UNITED STATES PATENT AND TRADEMARK OFFICE

UNDER SECRETARY OF COMMERCE FOR INTELLECTUAL PROPERTY AND
DIRECTOR OF THE UNITED STATES PATENT AND TRADEMARK OFFICE

July 6, 2022

Robert M. Califf, M.D.
Commissioner of Food and Drugs
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Dr. Califf:

I am following up on the letter your colleague Dr. Janet Woodcock sent pursuant to President Biden's Executive Order on "Promoting Competition in the American Economy." As you know, in that Executive Order, President Biden expressed concern that "too often, patent and other laws have been misused to inhibit or delay—for years and even decades—competition from generic drugs and biosimilars, denying Americans access to lower-cost drugs." The order also provides, in relevant part, that the Secretary of Health and Human Services shall:

> to help ensure that the patent system, while incentivizing innovation, does not also unjustifiably delay generic drug and biosimilar competition beyond that reasonably contemplated by applicable law, not later than 45 days after the date of this order, through the Commissioner of Food and Drugs, write a letter to the Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office enumerating and describing any relevant concerns of the FDA.

I share the Administration's mission with regard to drug accessibility. Specifically, our laws, including our patent laws, were created to work for our country and for the benefit of our people. The patent system was developed to promote economic growth and a higher standard of living for all. The United States is a global leader in new drug development due to its strong patent system and the ecosystem envisioned by Congress with the Drug Price Competition and Patent Term Restoration Act (Hatch-Waxman Act) of 1984, and more recently the Biologics Price Competition and Innovation Act (BPCIA). Though 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.

I could not be more excited to work with you on this endeavor.

I look forward to setting up a meeting at your earliest convenience so we can start working together on our collective mission and further the Biden-Harris Administration's goal of facilitating access to affordable drugs. To support our discussion, I am attaching below the USPTO's current thoughts on what we can do as an agency, and in collaboration with the FDA, to make real progress. I look forward to discussing these ideas and any others you may have.

Sincerely,

Katherine Kelly Vidal

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

USPTO Initiatives Regarding Drug Pricing

The Administration believes in robust and reliable patents and that such patents are needed to incentivize and protect the immense research and development that is essential to bringing life-saving and life-changing medicines to market. 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.

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. Because this issue is so important to our country, the United States Patent and Trademark Office (USPTO) is prioritizing the following initiatives, most of which will strengthen our patent system for all technologies.

1. Enhance collaboration with other agencies on key technology areas, including pharmaceuticals and biologics. The USPTO will seek to create formal mechanisms to collaborate with other agencies such as the Food and Drug Administration (FDA).[1] Specifically, the USPTO will:

    a. Continue discussions with the FDA on this topic and the initiatives outlined here and work collaboratively on these and other initiatives.

    b. Explore joint USPTO-FDA public engagement through listening sessions, dissemination of a Request for Comments and other procedures for collecting broader stakeholder input.

    c. Provide examiners with training, in collaboration with the FDA, on publicly available FDA resources that can be utilized in prior art searches and on the state of the art in the pharmaceutical and biopharma areas and provide resources to the FDA to support its work on matters influenced by patent law and policy.

    d. Explore consistency in representations made to the USPTO and the FDA. The USPTO will work with the FDA to evaluate consistency in representations to the USPTO (made both during prosecution of patent applications and in America

[1] Although these initiatives focus mostly on collaboration with the FDA, the USPTO is interested in exploring further interagency communications.

Invents Act (AIA) and other post-issuance proceedings) and the FDA. The USPTO is also exploring initiatives to require patent applicants to provide relevant information to the USPTO that has been submitted to other agencies and to remind patent applicants of their disclosure obligations and the ramifications of failing to disclose required information at the USPTO. The USPTO will explore with the FDA whether other avenues exist to determine whether patent applicants have submitted inconsistent statements between the agencies.

e. Engage in greater FDA collaboration in AIA proceedings. In addition to improving the robustness and reliability of patents that are granted in the first place, the USPTO will work with the FDA on processes and procedures for (1) notifying the FDA of AIA proceeding filings on any Orange Book-listed patents and/or Purple Book-listed patents, and (2) potentially sharing more information between the agencies. The USPTO will also work with the FDA to assess why there have been so few filings of AIA proceedings on Orange Book-listed patents and biologic patents and why the number of AIA filings for pharmaceutical patents has generally declined.[2]

f. Revisit patent term extension practice, required under 35 U.S.C. § 156 due to the product being subject to an FDA regulatory review period. Though a recent report found that the USPTO accurately and fairly grants patent term extensions based on FDA regulatory review periods, the USPTO will collaborate with the FDA to determine if there are any areas for improvement through information sharing or otherwise. The USPTO also is exploring ways to facilitate public access to information on patent term extension applications and grants.

g. Work with the FDA to understand how else the agencies' authorities and responsibilities overlap, such as exploring the policies surrounding the use of "skinny labels," the connection between method of use patents and associated use codes, and the patenting of risk evaluation and mitigation strategies that the FDA requires for certain medications with serious safety concerns. Where the agencies' functions overlap, the USPTO will work with FDA to optimize information sharing and policy within our respective frameworks and legal restrictions.

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[2] Orange Book patent/biologic patent study update through June 2021, available at https://www.uspto.gov/sites/default/files/documents/PTABOBbiologicpatentstudy8.10.2021draftupdatedthruJune2021.pdf.

h. Remain open to discussing with the FDA, other agencies, the Administration, and stakeholders the FDA's concerns over practices referred to as "patent thickets," "evergreening," and "product hopping."

2. Improve procedures for obtaining a patent so that the USPTO issues robust and reliable patents. Specifically, the USPTO will:

   a. Introduce more examining time into the patent examination system. The USPTO recently made changes to examination time and is exploring further changes, particularly in cases with several continuations (large family cases) and cases with evidence submitted in support of patentability.

   b. Give patent examiners more training and resources. The USPTO has released a new search system for patent examiners to use in identifying relevant prior art to make patentability determinations. The new Patents End-to-End Search system includes significant enhancements, such as access to more than 76 million foreign documents with high-quality English translations and new, improved search capabilities. The USPTO is exploring additional technology and resources of prior art to improve patent examination. The USPTO also recently announced a collaboration with the American Intellectual Property Law Association and the Intellectual Property Owners Association to develop examiner training on enhancing the clarity of the prosecution record. The USPTO also is exploring additional training for examiners on new matter, assessing claim scope, and the use of functional claiming.

   c. Enhance communication between patent examiners and the Patent Trial and Appeal Board (PTAB), which hears challenges to patents once they have issued as well as appeals from rejections of pending patent applications during examination. The USPTO has put in place processes for the PTAB to share feedback as it relates to *ex parte* appeals, including sharing final decision tables with detailed information about the PTAB's ruling on each individual rejection and claim in an *ex parte* appeal and using surveys to facilitate information sharing between PTAB judges and the patent examination corps. Examiners are also notified when they have an application related to an AIA proceeding, so they can easily access prior art and relevant statements that may impact their examination in the application before them. In addition, examiners are now able to more quickly identify prior art relied upon and PTAB's rulings on each individual ground and claim in the post-grant proceeding via final written decision tables, which are now incorporated into all final written decisions. The USPTO is also

exploring how data collected from the decision tables in both *ex parte* appeal and AIA proceedings can be relied upon to identify trends, such as prior art trends in post-grant proceedings (e.g., commonly relied upon non-patent literature and foreign language patents) as well as opportunities to develop examiner training or guidance based on findings or lessons learned from surveys.

d. Consider enhancing the process for information disclosure statements. The USPTO will continue our efforts to explore changes to the procedures for identifying prior art on information disclosure forms to provide efficiencies for applicants and to allow examiners to more readily identify key prior art through the development of an automated tool for USPTO examiners that imports relevant prior art and other pertinent information into pending U.S. patent applications.

e. Consider applying greater scrutiny to continuation applications in large families and/or the use of declaratory evidence to overcome rejections. The USPTO is considering additional guidance for examiners and reviews by the Office of Patent Quality Assurance when continuation applications in large families are filed, or when applicants submit declaratory evidence to rebut an examiner's determination of unpatentability.

f. Revisit obviousness-type double patenting practice. Obviousness-type double patenting occurs when a patent owner tries to secure a patent for an obvious variation of the innovation covered by another of their own patents. In these instances, under current practices, a patent applicant is required to file a terminal disclaimer so that the later patent application on an obvious variant of an earlier-patented invention may not be used to extend the term of patent protection. Although a terminal disclaimer ensures that the later patent will remain commonly owned with and have the same patent term as the earlier patent, multiple patents directed to obvious variants of an invention could potentially deter competition if the number of patents is prohibitively expensive to challenge in post-grant proceedings before PTAB and in district court. And later issued patents to obvious variants may delay resolution of ongoing district court litigation thereby potentially delaying generic and biosimilar entry into the market. The USPTO will explore whether any changes need to be made to the patent system regarding obviousness-type double patenting.

g. Revisit procedures for third-party input. The USPTO is considering revising its procedures for allowing third-party input during prosecution. The USPTO currently has a procedure to allow third-party submissions of prior art in

applications under examination. This procedure is not widely used. The USPTO will seek public input on whether aspects of the current procedure could be changed to make it more useful.

h. Conduct a comparative analysis of the examination and issuance of pharmaceutical and biological patents in the U.S. versus in other countries and any underlying lessons learned from the same. The USPTO plans to conduct a comparative analysis to evaluate whether any additional initiatives or changes will strengthen our intellectual property system. Director Vidal and the USPTO team will also explore this topic in bilateral and multilateral discussions with other countries.

i. The USPTO will provide technical input on proposed legislative efforts.

3. Improve the process for challenging issued patents before the PTAB (AIA proceedings)

   a. Consider additional scrutiny in specific cases. The USPTO is considering whether to apply additional scrutiny to continuation patents in large families, or when applicants have submitted declaratory evidence to rebut an examiner's determination of unpatentability, when deciding whether to institute AIA petitions.

   b. Consider procedures for third-party input. The USPTO is considering whether to allow third-party input in AIA proceedings and what that input could look like.

   c. Consider whether the USPTO should explore weighing the utility and integrity of the patent system in certain circumstances when deciding whether to institute AIA petitions.

4. Improve public participation

   a. Hear more diverse viewpoints, including by adding public interest representatives to the Patent Public Advisory Committee (PPAC). The USPTO has already started the process of incorporating more diverse views when nominating PPAC members and expanding the breadth of the PPAC in the future.

   b. Improve coordination with stakeholders and public interest groups. The USPTO plans to enhance its coordination with stakeholders and existing public interest groups. In addition to Director Vidal holding a series of listening sessions with stakeholders within her first 100 days (as outlined in her Day One public message

to stakeholders), the USPTO will look for ways to continually engage a broad range of stakeholders, including industry and public interest groups.

5. Consider and evaluate new proposals for incentivizing and protecting the investment essential for bringing life-saving and life-altering drugs to market while minimizing any unnecessary delay getting generic, biosimilar, and more affordable versions of those drugs into the hands of Americans who need them.