U.S. Chamber of Commerce

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April 26, 2023

The Honorable Jim Jordan
Chair
Committee on the Judiciary
United States House of Representatives
Washington, DC 20515

The Honorable Jerry Nadler
Ranking Member
Committee on the Judiciary
United States House of Representatives
Washington, DC 20515

The Honorable Darrell Issa
Chair
Subcommittee on Courts,
Intellectual Property, and the Internet
United States House of Representatives
Washington, DC 20515

The Honorable Hank Johnson
Ranking Member
Subcommittee on Courts,
Intellectual Property, and the Internet
United States House of Representatives
Washington, DC 20515

Dear Chair Jordan, Ranking Member Nadler, Chair Issa and Ranking Member Johnson:

The Global Innovation Policy Center ("GIPC") of the U.S. Chamber of Commerce appreciates the opportunity to share its thoughts regarding today's hearing entitled *"Oversight of the U.S. Patent and Trademark Office."* The Chamber has a broad and diverse membership representing the entire innovation ecosystem, and our comments reflect that diversity.

While the Chamber supports and applauds many of the recent efforts undertaken by the United States Patent and Trademark Office ("USPTO"), especially Director Kathi Vidal's efforts to promote inclusive innovation, we are concerned about the impact some of the agency's recent contemplated actions will have on the life-sciences innovation ecosystem. We are also concerned about the breadth and complexity of the USPTO's recent advance notice of proposed rulemaking on the post-grant review process, even as we continue to review the issues raised. The Chamber's immediate comments and concerns regarding recent USPTO actions can be summarized in five key points:

1. USPTO's and Director Vidal's relentless focus on promoting inclusive innovation is necessary because more people must be engaged in the patent system to unleash American innovation, and Congress should take all the necessary steps required to support the agency's efforts;
2. Congress should support USPTO's efforts to improve patent quality through enhanced examination processes, more technology, resources, and personnel by ending fee diversion and reappropriating previously diverted fees to the USPTO;

3. USPTO must renounce measures that undermine the life-sciences innovation ecosystem, including contemplated changes to continuation practices, examination guidance, and so-called "collaboration" efforts with the Food and Drug Administration ("FDA");
4. As the expert agency, USPTO must advocate against the imposition of additional price controls which undermine the ability of American patients to access new, life-saving medications; and
5. USPTO must continue to be the United States government's champion for IP rights and must play an active role in advancing IP protections both domestically and globally.

Our concerns and suggestions are outlined in more detail below.

I. Inclusive Innovation Unleashes Economic Potential, Makes America Stronger, and Ensures America's Continued Global Leadership.

The Chamber applauds USPTO's focus on inclusive innovation. While USPTO has emphasized inclusive innovation in previous years, Director Vidal's dedicated focus on this issue should be commended. Since her confirmation as Director, she has relentlessly championed efforts to enhance and promote inclusive innovation, ensuring that all Americans, regardless of personal background, social, or economic status, are empowered to do what Americans do best: create the next best innovation that will change the world.

Unfortunately, far too many Americans are underrepresented in our patent system and face barriers to innovation and entrepreneurship. This is especially true for women and people of color. Research shows that, as recently as 2016, the "woman inventor rate" was only 12%, even though women account for more than half of the U.S. population.[1] For people of color, the patent gap is even more pronounced, with some studies suggesting that people of color only hold six patents per million people and patent less than half as many inventions as their Caucasian counterparts.[2] And due to the lack of sufficient and adequate data, it is difficult to quantify the patent

[1] Robin Rasor, Testimony Before the Senate Judiciary Committee Subcommittee on Intellectual Property, *TRAILBLAZERS AND LOST EINSTEINS: WOMEN INVENTORS AND THE FUTURE OF AMERICAN INNOVATION, April 3, 2019* ("The number of patents with at least one-woman inventor increased from about 7% in
the 1980s to 21% by 2016. Despite this increase, the percentage of all patent inventors that are women, or the
annual "women inventor rate," reached only 12% in 2016, even though women represent close to 30% of the total science and engineering workforce.").

[2] Holly Fechner and Matthew S. Shapanka, *CLOSING DIVERSITY GAPS IN INNOVATION: GENDER, RACE, AND INCOME DISPARITIES IN PATENTING AND COMMERCIALIZATION OF INVENTIONS*, Technology and Innovation, Vol. 19, 2018.

gap for LGBTQ individuals, veterans, and those who face geographic and economic challenges.

These Americans face difficulty accessing the patent system for several reasons. Some lack a strong network of mentors to help them learn about inventing, patenting, and entrepreneurship.[3] Others, especially those lacking institutional support resources or legal backgrounds, face difficulties navigating the complex and confusing patent system. Many others simply lack the economic resources to hire attorneys and proceed through the costly patent prosecution process, especially since they will face additional costs to defend against patent infringements or the post-grant invalidation processes.

Promoting inclusive innovation and reducing the patent gap is not just a moral imperative but also critical to America's economic and national security. Inclusive innovation could add trillions of dollars to our economy, creating tens of thousands of new businesses and hundreds of thousands of new jobs.[4] Like all jobs in IP-intensive industries, these jobs pay solid middle-class wages, provide stability, and allow their recipients to achieve the American dream.

The Chamber commends USPTO's efforts to date to improve inclusive innovation. USPTO and Congress should use any and every option on the table—from improving industry collaboration, providing financial resources and educational materials, and establishing early mentorship networks—to achieve this goal. A whole-of-government and society approach is needed. The Chamber and its innovative members stand ready and willing to work with Members of Congress and USPTO to achieve this goal, and we hope you will take advantage of our diverse membership's expertise, experiences, and resources to promote inclusive innovation.

II. Efforts to Improve Patent Quality by Investing in More Technology, Resources, and Personnel is Warranted, and Congress Should Support Such Efforts by Ending Fee Diversion and Reappropriating Previously Diverted Fees to USPTO.

The Chamber praises USPTO's focus on improving patent quality by investing in technology, resources, and personnel. As the Chamber noted in multiple recent submissions to the agency, many of our innovative and diverse companies have

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[3] Dr. Barbara Gault, Testimony Before the Senate Judiciary Committee Subcommittee on Intellectual Property, TRAILBLAZERS AND LOST EINSTEINS: WOMEN INVENTORS AND THE FUTURE OF AMERICAN INNOVATION, April 3, 2019.

[4] Lisa D. Cook, *Policies to Broaden Participation in the Innovation Process*, Policy Proposal 2020-11 (Washington, DC: The Hamilton Project, August 2020); Jennifer Hunt et al., *Why Don't Women Patent?*, National Bureau of Economic Research Working Paper 17888 (Cambridge, MA: National Bureau of Economic Research, March 2012).

legitimate concerns around patent examination quality in their art areas. Investing in these critical topics will improve the patent examination process, lead to higher patent quality and stronger patent rights, and reduce excessive – and excessively costly - litigation.

Without repeating the Chamber's submission to the USPTO in full, we appreciate that so much of the agency's action is dedicated to the very common-sense, low-hanging fruit the Chamber previously identified: hiring more examiners, increasing coordination between art units, enhancing training, providing new and updated prior art search software.[5] The Chamber also is fully supportive of and intrigued by the USPTO's embrace of enhanced AI capabilities to ensure a more robust examination process. While so much of the policy conversation surrounding AI and patent examination focuses purely on improving prior art searches, the prospect of integrating AI applications into the *entire* examination process presents a very real and unique opportunity to improve efficiencies, reduce examination time, and enhance patent quality and technological innovation.

While supportive of all these patent quality improvement measures, the Chamber will reiterate its previous comment that such actions will take significant financial investments and resources which may be beyond the USPTO's current budgetary capabilities. To fully implement these measures and invest in the success of USPTO, the Chamber believes that USPTO needs access to all previously diverted fees. These fees, totaling almost $1.2 billion, have unfairly been withheld by Congress and must be appropriated to and invested in USPTO. The Chamber and its member companies stand ready and willing to work with you to secure these appropriations so that you may invest in the necessary tools needed to improve patent examination and patent quality.

The Chamber also encourages this Committee to engage in robust oversight of USPTO's implementation of the *Unleashing American Innovators Act*. As the Chamber noted in its comments on the USPTO's Draft 2022-2026 Strategic Plan, USPTO should quickly study its fee structure as mandated by that act. In doing so, the Chamber recommended that USPTO study whether the fees for examination match the actual cost of the examination. Additionally, the Chamber urged USPTO to explore what incentives are created by using maintenance fees to cover examination costs. To support this objective, the Chamber suggested that USPTO study data related to the amount and timing of examination costs, examination fees, and maintenance fees. The Chamber urges this Committee to utilize its oversight responsibilities to ensure

[5] *See* GIPC comments to USPTO on robust and reliable patent rights, February 2, 2023; *See also* GIPC comments to USPTO on 2022-2026 Draft Strategic Plan, February 17, 2023.

that USPTO appropriately and adequately implements the provisions of the *Unleashing American Innovators Act*.

III. USPTO must renounce misguided efforts that undermine America's life-sciences innovation ecosystem, including contemplated changes to patent examination practices and alleged "collaboration" efforts with other agencies.

As the Chamber indicated in its comments to USPTO earlier this year[6], we are alarmed by several contemplated agency actions. Specifically, the Chamber is concerned about proposals which would change life-sciences patent examination and continuation practices to require so-called "collaboration" with non-expert agencies. While we appreciate and share the USPTO's goal of improving overall patent quality, we believe these efforts are unwarranted, unsupported by evidence, and should be abandoned.

A. Contemplated Changes to Life-Sciences Patent Examination Practices.

As the Chamber noted in its February comments to USPTO, we do not believe that the agency's contemplated changes to life-sciences patent examination practices are in any way supported by independent, objective facts. All federal policymaking should be evidence-based and premised on the best available data. Effective and empirical research is the best metric for deciding if any policy should be undertaken. In contrast, the USPTO's contemplated proposals come in response to political hyperbole driven by activists that equate the mere existence of patents with a barrier to access.

In their request for comments, USPTO did not once reference any objective study or data point supporting the necessity for taking the scope of systemic regulatory actions contemplated. While advocates for weakened patent rights for life-saving treatments routinely cite studies that parrot false narratives regarding so-called "patent thickets" and "evergreening,"[7] these studies have been rightly criticized for their inaccurate use of underlying data, lack of transparency, and flawed methodology.[8] In fact, these studies are so flawed, unreliable, and laden with mistakes

[6] *Id.*

[7] *See Overpatented, Overpriced: How Excessive Pharmaceutical Patenting is Extending Monopolies and Driving up Drug Prices*, The Initiative for Medicines, Access & Knowledge; *See also* Evergreen Drug Patent Search Database, University of California College of Law.

[8] Adam Mossoff, *Unreliable Data Have Infected the Policy Debates Over Drug Patents*, The Hudson Institute, January 2022; Erika Lietzan & Kristina M.L. Acri née Lybecker, *Solutions Still Searching for a Problem: A Call for Relevant Data to Support "Evergreening" Allegations,* Fordham Intellectual Property, Media & Entertainment Law Journal, Vol. 33, Sep. 26, 2022; *Ltr. from Senator Thom Tillis, Ranking Member, Senate Judiciary Committee Subcommittee on Intellectual Property to Tahir Amin*, January 31,

that the Ranking Member of the Senate Judiciary Committee Subcommittee on Intellectual Property, the Subcommittee with substantive jurisdiction over patent law, requested USPTO and the FDA conduct their own independent, objective assessment of the data and report on whether the claims made are factually accurate.[9]

The Chamber rejects the false and misleading narrative that so-called "patent thickets,"[10] a label that unfairly and inaccurately stigmatizes the necessity of filing additional patent claims (collectively, a "family") covering improvements to existing medicines, are responsible for high drug prices and do not represent true innovation. Scholars have demonstrated that the idea of biopharmaceutical patent thickets is mostly a myth.[11]

If anything, both practice and reality suggest that more patents in a family strongly support innovation and economic growth, patient choice, and the public good. Innovation is not a one-off, siloed process. Often, when a life-sciences innovator files an initial patent claim, they do so in the early stages of research and development, years before an intended product reaches the market and all aspects of its applications and treatments have been clinically tested. Extensive clinical trials and investments in research and development are required to discover subsequent health conditions that the initial product may treat. to realize the full potential of a discovery, which may include identifying subsequent health conditions that the initial product may treat, in addition to other improvements. From delivery efficacy and patient compliance to dosages, mitigation of side effects, extended-release formulations, and entirely new treatments, continuing innovations deliver invaluable benefits to patients and consumers. [12]

Each stage of innovation requires new investment and risk, made possible by incentives like the potential for patent protection. According to one study, the median cost of getting a new life-sciences innovation to market was $985 million, with an average overall cost of $1.3 billion.[13] Other studies estimate the cost, based on the

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2022; Professor Kristen Osenga, *Are "patent thickets" to blame for high drug prices,* Richmond-Times Dispatch, Nov. 30, 2022.

[9] *See Ltr. from Senator Thom Tillis, Ranking Member, Senate Judiciary Committee Subcommittee on Intellectual Property to Dr. Janet Woodcock and Mr. Drew Hirshfeld,* January 31, 2022.

[10] Individuals and organizations variously define a patent thicket in this context as the process of a branded company obtaining purportedly obvious variants of the same patent with the sole purpose of delaying the entry of a generic competitor. *See* Osenga, *supra* note 3.

[11] *Id; see also* Mossoff, *supra* note 3.

[12] *Osenga,* supra note 3 ("It's no secret that drug manufacturers regularly continue to innovate drugs long after they're originally proven safe and effective. There are countless legitimate reasons to do so. Sometimes, post-market research suggests that a particular dosage or delivery method could be superior to the original.").

[13] *See generally* Wouters OJ, McKee M, Luyten J, *Estimated Research and Development Investment Needed to Bring a New Medicine to Market*, 2009-2018, JAMA, March 3, 2020

amount of research and clinical trials required, could be as high as $2.8 billion.[14] The reality is that cutting-edge medical treatment and the hope it gives patients with previously uncurable diseases and illnesses is costly. To justify these substantial costs and investments, many of which never materialize or become profitable, innovators must have access to potential patent protection for innovation that arises later in the product's development lifecycle. Simply put, given the significant costs associated with bringing any iteration of a product to market, without continuations to facilitate claiming of previously disclosed embodiments, or without the ability to secure full scope of protection through the use of terminal disclaimers and additional protections for follow on innovations, life-sciences companies will not invest in new or improved versions of their medicines.

For the Chamber, it is clear that the innovation life-sciences ecosystem, and the patent system that supports it, are working. Continued innovation, and the patent practices which facilitate it, provide innumerable benefits to patients, giving them better, more effective medicines and allowing public access to more data, which can and will spur future innovations. Moreover, current continuation practice and related practice concerning terminal disclaimers are crucial to the flourishing of this innovation – and are a foundational element of the US system that has promoted American innovation and continues to be a draw for investment in the pharmaceutical sector even when compared to other advanced economies. Continuations provide the flexibility to pursue protection for different inventions described in the initial patent description without fear that deserving inventions would lose protection solely due to decisions to pursue a different embodiment earlier. This not only promotes innovation but also facilitates efficient and higher-quality patent examination by dividing claim sets into more manageable pieces and, perhaps more importantly, provides incentives to accelerate disclosure of information to the public as inventors will have no fear that they would lose protection if an invention were disclosed early but is not claimed at that time. A restrictive approach to these applications or limits on terminal disclaimer practice – which permits the grant of obvious variants to ensure the full scope of patent protection – would be counter to these policy goals.

The Chamber also notes that while proposals aimed at changing patent examination practices are targeted towards the life-sciences industry, in fact such changes will apply, consistent with the technologically neutral nature of the patent system, to all sectors. It is unwise for the agency to consider changes to examination practices, which will, under well-established US and international law, apply to all art units and technology sectors, simply to address a ***perceived*** problem in life science patent examinations.

[14] Robert Zirkelbach, *The Cost of Innovation*, PHRMA, November 19, 2014.

Given this, the Chamber believes that too much is at risk—from patient benefits to economic growth and consumer choice—for USPTO to proceed with its contemplated amendments to life-sciences patent application processes. The Chamber urges the Members of this Committee to resist efforts by USPTO to make these harmful changes and to exercise appropriate oversight and hold the agency accountable if it attempts to do so.

B. Proposed Interagency Collaboration Efforts.

In general, the Chamber believes that inter-agency coordination is good governance. However, the current collaboration initiative with the FDA, which is under consideration by USPTO, fails to identify a problem[15] that needs to be solved and appears to repeat activist language. This, in our opinion, raises a false narrative that there are "too many patents on innovative medicines." This simplistic conflation of a single patent with a single medicine is technologically inaccurate and spectacularly counter-productive from a policy perspective.

The USPTO's proposed collaboration also ignores the failures that have occurred from similar collaborations in other countries. As Members of this Committee may know, in 2021, the United States " welcome[d] limits on the role of Brazil's National Sanitary Regulatory Agency (ANVISA) on issues relating to the patentability of new pharmaceutical inventions but continues to monitor the situation in light of long-standing concerns about duplicative reviews by ANVISA of pharmaceutical applications."[16] The United States found that ANVISA's disastrous intrusion into patent matters in Brazil, and the lingering concerns about duplicative reviews, was damaging and undermining life-saving innovations.

The agency's current collaboration proposal shares similarities with many of the failed restrictions and measures the United States successfully opposed in Brazil. It is perplexing that ideas long criticized by U.S. Administrations of both parties, such as involving drug regulatory agencies in patent examination, are now gaining currency in the United States.[17] Members of this Committee should encourage the agency to abandon its current misguided collaboration efforts and reject legislative efforts to require such collaboration.

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[15] *See* Emily Morris, Mark Schultz, and Joshua Kresh, *Response to Request for Comments on USPTO Initiatives to Ensure the Robustness and Reliability of Patent Rights (PTO-P-2022-0025)*, February 1, 2023; *See also* Erika Lietzan & Kristina Acri, *Distorted Drug Patents*, Washington Law Review v. 95, October 1, 2020.

[16] 2021 Special 301 Report, available at https://ustr.gov/sites/default/files/files/reports/2021/2021%20Special%20301%20Report%20(final).pdf

[17] See generally, comments to joint FDA-PTO listening session Jan. 19, 2023, available at https://www.regulations.gov/document/PTO-P-2022-0037-0001/comment

IV. Implementation of harmful price controls will limit the ability of American patients to access new, life-saving medications. As the expert agency, USPTO must advocate against the imposition of these policies.

In March, the Chamber released its *2023 Patient Access Report (Phase One)* ("The Report"). As the Chamber recently explained in a letter to the Department of Health and Human Services ("HHS") Secretary Xavier Becerra, the Report confirms what proponents of the free market system already know: marketplace competition and effective intellectual property protections give patients greater access to the latest life-saving medicines.[18] In contrast, the Chamber's research shows that market-restrictive policies-like artificial price controls-deter future innovation, inhibit patient access, and ultimately limit patient choice.

Reducing barriers to access has long been a health policy priority and focus for Congress and the business community. The Chamber supports appropriate, practical efforts to help mitigate and overcome obstacles to life-saving medicines. However, government price setting will create additional access challenges for Americans.

Unfortunately, many have accepted the failed premise that government intervention and price setting is the most effective way to provide patients with life-saving innovations. This approach is embodied within the drug pricing provisions of the *Inflation Reduction Act* ("IRA"). While the IRA claims to promote access by controlling prices through so-called "negotiation," the reality is that innovators are forced to comply with the government's arbitrary and coercive price control scheme or face crippling penalties. At the same time, incentives to develop generic and biosimilar medications, one of the critical components in the innovative ecosystem in today's biopharmaceutical market, are virtually destroyed – embedding price controls in the U.S. market in a way that would be virtually irreversible for future generations of medicines.

The Chamber's Report cautions that the IRA's drug pricing penalties will harm patients by causing them to forfeit early and extensive access to the best life-saving medications. The Report's methodology shows that in other OECD countries which have implemented price controls, patients see fewer overall biopharmaceutical product launches, including biologics and oncology products, and have delayed access to medicines.[19] For example, before enacting the IRA's price controls, out of 104 new oncology products released globally, 80% were launched in the U.S., while only 58% were launched in Europe. Similarly, in several benchmark countries, patients

[18] Ltr from David Hirschmann, President and CEO, Global Innovation Policy Center, to Secretary Xavier Becerra, March 22, 2023.

[19] The report found that fewer biopharmaceutical products overall launched in Canada, Japan, South Korea, Australia, and European Union member states than in the United States over the past 20 years.

can often wait up to several hundred days to receive access to life-saving treatments, waiting an average of 133 days in Germany and up to 500 days in Spain.

The IRA's anticipated harms have already revealed themselves through the numerous life-sciences innovators who have officially ended product research and development programs, citing the new price controls. Anecdotally, for example, Eli Lilly CEO Dave Ricks said the company had already dropped a blood cancer drug from its R&D pipeline because they "couldn't make the math work . . . [i]n light of the Inflation Reduction Act, this program no longer met our threshold for continued investment."[20] Similarly, Novartis warned that the new law could discourage research in its most promising areas of research: RNA and radioligands.[21] Finally, Alnylam has stopped developing a treatment for a rare eye disease due to the need "to evaluate impact of the Inflation Reduction Act." [22]

In addition, research by The Pharmaceutical Research and Manufacturers of America ("PhRMA") shows that the IRA's pricing provisions may put the development of more than 400 new medicines at risk.[23] This research indicates that these potential medicines under development target some of the most common yet serious chronic diseases affecting America's seniors, including Alzheimer's, diabetes, and congestive heart failure.[24] Unfortunately, this report also demonstrates that the IRA's ill-conceived price controls are already having a "chilling effect" on research and development. According to the report, life-sciences innovators believe the IRA's current framework will undermine advances critical to patient well-being.[25] When asked, some 82% "or more of companies with pipeline projects in cardiovascular, mental health, neurology and cancers expect substantial impacts on R&D decisions…."[26]

These are but a few of the most prominent examples of innovative, life-saving products whose realization, availability, and access are ironically threatened by the IRA's price controls to purportedly improve access. As more information comes to light, it is likely to become clear that the most vulnerable patients – including older Americans, those diagnosed with rare diseases, and underserved populations– will pay the price for innovation lost to the IRA.

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[20] Joe Grogan, *The Inflation Reduction Act Is Already Killing Potential Cures*, The Wall Street Journal, November 3, 2022.
[21] Ludwig Burger, *Novartis warns U.S. plan to curb drug prices could hit key research*, Reuters, January 20, 2023.
[22] Grogan, *supra* note 1.
[23] Medicines in Development, 2023 Report, Pharmaceutical Research and Manufacturers Association of America.
[24] *Id.*
[25] *Id.*
[26] *Id.*

Unfortunately, instead of recognizing this growing body of evidence and changing course, the Biden Administration is doubling down and calling for even more restrictive price controls. Under the President's proposals, the number of life-saving medications subject to disastrous price controls could be quadrupled to as much as 40. In addition, the President's proposals would decrease the time such products could sell at fair market prices before arbitrary price controls kick in. Finally, the President's proposal would extend price controls to the private sector market.

To describe these proposed additional price control policies as disastrous for American innovation would be an understatement. First, these proposals signal to America's life-sciences companies that there is no support for the development of further inventions and cures. According to Nick Shipley, Chief Advocacy Officer for the Biotechnology Innovation Organization, the President's proposals would "further destabilize Medicare, slow critical investment in future research and development, stall drug innovation, and ultimately harm patients." This would, in sum, represent another blow to the millions of patients suffering from debilitating diseases that depend on America's private sector to innovate new cures and treatments.

Government intervention in the market establishment of prices undermines the innovation ecosystem that enabled the U.S. to become one of the most inventive countries in the world. As a practical matter, price controls nullify one of the critical rights associated with intellectual – or any other form of – property, putting biopharmaceutical innovation effectively on a non-market footing. As the expert agency tasked with advising the President and Congress on IP matters, USPTO must consider the implications of price controls for patients and engage with CMS before it proceeds further with implementing the RIA's framework, which would jeopardize U.S. leadership on biopharmaceutical innovation and access to treatments. In addition, USPTO must assert itself and resist further calls for price controls from this Administration and Congress.

The Members of this Committee should work with USPTO to rectify the harmful anti-innovation policies promoted by the IRA. The ability of American patients to access life-saving innovations in a timely manner depends on it. Surely the outcome which will result from the IRA and further price controls—less innovative medicines and longer wait times—isn't what any Member of this Committee or the USPTO want.

V. USPTO must continue to be the government's champion for IP rights, reassert its influence, and take a more active role in advancing IP protections both domestically and globally.

The Chamber appreciates USPTO's focus on global IP enforcement and collaborative stakeholder engagement. These are worthy and laudable efforts and are critical to USPTO's central mission as America's leading innovation agency. The Chamber particularly appreciates the USPTO's focus on global engagement through the Global IP Academy.

However, the Chamber also suggests that USPTO should take a more assertive, forward-leaning role on domestic and global IP issues, consistent with its role as the primary advisor to the President and the Administration on IP-related matters. The USPTO must take account of this reality and boldly assert that it, as opposed to another agency, should be leading the inter-agency process affecting IP policy decisions for the Executive Branch.

There are continuing challenges worldwide that deny adequate and effective intellectual property with a negative impact on crucial American industries that run the gamut from motion pictures to innovative pharmaceuticals. From global IP frameworks and protections to domestic policy, the expert agency must reassert its leadership and ensure that focus is not limited solely to particular enforcement goals. The agency should also focus on addressing global challenges for innovative American industry, including support for strong IP at multilateral organizations and assurances that IP protections will be available and enforceable with trading partners.

The Chamber encourages Congress and Members of this Committee to provide USPTO with the resources, statutory authority, and support it needs to reassert itself as the principal agency on all aspects of global IP issues.

VI. Conclusion

The Chamber appreciates the opportunity to submit these comments for the record for this hearing. We stand ready and willing to work with this Committee to find ways to ensure the USPTO maintains patent quality, promotes inclusive innovation, and does not engage in practices that harm America's life-sciences innovation ecosystem.

Sincerely,

Patrick Kilbride
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U.S. Chamber of Commerce