Interagency Patent Coordination and Improvement Act of 2023
Section-by-Section
Prepared by Office of Sen. Durbin (D-IL)

Short Summary of Legislation: This legislation would establish a task force between the U.S. Patent and Trademark Office (PTO) and the Food and Drug Administration (FDA) to foster good governance and enhanced communication and coordination in implementing each agency's activities related to patents, while respecting their distinct purviews.

Background: Currently, there is very limited collaboration between PTO and FDA, despite both agencies playing a role related to patents and competition for pharmaceutical products. Given the shared interaction and overlapping equities between PTO and FDA, this legislation promotes efficiency and good governance by promoting communication between the two agencies on their processes. This would ensure PTO and FDA have greater visibility into the implications of their activities in the domains of the other agency and in context of broader industry trends, and allow for additional expertise to be made available in certain circumstances. Additionally, it would help prevent conflicts by establishing clearer rules of the road between PTO and FDA and help avoid patent litigation by providing greater clarity and information for all stakeholders. This could also serve to boost competition, including from lower-cost generic drugs, by ensuring quality and appropriate applicability of existing laws when evaluating patent decisions.

Section-by-Section of Legislation

Section 1: Short Title

Section 2: Findings

Section 3: Report by United States Patent and Trademark Office

This section establishes a reporting requirement for the PTO Director to submit a report within four years of enactment of this legislation to the Senate and House Judiciary Committees. The report will contain information on the Interagency Taskforce on Patents established by section 4 of this Act, including: a description of the frequency with which information is provided by the FDA to the PTO through the Task Force and how often it is used in patent examinations; which information is most useful to patent examiners; any recommendations to be made to the Task Force; and an identification of any other Federal agencies with which the PTO should explore opportunities for coordination.

Section 4: Interagency Task Force on Patents

Amends 35 U.S.C. 2(c) by adding at the end a new subparagraph, (6)(A) stating that the USPTO Director shall consult with the FDA Commissioner in exercising their powers and duties under section 2(c) relating to patents, and decisions and actions involving patents, for human drugs and biological products through the Interagency Task Force on Patents which is established at 35 U.S.C. 15.

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Adds 35 U.S.C. 15, establishing the Interagency Task Force on Patents. The Task Force will be made up of employees of the PTO and FDA, appointed by the Director and Commissioner, respectively. This Task Force will coordinate efforts between the PTO Director and FDA Commissioner regarding communication about, evaluation of, and effective implementation of the activities of the PTO and FDA with respect to patents, and decisions or actions involving patents, for human drugs and biological products. This includes:
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- Sharing information on general agency processes, standards, and methods;
- Sharing information on new technologies and scientific trends;
- Promoting confidential reciprocal access to information, if requested and only as needed, on key approval dates to assess prior art; ensure accurate representations by companies between the two agencies; ensuring accuracy of patent listings; and to furnish other appropriate information.

The task force will also establish appropriate protocols to safeguard confidentiality and prevent the inappropriate disclosure of information when sharing information between the PTO and FDA, including potential remedies for any potential injury suffered as a result of the sharing or disclosure of confidential information.