The Honorable Richard Durbin (D-IL)
The Honorable Patrick Leahy (D-VT)
The Honorable Thom Tillis (R-NC)
The Honorable John Cornyn (R-TX)
The Honorable Chuck Grassley (R-IA)
The Honorable Chris Coons (D-DE)

December 13, 2022

Dear Senators:

We write to express our concern about the Interagency Patent Coordination and Improvement Act of 2022 (S. 4430) and, in particular, Congress moving forward with this legislation before the U.S. Patent and Trademark Office (USPTO) and the Food and Drug Administration (FDA) have the opportunity to collect public comment and consider further steps in its ongoing efforts to address issues related to drug patents.

The Council for Innovation Promotion (C4IP) is a bipartisan coalition, led by former administration officials and judges, dedicated to promoting strong and effective intellectual property (IP) rights that drive innovation, boost economic competitiveness, and improve lives in the United States and around the world. C4IP stands as a trusted partner to Congress and the administration as officials seek to develop policies to ensure a well-functioning IP system that bolsters U.S. innovation and investment in new technologies.

As you know, S. 4430 would establish an interagency task force to facilitate sharing of information between the USPTO and the FDA. The bill also would require the USPTO to report to Congress on how often the FDA provides information through the task force and whether that information is used in patent examinations. We believe legislation at this point is premature and could place significant burdens on these two important agencies without clear benefit. We have also seen inaccurate and misleading data reports we believe are driving some of the public discussion related to drug pricing.

The bill attempts to address issues for which there are already significant safeguards, namely preventing parties from making inconsistent statements to the FDA and USPTO. For example, parties engaging with the USPTO have a duty of candor to disclose information material to patentability and, if they violate this duty, the patent can be held unenforceable when the issue comes up in court. Further, if legislation is warranted in this area, we believe that it must ensure that confidential and/or trade secret information obtained from the FDA is not unnecessarily released to the public.

In addition, the administration has in recent months already identified specific initiatives to address these issues. These efforts are in response to an executive order issued on July 9, 2021, on promoting competition. Among other things, we understand that the USPTO is conducting a public listening session on January 19, 2023, to address some of these issues, and has solicited written comments from the public as well.[1]

Given the above concerns and timing of ongoing efforts, we believe the relevant agencies should be given the chance to seek public input and propose collaborative solutions before Congress takes action. These issues are complicated and can lead to unintended consequences in a carefully balanced system, and require thoughtful actions by the expert agencies based on accurate data. Of course, oversight from Congress is also needed to avoid negatively impacting the innovative industries that produce the life-saving drugs Americans and patients around the world so desperately need.

Thank you again for your attention on this issue. C4IP would welcome the opportunity to further discuss this and related issues important to the U.S. economy.

Frank Cullen
Executive Director
Council for Innovation Promotion (C4IP)

[1] USPTO has also been updating the public on these various initiatives and engagement on its website at: USPTO - FDA Collaboration Initiatives | USPTO