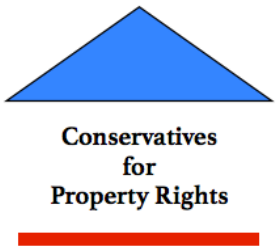

December 13, 2022

The Honorable Dick Durbin
Chairman
Senate Judiciary Committee
224 Dirksen Senate Office Building
Washington, D.C. 20510

Dear Chairman Durbin:

Conservatives for Property Rights writes to express concerns regarding S. 4430, the Interagency Patent Coordination and Improvement Act. We commend you as one of the propatent, proinventor stalwarts in the U.S. Senate. Thus, CPR believes you will give our concerns due consideration. We are confident you will be open to addressing these concerns.

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 proudly work on both sides of the aisle when possible on issues of concern. For example, CPR has endorsed in serial Congresses Sen. Coons's STRONGER Patents Act and vigorously opposed Republican-led patent legislation that would diminish patents, weaken intellectual property rights, and favor patent infringers while disadvantaging inventors and patent owners.

First, we believe S. 4430 would unduly expand the involvement of the Patent and Trademark Office and the Food and Drug Administration beyond what would be constructive and too far into each other's core mission. PTO is expert at examining inventions for patent eligibility, novelty, usefulness, and obviousness. FDA is expert at determining new medical technologies and products for safety and efficacy. Their respective assessments may converge around the same invention, but the FDA has no expertise in patent examination, nor does PTO have any expertise in drug or medical device regulatory approval or clearance. This bill may well breach the prudent boundaries of these respective agencies' expertise. CPR urges extreme caution in considering such a move.

Appropriate agency coordination already exists pursuant to the Hatch-Waxman Act. The PTO and FDA have a memorandum of understanding in place for collaboration and information-sharing when determining the appropriateness of patent extension due to the timing of patent grant and drug marketing approval.

In contrast, S. 4430's design exceeds what might be constructive into intermingling of agencies' missions, expanding their respective missions where expertise is lacking. Were each agency to develop expertise in the other's area of responsibility, this would be duplication of effort. All this is highly likely to result in squandered resources, poor judgment calls, and unnecessary confusion, delay, and wasted investment in research and development, with such misjudgments almost guaranteed to lead to protracted litigation. Another consequence would be even more time spent in the complex processes of patent prosecution and new drug approval.

Second, S. 4430 would undermine a core quality of the U.S. patent system: technological neutrality. A hallmark of our patent system has from the outset been patentability criteria and processes that assess and apply to all inventions the same, no matter the art or patentable subject matter. The bill would subject patents on biopharmaceuticals to different criteria and scrutiny than patents of other types of technologies. Then-PTO Director Andrei Iancu took issue with an adverse exception to the historical norm in the similarly technology-biased "covered business methods" PTAB proceeding.[1] CBM was created by the America Invents Act in order to cancel a financial services-related business method patent.[2] Director Iancu called CBM "inherently problematic in that it isolates a particular area of technology. And as we've been discussing throughout . . . 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."[3]

Moreover, to create another such technology bias toward certain types of inventions would take another step away from historical U.S. global innovation leadership, including our advancing technology neutrality in foreign patent systems. Thanks to American leadership, the TRIPS agreement requires signatories to maintain technological neutrality in patenting. Regrettably, the framework that S. 4430 would enact would raise concerns under the TRIPS agreement because its treatment is particular to biopharma inventions.

Third, significantly increasing cross-agency information-sharing about specific medical products, including disclosing to each other commercially sensitive or confidential information, would increase the risk of breaching confidentiality of intellectual property belonging to an innovator company. S. 4430 could further ease concerns about heightened risk of government disclosure of private information, initially shared with one federal agency for one set of laws and regulations, if the legislation bolstered its safeguards against misuse or disclosure of such information or data by government actors.

Additional safeguards should prescribe civil, criminal, and federal employment ethics sanctions. A private party harmed by such unlawful disclosure should have judicial recourse that ensures both personal and government agency liability for the economic harm, lost commercial opportunity, and lost IP and innovative opportunities. Adding such robust measures to protect an innovator company's economic interests at stake from the interagency

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[1] https://www.property-rts.org/_files/ugd/651e0c_427ba0ea8a7e43d3b0ce85c32cf7c5d4.pdf

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

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

collaboration would help mitigate the potential for negligence or malicious conduct, while guaranteeing respect for the exclusive rights that patents secure.

Fourth, CPR views the premise not only of S. 4430, but of antitrust legislation aimed at so-called "patent thickets" and "product hopping" and of the 2021 executive order on competition, as troubling. For example, the figures from I-MAK have been exposed as 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."[4]

In closing, patent law expert Adam Mossoff warns that S. 4430 "portends a fundamental change in the U.S. patent system . . . threaten[ing] to undermine the efficient functioning of the U.S. patent system as a technology-neutral property rights system that has successfully promoted new innovations and spurred the growth of the U.S. economy."[5] CPR is convinced that Professor Mossoff's assessment is correct. Therefore, we urge you to withdraw S. 4430 in its current form and work with CPR and other propatent stakeholders to ensure that your well-intentioned legislation doesn't result in unintended harm.

Respectfully,

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

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Dick Patten
President
American Business Defense Council

Colin Hanna
President
Let Freedom Ring

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

[5] Adam Mossoff, "For Biomedical Innovation, Congress Should Follow the Maxim 'First, Do No Harm,'" Heritage Foundation Report, Nov. 14, 2022.

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