



May 14, 2024

The Honorable Kathi Vidal
Under Secretary of Commerce for Intellectual Property and Director
United States Patent and Trademark Office
600 Dulany Street
Alexandria, VA 22314

Re: Request for Comments on Unlocking the Full Potential of Intellectual Property by Translating More Innovation to the Marketplace

Dear Director Vidal:

The undersigned individuals and organizations appreciate the opportunity to comment on the commercialization of intellectual property. We also appreciate The United States Patent and Trademark Office's ("USPTO") attention to the important matter of facilitating job creation, economic growth, and solutions to global problems by facilitating innovation and the licensing of intellectual property ("IP") rights. Our comments can be found in more detail below:

I. We agree with USPTO that Intellectual Property Promotes Innovation, Economic Growth, and Social Benefits

The USPTO Notice begins with the clear statement:

American innovation is a cornerstone of our strong, vibrant economy, with robust development of emerging and early-stage innovation spurring entrepreneurship and other economic activity. Intellectual property (IP) forms the bridge that moves innovation to impact for the benefit of society.¹

The undersigned could not agree with that statement more. Likewise, we eagerly endorse USPTO's galvanizing recitation of the role of IP:

Intellectual property rights create a critical engine that powers our economy and supports our nation as a global leader in innovation and entrepreneurship. For example,

¹ 89 F.R. 18907, March 15, 2024.

patents drive our nation’s technological progress and achievement by incentivizing and protecting new ideas, encouraging investment in creative problem solving, and promoting knowledge sharing to inspire others to engage in follow on innovation. When brought to the market through commercialization, patented products save lives, improve our standard of living, and address some of the pressing issues to solve global challenges.²

These issues are at the core of our beliefs. That is why last year, when the U.S. Chamber of Commerce (“Chamber”) and more than thirty partner organizations reiterated their core beliefs about IP,³ they referred to IP, licensing, and commercialization repeatedly. For example, they noted that “IP rights facilitate collaboration and technology transfer to address society’s greatest challenges through licensing and rights management that gives confidence to both inventors and users that their rights will be respected.” They also made clear that IP rights are critical for the “dissemination of new technologies” and that IP protections “are a benefit to society, serving as...a mechanism to facilitate commercialization of new, creative, and inventive ideas.”

Given the importance of licensing in the business of innovation, it should be no surprise that “Commercialization of IP Assets” constitutes an entire section of the analysis in the Chamber’s annual International IP Index (“Index”).⁴ The inclusion of six distinct indicators in this section reflects a recognition that governments can either help facilitate the commercialization of new technologies or inhibit their dissemination in global markets. For example, the Index evaluates the use of tax incentives and IP as an economic asset as enabling measures that economies can embrace to enhance IP commercialization. Conversely, measures that create barriers to market access, require registration of licensing agreements, or allow for direct government intervention in setting licensing terms inhibit the ability of the business community to bring new, innovative technologies to market.

When policy is founded on the rule of law and respect for private property rights, governments can promote the commercialization of IP. The United States has been a longstanding global leader in protecting and enforcing IP rights, ranking first overall in the Chamber's Index. However, recent actions taken by the Administration have undermined the marketplace for licensing of IP rights and directly impact American innovative companies' investment in innovation. The recent U.S. experience following the passage of the Inflation Reduction Act (IRA) illustrates that public policy

² 89 F.R. 18908, March 15, 2024.

³ <https://www.uschamber.com/assets/documents/A-Principled-Approach-to-a-New-Narrative-on-IP.pdf>

⁴ https://www.uschamber.com/assets/documents/IPIndex2024_Full-Report_v3.pdf

can directly impact the future of the innovative pipeline with multiple companies discontinuing investment in innovative treatments as a result of that legislation. Ultimately, the American public and the larger world suffer when private actors are inhibited from doing what they do best: developing the next invention that will change the world. We urge the USPTO to defend the ecosystem for IP-enabled innovation through ongoing debates in the multilateral organizations and a reversal of the Administration's recent policy proposal on march-in rights."

II. **The Biden Administration Must Reassert U.S. Global Leadership on IP Rights in Multilateral Forums.**

The repercussions of public policy on the innovative pipeline make it increasingly important to have established global IP standards in place in order to ensure that multilateral policies can help foster investment in countries around the world. USPTO's Notice asserts that "Trade-Related aspects of Intellectual Property rights waivers...are beyond the scope of this request for comment."⁵ But on the very *same page*, USPTO touts that "[w]ithout IP commercialization, we might not have...life-saving COVID-19 therapies."⁶ Throughout the pandemic, voluntary licensing agreements—enabled by IP protection—helped innovative industry to share their technical expertise and know-how with partners at home and around the world. This information sharing supported the rapid development of vaccines, treatments, and diagnostics and the ability to deliver them to global consumers. At the very same time that life-saving work was going on, the waiver discussions proceeded in politicized conversations in Geneva in contradiction with these realities.

Despite the Administration's recent position on IP rights at the World Trade Organization, the U.S. government can play a critical role in promoting IP commercialization through the World Health Organization's Pandemic Agreement. The Chamber is grateful for the Administration's efforts to protect the framework for voluntary technology transfer through the Agreement. However, we remain concerned with provisions that call for government-funded research and development agreements to include provisions on equitable access and the publication of terms in government funding agreements. While we support of the goal of enhancing access to innovative medical solutions, the existing IP framework successfully enabled the investment in and licensing of vaccines, therapeutics, and diagnostics during the COVID-19 pandemic. We urge USPTO to help preserve the infrastructure which enabled the innovative business community to successfully support the response to the global pandemic.

⁵ 89 F.R. 19908, March 15, 2024.

⁶ *Id.*

III. The Biden Administration’s Proposals to “March-in” and Confiscate Private Property is Patently Unlawful, Would Undermine the Bayh-Dole Act, and Would Chill American Innovation.

While debates over the value of IP rights continue in multilateral forums, there are also ongoing domestic policy discussions by the Administration that would lead to the confiscation of private property rights. This drastic policy change⁷, which calls for using march-in rights on patents when the Administration disagrees with the price of a product, violates not only the plain text of the law, but also undermines more than forty years of bipartisan work to promote public-private partnerships.

The law in question, the Bayh-Dole Act, incentivizes the private sector to build upon government funded basic research to advance relevant scientific discoveries through its own investment in applied research. If the applied research allows for an invention to be commercialized, the Bayh-Dole Act protects the private sector investment and consumers’ ability to access new products. The Bayh-Dole Act has been, since its passage, a foundational element in America’s success in research and development. The Bayh-Dole Act enables public-private collaborations and allows expanded access to new, life-changing innovations that help make the U.S. the global innovation leader.⁸

By any measure, the Bayh-Dole Act has been extraordinarily successful. According to some estimates, since its passage, the Bayh-Dole Act has contributed \$1.9 trillion to the U.S. economy, supported 6.5 million jobs, and helped lead to more than 15,000 start-up companies.⁹ In addition, the Bayh-Dole Act has enabled thousands of commercial products stemming from university research to be introduced to the public.¹⁰ As *The Economist* put it, the Bayh-Dole Act “unlocked all the inventions and discoveries that had been made in laboratories throughout the United States....”¹¹

⁷ 88 F.R. 85593, Dec. 8, 2023.

⁸ Tom Wilbur, *IP Explained: Four things to know about the Bayh-Dole Act*, September 13, 2019 (“Adopted by Congress in 1980, the bipartisan Bayh-Dole Act allows institutions and grant recipients, such as universities, to hold the title to patents on inventions stemming from government-funded research and to license the rights to those inventions to private sector partners who further develop them for commercialization. These private sector partners, including biopharmaceutical companies, assume the full risk of developing and commercializing the technologies that may eventually prove to be viable products. This can generate royalties for the research institution, paid by the commercial developer, once a product is brought to market.”); see also Stephen Ezell, *The Bayh-Dole Act’s Vital Importance to the U.S. Life-sciences Innovation System*, ITIF, March 2019, available at <https://www2.itif.org/2019-bayh-dole-exec-summary.pdf>

⁹ Home - The Bayh-Dole Coalition (bayhdolecoalition.org).

¹⁰ See <https://autm.net/surveys-and-tools/databases/statt>.

¹¹ *Innovation’s golden goose*, *The Economist*, December 14, 2002 (Describing how the Bayh-Dole Act was perhaps the most inspired piece of legislation enacted in the last half century.).

Each Administration since the law's enactment, including the Biden Administration as recently as last year, have recognized that the law is clear, confirming that the price of a product has no role to play in determining whether to exercise march-in rights. If the Administration's current policy were to be implemented, it would transform four decades of undisputed success of promoting IP commercialization into a mechanism for unelected, unaccountable bureaucrats to implement de facto price-controls in broad swaths of the U.S. economy.

We are deeply concerned that the Administration's march-in proposal could seriously undermine American innovation. Perplexingly, at a time when the United States is focused on reshoring critical industries, the Administration's property confiscation proposals would cast a pallor of uncertainty over public-private collaborations. Under this proposal, public-private partnerships would once again be encumbered with legal risk and unpredictability, making it more difficult for universities and private sector inventors to attract the partners and capital needed to develop nascent inventions.

The Chamber and its innovative member companies believe that free enterprise and private business, and not the government, are best suited to bring products to market at competitive prices. That is why the Chamber has formed a new coalition—the Business Alliance to Stop Innovation Confiscation Coalition (BASIC)¹²—to defend free enterprise, property rights, and the consequent commercialization of those rights as envisioned in the USPTO Notice. The BASIC Coalition is committed to halting the implementation of the Administration's march-in guidance and to defending robust, dynamic IP rights.

IV. Conclusion

USPTO correctly recognized that IP rights are a critical engine, indeed a cornerstone of American innovation, economic growth, and global competitiveness, and produce benefits for society. Given this, the protection and enforcement of IP should be addressed with a consistent, all-of-government approach that incentivizes investment, upholds property rights, and supports licensing and commercialization that lead to benefits for Americans and the entire world.

Unfortunately, the Biden Administration has so far demonstrated a reluctance to protect the framework that successfully enabled the U.S. to become a global leader in fostering IP-driven innovation. However, there is still time for the Administration to change course and defend American innovation. To the extent the Administration is

¹² <https://www.uschamber.com/intellectual-property/u-s-chamber-mobilizes-entrepreneurs-for-new-coalition-to-protect-u-s-innovation-from-government-confiscation>

willing to do so, the Chamber stands ready and willing to work with USPTO to promote American innovation and ingenuity.

Sincerely,

The United States Chamber of Commerce
The Business Alliance to Stop Innovation Confiscation
Judge Paul R. Michel (Ret.)
Judge Susan Braden (Ret.), Jurist-In-Residence, Center for Intellectual Property
and Innovation Policy, Scalia Law School
The Washington Health Innovation Council
The Maryland Chamber of Commerce
United Inventors Association