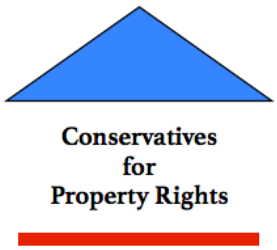

February 1, 2023

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

RE: Request for Comments Regarding Joint USPTO–FDA Collaboration Initiatives (Docket No. PTO-P-2022-0037)

To whom it may concern:

Conservatives for Property Rights (CPR) is pleased to respond to the Request for Comments Regarding Joint USPTO–FDA Collaboration Initiatives (Docket No. PTO-P-2022-0037).

CPR is a coalition of public policy organizations dedicated to preserving and protecting private property rights with respect to all forms of property. CPR educates and advocates on issues related to property rights, including intellectual property. We have closely followed and weighed in,[1] not only on IP policy issues as such, but where issue areas intersect, such as patent exclusivity and antitrust's competition focus.[2] Each property issue area is important. However, 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. That creates a contradictory, counterproductive morass.

The July 2021 Executive Order on "Promoting Competition in the American Economy," containing more than 70 directives to agencies across the federal government, takes aim at industries across the American economy while involving vastly different policy areas. The exercise represented in this request for comments is but one such directive. It targets the patent rights and protections of a highly important innovative industry sector in health care for which patent exclusivity is lifeblood.

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

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

[2] 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).

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.

This directive and regulatory exercise risk upsetting the delicate balance of FDA's mission of drug approval based on safety and efficacy and of PTO's mission of ascertaining that an innovation incorporated in a biopharma product is novel, useful, and nonobvious. The implications of the directive are counterproductive for dynamic competition within the biopharmaceutical industry. Patent exclusivity enables innovators to try to compete with established corporations, domestically and internationally. Yet the E.O. seems to presume IP exclusivity harms competition. In fact, the opposite is true.

We observe that neither the PTO nor the FDA holds any authority over the prices of patented products, including pharmaceutical products. The E.O. seems to direct the agencies to conjure ways around the constraints of law and administrative guardrails as a means of affecting product prices—and in one direction only, artificially driving down prices.

The E.O.'s directive that the two agencies collaborate against "unjustifiably" delayed generic drug and biosimilar market entry raises the risk of disrupting the balance struck by the Hatch-Waxman Act and the Biologics Price Competition and Innovation Act between biopharma innovation and market entry by generic drugs and biosimilars. Manipulating the patent system to diminish innovators' rights to market exclusivity is likely to result in fewer new medicines and thus fewer generics and biosimilars. This will amount to politicians getting short-term praise in the headlines on a political hot topic, but long-term costs to society of fewer new classes of medicines, fewer new uses and new versions of existing drugs, and fewer brand medicines on the market whose patents will expire, thus becoming available as generics (which already constitute about 90 percent of the prescriptions filled in the United States).

CPR is concerned about the potential for undue expansion of PTO and FDA collaboration beyond that which is constructive. We fear inordinate involvement in each other's mission. PTO is expert at examining inventions for patent eligibility, novelty, usefulness, and obviousness. FDA is expert at determining new medical technologies' and products' safety and efficacy. Their respective assessments may converge around the same invention, but the FDA lacks expertise in patent examination, nor does PTO have expertise in drug and medical device regulatory approval or clearance. We urge guarding against breaching the prudent boundaries of the respective agencies' expertise.

Certainly, collaboration has its place. But patents secure the right to exclude. It is exclusivity over an invention that actually facilitates constructive collaboration between a patent owner and business partners. Thus, PTO and the FDA must take the utmost caution not to impose changes regarding their collaboration that will deprive inventors and patent owners (individual or corporate) of their exclusive rights and the more important collaboration, that in the commercialization phases that bring practical benefits from inventions. Appropriate agency coordination already exists pursuant to the Hatch-Waxman Act. The agencies' memorandum of understanding addresses collaboration and information-sharing as the two agencies collaborate when determining the appropriateness of patent term extension on a pharmaceutical to compensate for part of the period between patent grant and drug marketing approval.

CPR urges PTO's caution so as not to exceed what is beneficial and working well into intermingling of agencies' missions to where expertise is lacking. Were each agency to develop expertise in the other's area of responsibility, as implied in several of PTO's contemplated initiatives, duplication of effort is the sure result. That will mean squandered resources, poor judgment calls, and unnecessary confusion, delay, and wasted investment in R&D. Such bureaucratic misjudgments are practically guaranteed to cause protracted litigation. Another foreseeable consequence will be even more time spent in already complicated processes of patent prosecution and drug approval. All this hardly fosters lower drug prices.

Further, we warn of the potential for undermining technological neutrality. The U.S. patent system has traditionally applied the same patentability criteria and processes to inventions of every type. PTO proposes subjecting patents on biopharmaceuticals to unique criteria.

The "covered business methods" (CBM) PTAB proceeding is instructive here. This defunct proceeding reviewed patent claims for a "method" or "apparatus" for performing data processing or a similar operation relating to the practice, administration, or management of a financial product or service.[3] Former PTO Director Andrei Iancu commented on CBM's technology bias. CBM always was "inherently problematic in that it isolates a particular area of technology. And . . . as a general principal, it's not good and it's not in the tradition of the American patent system to isolate for whatever purpose a particular area of technology."[4] Allowing government agencies to initiate patent challenges or otherwise treat certain technologies differently is technology bias. As contemplated in the proposal, American leadership promoting technology neutrality in the TRIPS Agreement and elsewhere is compromised. This hands foreign competitors an excuse to adopt technology biases in their patent systems, which can be used as a weapon against U.S. innovators.

In addition, significantly increasing crossagency information-sharing about innovative details pertaining to specific medical products—including disclosing to each other commercially sensitive or confidential information such as trade secrets or undisclosed information from pending patent applications—could breach the confidentiality of intellectual property belonging to an innovator company. Proposed mechanisms for determining inconsistent statements to the agencies heighten the risk of government disclosure of just such private information, which was initially shared with one federal agency for a specific set of laws and regulations. The heightened potential for government actors' misuse or disclosure of such information or data constitutes a major confidentiality concern.

Confidentiality, which has characterized PTO in the past, would be further compromised by liberalized information swapping. Information shared in confidence with the agency during patent prosecution belongs to the inventor. Interagency sharing of such information during patent examination risks public disclosure, which makes the information prior art. This kind of unauthorized disclosure in the course of interagency collaboration carries serious risks, damage, and economic and innovative disadvantage for the harmed party. Thus, strict safeguards should accompany any expansion of interagency information-sharing. If PTO and

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[3] James Edwards, "The Covered Business Methods Program Must Finally Be Laid to Rest," IPWatchdog, Aug. 10, 2020.

[4] Hudson Institute, "A Conversation with USPTO Director Andrei Iancu on the Patent System and the Innovation Economy," YouTube, Sept. 15, 2020.

FDA follow this fraught path, any such rule must prescribe civil, criminal, and federal employment ethics sanctions. Both personal and government agency liability should be provided in order to account for the economic harm, lost commercial opportunity, and lost IP exclusivity and future innovative opportunities.

Regarding "patent thickets" and "product hopping," which have been the focus of misguided legislation,[5] CPR again urges caution. Discussions of the supposed practices are typically accompanied by 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."[6]

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.[7] 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.[8] 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.

Disturbingly, a surprising amount of what PTO proposes casts shadows on the patent agency's commitment to stay true to the fundamental principles of invention and patent rights. We urge PTO to make sure FDA does not steer any initiative into territory detrimental to patents and invention.

In closing, secure, reliable patents remain the key to promoting innovation, commercializing new products that raise the standard of living, and growing the U.S. economy. We ask PTO to ensure that this effort doesn't result in unintended harm to America's inventors, patent system, life sciences economic sector, and the sick and suffering who stand to benefit directly from the fruits of our biopharma industry's labors. Ultimately, this comes down to safeguarding property rights essential to commercializing the small handful of successful inventions in a high-risk innovation field or weakening key elements of the biopharma innovation ecosystem.

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

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

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

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

Respectfully,

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