Neither court required the Director to personally handle PTAB cases.

This approach introduces several issues. It places a substantial burden on the time of the Director, detracting from the key work of the vast majority of the Office to issue patents and register trademarks. Additionally, requiring personal review creates opportunities for perceptions of political interference, particularly given the Director's public role and the potential for ex parte communications. The PTAB should not—and cannot—become the Director's sole focus or be seen as their personal fiefdom. The solution, fortunately, is straightforward.

The administration should:

- **Rescind the rules allowing for the Director to personally review PTAB decisions.**
- **Delegate the Director's review authority to an office of career officials, similar to the Director's authority in other parts of patent and trademark examination.**

18. Increase publication of the USPTO's collected patent quality data, including past data, to allow for more independent research.

The USPTO's Office of Patent Quality Assurance (OPQA) conducts thorough oversight of patent examinations, with its team reviewing the work of individual examiners. Independent analyses have shown that OPQA data generally reflects high overall patent quality.[85]

However, while OPQA collects detailed data during its reviews, only a subset is released to the public. This lack of access has hindered more comprehensive analyses that could identify areas for improvement.[86] The justification for withholding this data is unclear, especially since its release could support independent efforts to strengthen the patent system.

Accordingly, C4IP recommends that the administration:

- **Prioritize the release of all patent quality data collected by OPQA (and other sources) in a machine-readable, anonymized format that is readily accessible to the public.**

[85] *See* SWI Study, *supra* note 52.

[86] *Id.*

Conclusion

A robust intellectual property system is the key to America's world-leading economy. It's up to Congress and the Trump administration to strengthen this system so that inventors and entrepreneurs can bring their groundbreaking ideas to fruition.

This agenda points the way—and will help make the 21st century another American century.