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USPTO-FDA Collaboration

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Patent Public Advisory Committee meeting

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Background

President Biden stated 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.”

Executive Order (EO) directed 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 enumerating and describing any relevant concerns of the FDA.

Executive Order on “Promoting Competition in the American Economy”

FDA Letter

In response to the EO, FDA sent a letter to USPTO:

- Recognizing that "patents are critical to fostering innovation"
- Noting that the impact of certain pharmaceutical company patenting practices "has attracted attention within the debate over drug pricing"
- Stating that the FDA is "actively evaluating the impact of pharmaceutical patents" on access to drug products approved under abbreviated pathways
- Inviting the USPTO "to collaboratively engage" with the FDA in activities that "can advance competition and access in the marketplace"

FDA U.S. FOOD & DRUG ADMINISTRATION

USPTO Response

In response to FDA, USPTO outlined new initiatives to enhance patent quality:

- Enhancing collaboration with other agencies, such as the FDA, on key technology areas, including pharmaceuticals and biologics
- Improving procedures for obtaining a patent to ensure that the USPTO issues robust and reliable patents
- Improving the process for challenging issued patents before the Patent Trial and Appeal Board (PTAB)
- Improving public participation in the patent system
- Considering new proposals for incentivizing and protecting innovation while minimizing unnecessary delays in getting more affordable drugs to market

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Current efforts

Visit: www.uspto.gov/initiatives/fda-collaboration

Current notices, blogs, and news

- Federal Register notice on duties of disclosure and reasonable inquiry
- Blogs on collaboration initiatives and duty of disclosure notice
- New webpage to enhance accessibility to patent term extension (PTE) information

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See our Federal Register Notices and other news concerning USPTO-FDA collaboration initiatives.

Federal Register Notices (FRNs)

- FRN - Duties of Disclosure and Reasonable Inquiry (read pdf version) (July 29, 2022)

Agency blog posts

- The Biden Administration is acting to promote competition and lower drug prices for all Americans (July 6, 2022)
- Duty of disclosure and duty of reasonable inquiry promote robust and reliable patents, drive competition and economic growth, and bring life-saving drugs to the American people (July 28, 2022)

Other news

- New public webpage to enhance accessibility to patent term extension information (September 1, 2022)

Engagement with FDA

- September 16 cross-training event, hosted by USPTO, to share information with FDA on examiner searching and examination and use of FDA prior art in PTAB proceedings
- Future cross-training events being planned.

Engagement with public

- Requests for Comment (RFCs) on initiatives outlined in July 6 letter are forthcoming.
- Public listening session being planned for late fall; more details will be posted on www.uspto.gov/initiatives/uspto-fda-collaboration/engagements

In the meantime, please send public feedback or inquiries to USPTO-FDACollaboration@uspto.gov

Thank you!

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