

ADVANCES IN DRUG DEVELOPMENT

Current Developments in Oncology Drug Research

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Coordination Between the FDA and the US Patent and Trademark Office



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H&O What is the Executive Order on Promoting Competition in the American Economy and how does it relate to coordination between the FDA and the USPTO?

KV The Executive Order on Promoting Competition in the American Economy (EO) set out the Biden Administration's policy to promote competition and innovation and includes goals of lowering prescription drug prices and increasing competition in the pharmaceutical marketplace.¹ In support of these goals, section § 5(p)(vi) of

the EO states that the Secretary of Health and Human Services shall "...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 [USPTO] enumerating and describing any relevant concerns of the FDA."

In response to the EO, the FDA sent a letter to the USPTO in September 2021, offering to collaborate with the USPTO on ways the 2 agencies can work together to lower drug prices for Americans.² In our reply, the USPTO outlined specific initiatives to ensure that our system does not unnecessarily delay getting generic and more affordable versions of drugs into the hands of Americans who need them. These initiatives outline the scope of the collaboration between the USPTO and the FDA.³

H&O How does the collaboration between the FDA and the USPTO contribute to protecting innovation, promoting marketplace competition, and lowering barriers to patients access to needed medications in the pharmaceutical industry?

KV The USPTO-FDA collaboration is focused on 4 main initiatives: (1) enhancing interagency collaboration; (2) ensuring the robustness and reliability of patent rights; (3) improving the process for challenging issued patents; and (4) improving public participation in the patent system.

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All of these initiatives are aimed at ensuring that the patent and regulatory systems work for the public good. At the USPTO, that means we are focused on ensuring that the patents we issue are robust and reliable, and protect only subject matter that meets the standards for patentability mandated by Congress. This means ensuring that patent examiners have access to all the information necessary to assess patentability, reassess our internal procedures to determine if improvements are needed, and engage in dialogue with members of the public holding diverse viewpoints to ensure that the patent system works for the good of all.

H&O What specific initiatives or actions have the FDA and USPTO taken to enhance coordination and promote US innovation?

KV Within these 4 main initiatives outlined in USPTO's letter, the USPTO and the FDA have conducted cross-training sessions to provide each agency with a deeper understanding of the policies and processes of the other.⁴ These sessions have helped each agency assess areas of overlap between our workstreams and explore ways to improve our respective internal processes and procedures.

In addition to sharing information with each other, the agencies jointly held a listening session in early 2023 to hear from the public on many areas, including patenting practices in the pharmaceutical sector.⁵ The speakers presented a wide array of perspectives, with subject matter experts and policymakers from both the USPTO and the FDA present. The agencies are jointly discussing the public comments and assessing areas of potential further collaboration.

The USPTO also is exploring changes to certain patent examination procedures to ensure robust and reliable patent rights.⁶ We published a request for public comment on several proposals. The agency is considering the comments we received and assessing the next steps for proposed rulemaking and fee setting.

With respect to processes for challenging issued patents, the USPTO published an Advance Notice of Proposed Rulemaking on a variety of potential changes to post-grant proceedings before the Patent Trial and Appeal Board.⁷ This notice has allowed the USPTO to explore many possible improvements and changes to the post-grant challenge process. Based on public input, the office is now preparing a Notice of Proposed Rulemaking on some of the proposals.

The USPTO has also worked to ensure a robust and reliable patent system that incentivizes solutions to today's global problems. Those efforts include supporting the White House's Cancer Moonshot initiative with our Cancer Moonshot Expedited Examination Pilot Program.

The Program expedites examination for a broad scope of technologies to prevent cancer and cancer mortality.

Finally, to increase public participation in the patent system, the USPTO enhanced accessibility to information by redesigning its patent term extension web page to make it easier to track patent term extension applications.⁸ We are working on further initiatives to increase public engagement that we plan to announce soon.

H&O How does the FDA ensure that its expertise on drug safety and efficacy is effectively communicated to the USPTO during the patent examination process, and what expertise does the FDA have that is not present in the USPTO?

KV Examination of patent applications in any discipline involves ensuring that the application, including the claims, complies with the patent statutes, regulations, other office guidance, and relevant case law. At a high level, a claimed invention, as presented in a patent application, must have utility and be eligible for patenting (35 USC § 101), must be new and non-obvious over the prior art (35 USC §§ 102 and 103), and must be adequately described and disclosed so that another person skilled in that art can make and use the claimed invention (35 USC § 112). These conditions of patentability are not limited to pharmaceutical and biotechnology patents and apply to all technology areas.

During the patent examination process, patent examiners make determinations as to whether the claimed invention presented in a patent application complies with the statutory provisions enumerated earlier. Part of that process involves conducting a prior art search, comparing relevant prior art to the claimed invention, and making determinations on the novelty and obviousness of the claimed invention. Examiners, then, upon analyzing the prior art and comparing it with the claimed invention, either reject the claimed invention if it is known or obvious in view of the prior art, or grant a patent if the claimed invention is new and nonobvious in view of the prior art (and meets the other patenting requirements discussed above).

Patent examiners review pharmaceutical inventions against these patentability standards and do not consider the same safety and efficacy issues that the FDA takes into account when deciding whether to approve a drug for human use.

USPTO patent examiners stay up-to-date on the latest technology through an established patent examiner technical training program. In this program, representatives from industry provide training on the latest technological developments in their fields. Through our cross-training efforts with the FDA, the agencies are exploring where

our agencies' work is complementary and are identifying topics relevant to patent examination that may be useful to include in cross-training.

H&O Is there any additional information or insights you would like to share?

KV The USPTO remains committed to supporting the goals of the President's EO and continues to work, in collaboration with the FDA, on the initiatives outlined above. We anticipate announcing further developments in the coming fiscal year.

Disclosures

Dr Vidal has no disclosures.

References

1. White House. Executive order on promoting competition in the American economy. <https://www.whitehouse.gov/briefing-room/presidential-actions/2021/07/09/executive-order-on-promoting-competition-in-the-american-economy/>. Published July 9, 2021. Accessed January 3, 2024.
2. U.S. Food & Drug Administration. Letter from Janet Woodcock, MD to Andrew Hirshfeld. <https://www.uspto.gov/sites/default/files/documents/EO14036-FDALettertoPTO.pdf>. Published September 10, 2021. Accessed January 3, 2024.
3. United States Patent and Trademark Office. Letter from Katherine K. Vidal to Robert M. Califf, MD. <https://www.uspto.gov/sites/default/files/documents/PTO-FDA-nextsteps-7-6-2022.pdf>. Published July 6, 2022. Accessed January 3, 2024.
4. United States Patent and Trademark Office. USPTO-FDA joint engagements. <https://www.uspto.gov/initiatives/uspto-fda-collaboration/engagements>. Accessed January 3, 2024.
5. United States Patent and Trademark Office. Joint USPTO-FDA public listening session on collaboration initiatives. <https://www.uspto.gov/about-us/events/joint-uspto-fda-public-listening-session-collaboration-initiatives>. Accessed January 3, 2024.
6. FederalRegister.gov. Request for comments on USPTO initiatives to ensure the robustness and reliability of patent rights. <https://www.federalregister.gov/documents/2022/10/04/2022-21481/request-for-comments-on-uspto-initiatives-to-ensure-the-robustness-and-reliability-of-patent-rights>. Published October 4, 2022. Accessed January 3, 2024.
7. United States Patent and Trademark Office. USPTO announces advance notice of proposed rulemaking for potential PTAB reforms [press release]. <https://www.uspto.gov/about-us/news-updates/uspto-announces-advance-notice-proposed-rulemaking-potential-ptab-reforms>. Published April 20, 2023. Accessed January 3, 2024.
8. United States Patent and Trademark Office. Applications for patent term extension and patent terms extended under 35 U.S.C. § 156. <https://www.uspto.gov/patents/laws/patent-term-extension/patent-terms-extended-under-35-usc-156>. Accessed January 3, 2024.