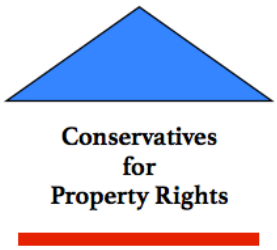

February 24, 2023

U.S. Patent and Trademark Office
600 Dulany Street
P.O. Box 1450
Alexandria, VA 22313

RE: Request for Comments on USPTO Initiatives to Ensure the Robustness and Reliability of Patent Rights (Docket No. PTO-P-2022-0025)

To whom it may concern:

Conservatives for Property Rights (CPR) is pleased to respond to the Request for Comments regarding Initiatives to Ensure the Robustness and Reliability of Patent Rights (Docket No. PTO-P-2022-0025).

CPR is a coalition of center-right public policy organizations dedicated to preserving and protecting private property rights for all forms of property. CPR educates and advocates on issues related to property rights, including intellectual property. We recently responded with comments on the Joint USPTO–FDA Collaboration Initiatives (Docket No. PTO-P-2022-0037).[1]

We have closely followed and weighed in,[2] not only on IP policy issues as such, but where policy areas intersect, such as patent exclusivity and antitrust's competition focus.[3] Each property rights issue is important. Moreover, experience proves that the interplay of policy areas can dramatically encumber private property rights, create imbalance, or otherwise disrupt proper workings of the complementary areas of law and policy. The result is a contradictory, counterproductive morass holding broad consequences.

Like the USPTO–FDA Collaboration Initiatives, this current request for comments also emanates from the July 2021 Executive Order on "Promoting Competition in the American Economy." The E.O. contains more than 70 directives to agencies across the federal government and takes aim at industries across the American economy while wrapping in vastly different policy areas. Such a scattershot approach risks much danger, disruption, and disquiet to title of private property of many species. This request for comments is but one initiative resulting from the E.O.'s directives, risking the patent rights and protections of American innovation.

---

[1] https://www.property-rts.org/_files/ugd/651e0c_6cd979a32c8f4a65a0744a1c82b44fc6.pdf

[2] For example, see comments on Request for Information Regarding Patent Eligibility Jurisprudence Study (Docket No. PTO-P-2021-0032).

[3] For example, see comments on Draft Policy Statement on Licensing Negotiations and Remedies for Standards-Essential Patents Subject to Voluntary F/RAND Commitments (Docket No. ATR-2021-0001).

There are dangers in breathing unproven antitrust theory into patent policy. Neo-Brandeisian antitrust proponents have serious difficulty coming to grips with the fact that patent exclusivity is the lifeblood of invention; the essence of robust, reliable patent rights; the key to commercialization of patented inventions; and the foundation of dynamic competition.[4] Dynamic competition arises from innovation's creation of new markets.[5] Indeed, antitrust experts may not fully appreciate that exclusive rights of limited duration in a patent, if secure, reliable, and enforceable, enable the sort of dynamic competition that spurs new competition, benefits consumers, and sparks fresh rounds of innovation.

CPR's estimation of the concerning nature of the current (and related, recent) proposals underlying the request for comments (RFC) is borne out in comments to this docket by a highly distinguished, expert, bipartisan coalition, the Council for Innovation Promotion (C4IP). C4IP observes that "the current RFC directs the public to question fundamental functions of the patent system. The framing of the questions suggests that the USPTO is pursuing an imbalanced inquiry into our patent system, one that wrongly assumes that major problems exist."[6] CPR shares these concerns.

Furthermore, Professor Adam Mossoff, a nationally recognized expert in intellectual property law at the George Mason University Antonin Scalia Law School, raises similar concerns about the initiatives USPTO is considering in regard to the robustness and reliability of patent rights. Prof. Mossoff warns, "In considering whether to adopt new regulations restricting the ability of innovators to obtain reliable and effective patents, *it is imperative that the USPTO engage in evidence-based policymaking*. With this governing principle in mind, the examination rules currently under consideration by the USPTO, such as heightened restrictive scrutiny of continuation applications, among other proposed rule changes, would *represent systemic changes to the U.S. patent system that would impose additional costs and uncertainties* on all innovators who rely on patents both to recoup research and development expenditures and to commercialize their inventions in the marketplace. Thus, *any new regulatory initiatives that restrict the ability of all inventors to obtain reliable and effective patents should be based on rigorous studies and verifiable evidence that these rules ameliorate proven systemic inefficiencies in the patent system*" (emphasis added).[7] CPR shares these concerns and endorses these recommendations.

---

[4] See James Edwards, "Getting Antitrust Right Without Suffocating Technological Progress," Real Clear Markets (Jan. 26, 2021).

[5] See CPR statement following the conclusion of the Federal Trade Commission's costly, unfounded antitrust litigation against Qualcomm over the innovator's legitimate exercise of patent exclusivity. The statement said in part: "The Ninth Circuit's refusal to grant the Federal Trade Commission en banc review of that court's ruling in favor of Qualcomm appropriately lets stand a unanimous appellate decision that respects dynamic competition involving IP. This should close once and for all a dangerous, misguided application of antitrust against innovators exercising their patent rights.
"The appeals court's three-judge panel had closely weighed the case, gave the district court's questionable ruling de novo review, and came to the most reasonable, prudent, best conclusion based on the law and the facts. That crucial reversal is securely based on and protects private property rights."

[6] https://urlisolation.com/browser?clickId=B4FA23EB-ABF8-4A0B-8EBB-C9D3DCB5199E&traceToken=1676730889%3Bphrma_2_hosted%3Bhttps%3A%2Flnks.gd%2Fl%2FeyJhbGciOiJIUzI&url=https%3A%2F%2Fdownloads.regulations.gov%2FPTO-P-2022-0025-0081%2Fattachment_1.pdf

[7] https://urlisolation.com/browser?clickId=B4FA23EB-ABF8-4A0B-8EBB-C9D3DCB5199E&traceToken=1676730889%3Bphrma_2_hosted%3Bhttps%3A%2Flnks.gd%2Fl%2FeyJhbGciOiJIUzI&url=https%3A%2F%2Fdownloads.regulations.gov%2FPTO-P-2022-0025-0107%2Fattachment_1.pdf

The troubling direction and potential for encroaching on the patent rights of inventors leads us to reiterate verbatim from our recent comments: "The consequences of the Patent and Trademark Office's (PTO) and the Food and Drug Administration's (FDA) getting it wrong here will profoundly jeopardize the health and lives of millions of suffering patients in the United States and around the world. Further, getting it wrong regulatorily will set back progress in U.S. biopharmaceutical innovation, both in the short term and the long term. The adverse consequences for this industry will harm U.S. research-and-development (R&D) leadership, private investment, and U.S. innovators' competitiveness with China and other foreign countries in a technological area in which China and other nations are making concerted efforts to capture the lead. It will harm the U.S. economically and diminish well-paying American life sciences jobs, while weakening many local innovation ecosystems. Simply put, the stakes here are extremely high."

The concepts included in the RFC could impart dangerous limitations on the ability of innovators to obtain robust and reliable patent protections in any area that includes refinement of inventions over time. Continuation patents and terminal disclaimers have long been part of the patent system, and they encourage earlier disclosure of the invention to the USPTO and then the public. This fosters scientific knowledge and competition. Limitations and restrictions would run counter to this.

We add to this concern that the proposals considered in this RFC would apply generally to inventors and innovative, IP-centric companies in all technologies and the most innovative U.S. industrial sectors. That expansive scope widens the potential for harm exponentially. It could be said that at least these proposals are technology-neutral, as such proposals should be. But if the USPTO gets it wrong in its actions, the problem is that much greater.

Finally, we further reiterate from our recent comments the prevalence at the antitrust-patent juncture of misguided legislation[8] and regulation based on "fictional figures from advocates such as the Institute for Medicines, Access, & Knowledge (I-MAK). Patent-skeptical politicians and advocates regularly invoke I-MAK's and others' suspect statistics. Yet, these numbers have been shown to be dramatically inflated. '. . . I-MAK's reported numbers of issued patents, patent applications, and exclusivity periods for drugs are infected with serious questions of reliability and accuracy. There are repeated and vast discrepancies between I-MAK's numbers and the numbers found in official, publicly available governmental sources like the FDA's Orange Book and court opinions.'[9]

"Moreover, Sen. Thom Tillis, ranking Republican on the U.S. Senate Intellectual Property Subcommittee, has pursued inquiries about the opaque data sources and research methods of I-MAK and other interest groups that traffic in questionable drug patent figures.[10] The groups have stonewalled the senator. As you know, Sen. Tillis has requested PTO's and FDA's investigation into these suspect organizations and their questionable data and methods.[11]

---

[8] CPR statement, "Statement on Congressional Antitrust Hammers Against Biopharma Innovation," June 2, 2021.

[9] Adam Mossoff, "Unreliable Data Have Infected the Policy Debates Over Drug Patents," Hudson Institute, Jan. 2022.

[10] Eileen McDermott, "Tillis Wants More Info on I-MAK and Other Data Driving Anti-Patent Narratives Around Drug Pricing," IPWatchdog, Feb. 1, 2022.

[11] Sadaf Deedar, "Tillis Renews Request to FDA and USPTO for Independent Assessment of I-MAK Patent Data," IPWatchdog, April 5, 2022.

Therefore, federal agencies should exhibit skepticism of such dishonest numbers that call to mind Mark Twain's categories of lies as including statistics, particularly avoiding in any way their use as the basis for policymaking. Any reliance on or usage of I-MAK's or similar groups' asserted numbers will taint PTO-FDA collaboration and their decisions" (emphasis added).

In his comments in this docket, Prof. Mossoff showed the lack of credibility of I-MAK's numbers, methodology, and data. Prof. Mossoff warns against USPTO's falling for "apparent 'policy-based evidence-making'" in this round of regulatory activity. CPR concurs. In response, I-MAK included in its more recent comments assertions about the length of time biologics were on the market before biosimilar competition was launched. Those numbers, however, do not show what I-MAK asserts, as that time includes time on the market before Congress had even enacted a regulatory pathway for approval of biosimilars.

I-MAK is hardly the only special interest that publishes questionable statistics to back its policy goals. Thus, CPR asks USPTO to adopt a rule of prudence and heightened scrutiny of policy proposals, and associated suspect statistics, that would put at risk the fundamental property rights of inventors and inventive, IP-centric companies.

In closing, robust, reliable patent rights are vital for promoting innovation, commercializing new and improved inventions, and growing the U.S. economy. We urge PTO to avoid causing unintended harm to America's inventors, patent system, patent-centric economic sectors, and the many beneficiaries of the fruits of real innovators' labors.

Respectfully,

James Edwards, Ph.D.
Executive Director
Conservatives for Property Rights

Ed Martin
President
Phyllis Schlafly Eagles
Eagle Forum Education & Legal Defense Fund

Kevin L. Kearns
President
U.S. Business and Industry Council

Tom DeWeese
President
American Policy Center

Saulius "Saul" Anuzis
President
60 Plus Association

James L. Martin
Founder/Chairman
60 Plus Association

Seton Motley
President
Less Government

Ashley Baker
Director of Public Policy
The Committee for Justice

Curt Levey
President
The Committee for Justice

David Williams
President
Taxpayers Protection Alliance

Matthew Kandrach
President
Consumer Action for a Strong Economy