# United States Patent and Trademark Office

*Under Secretary of Commerce for Intellectual Property and*
*Director of the United States Patent and Trademark Office*


December 27, 2022

The Honorable Elizabeth Warren
United States Senate
Washington, D.C. 20510

The Honorable Pramila Jayapal
United States House of Representatives
Washington, D.C. 20515

Dear Senator Warren and Representative Jayapal:

Thank you for your letter of December 5, 2022, expressing concerns about drug pricing and the U.S. Patent and Trademark Office's (USPTO) policies and practices related to pharmaceutical patents.

Since your June 2021 letter on this important issue and the USPTO's August 2021 response, the USPTO has worked to ensure both that the United States' strong patent system continues to spur life-saving innovation, and that the intellectual property ecosystem continues to incentivize generic drug and biosimilar competition, as called for by the Drug Price Competition and Patent Term Restoration Act (Hatch-Waxman Act) of 1984 and the Biologics Price Competition and Innovation Act. This work includes ongoing collaboration with the Food and Drug Administration (FDA) and current and planned initiatives that seek to incentivize innovation and reduce potential uses of the system that stifle competition. As I stated in my July 6, 2022, letter to Robert Califf, Commissioner of Food and Drugs, "[t]hough patents play a critical role in incentivizing and protecting the investment essential for bringing life-saving and life-altering drugs to market, we must make sure our system as a whole does not unnecessarily delay getting generic, biosimilar, and more affordable versions of those drugs into the hands of Americans who need them."[1]

Robust and reliable patents are necessary for continuing to incentivize and protect the research and development that bring life-saving and life-changing medicines to market. As I said to Commissioner Califf:

> Going back to first principles, our patent system must work for the public good. We must not only incentivize and protect breakthrough innovation, we must also encourage inventors, companies, universities, and non-governmental organizations to collaborate and build on each other's ideas for the good of all. And, critically, we must bring innovation to impact for all Americans.

[1] Letter from USPTO Director Katherine Vidal to FDA Commissioner Robert Califf, July 6, 2022, at 1.

> In the pharmaceutical space, this means ensuring that our patent system promotes research and development and protects key innovation while not incentivizing, protecting, or permitting activity that will improperly or unnecessarily delay access to low-cost medicines.[2]

To that end, the USPTO is examining ways to improve procedures for obtaining a patent so that the USPTO issues robust and reliable patents across all technology areas. We are actively exploring further changes to examining time for specific applications and additional training for patent examiners, considering additional guidance for examiners for specific types of patent applications prior to issuance, and revisiting obviousness-type double patenting practice.[3]

As part of this process, the USPTO recently issued a request for comments (RFC) seeking public input on proposed initiatives directed at bolstering the robustness and reliability of patents and ensuring that the patent rights granted by the USPTO fulfill their intended purpose of furthering the common good, incentivizing innovation, and promoting economic prosperity without unduly delaying competition.[4] The RFC seeks comments on specific topics, such as prior art searching; support for patent claims; requests for continued examination; and restriction, divisional, rejoinder, and non-statutory double patenting practice. The RFC also requests comments on questions proposed by Senators Leahy, Blumenthal, Klobuchar, Cornyn, Collins, and Braun that cover topics similar to those set forth in your letter. The public comments are currently due no later than February 1, 2023, and are viewable at Regulations.gov. These public comments will play an important role in informing and guiding any improvements to the USPTO's procedures and the patent system as a whole.

In July, the USPTO also took steps to clarify the duty of disclosure and duty of reasonable inquiry through a Federal Register Notice.[5] As we explained in the notice, these duties are imposed to assist patent examiners and administrative patent judges in evaluating patentability effectively and efficiently. The duties help to promote robust and reliable patents, and help to drive competition and economic growth. The notice clarified the duties, including as to materials or statements material to patentability, or statements made to the USPTO that are inconsistent with statements submitted to the FDA and other governmental agencies. The USPTO continues to reinforce and amplify these duties through outreach to intellectual property bar associations and at speaking events.

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[2] *Id.*, at 3.

[3] A single product, particularly one as complex as a medicine or a cell phone, may contain several distinct inventions such that a single complex product can be covered by several patents directed to each distinct invention contained therein. That said, multiple patents directed to obvious variants of an invention could potentially deter competition. Even though our patent system allows the patenting of inventions that are obvious in view of each other with the filing of a terminal disclaimer, the sheer number of patents and claims may be prohibitively expensive to challenge. They can also impose a heavy burden on examiners, who are required to compare the claims in these multiple patents and pending applications to determine if the claims are patentably distinct from one another. With that in mind, we are revisiting how we can adapt processes within the USPTO to address these concerns.

[4] *See* Request for Comments on USPTO Initiatives To Ensure the Robustness and Reliability of Patent Rights, 87 FR 60130 (October 4, 2022); and the notice extending the comment period, Request for Comments on USPTO Initiatives To Ensure the Robustness and Reliability of Patent Rights, 87 FR 66282 (November 3, 2022).

[5] *See* Duties of Disclosure and Reasonable Inquiry During Examination, Reexamination, and Reissue, and for Proceedings Before the Patent Trial and Appeal Board, 87 FR 45764 (July 29, 2022).

An important part of the USPTO-FDA collaboration is the cross-training we have begun with our colleagues at the FDA. Earlier this fall, the USPTO hosted a hybrid event with the FDA at our Alexandria campus, where we held a productive discussion about information that is publicly available from the FDA that could be used by examiners as prior art during patent application examination. The USPTO and the FDA plan to hold similar cross-training events in 2023 as well.

In addition, our agencies will hold a joint public listening session[6] in January 2023 that will seek public input and comments on areas for USPTO-FDA collaboration and engagement, including many of the joint initiatives set forth in my response to Commissioner Califf. Topics on which the public is invited to speak include, but are not limited to:

- Patent examiner training on FDA resources for prior art searching;
- Mechanisms to assist patent examiners in determining whether patent applicants or patent owners have submitted inconsistent statements to the agencies;
- Opportunities and challenges related to the use of America Invents Act post grant proceedings to address the patentability of claims in pharmaceutical and biotechnological patents;
- Improvements in the information exchange between the agencies related to patent term extension applications;
- Improvements to the public accessibility of information on patent term extension applications and grants;
- Policy considerations and concerns related to carve-out labeling and patenting of risk evaluation and mitigation strategies; and
- Any other steps the agencies can take collaboratively to address concerns about the potential misuse of patents to improperly delay competition.

The USPTO is committed to issuing robust and reliable patents so that the patent system remains a key driver of economic growth, including by incentivizing the development of and access to medicines that can save millions of lives every year. The many ongoing initiatives set forth in this response are a priority for me. As these initiatives progress, I will provide updates to your offices. I also welcome the opportunity to further engage with each of you on these important issues and will provide additional information responsive to your questions as my USPTO colleagues and I continue this important work.

Sincerely,

Kathi Vidal

Kathi Vidal
Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office

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[6] *See* Joint USPTO-FDA Collaboration Initiatives; Notice of Public Listening Session and Request for Comments, 87 FR 67019 (November 7, 2022).