
UNITED STATES
PATENT AND TRADEMARK OFFICE
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International Generic and Biosimilar Medicines Association 25th Annual Conference

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February 16, 2023

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Background

July 9, 2021 Executive Order - "Promoting Competition in the American Economy"

The Executive Order directed that the Secretary of Health and Human Services:

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.

Letter Exchange

FDA letter to USPTO:

"The Agency recognizes that patents are critical to fostering innovation, including innovation in the pharmaceutical industry. Nonetheless, the impact of certain pharmaceutical company patenting practices on the pharmaceutical marketplace has attracted attention within the debate over drug pricing. … FDA is actively evaluating the impact of pharmaceutical patents in certain areas relevant to FDA regulation of drug products, with a focus on facilitating timely access to drug products approved under our abbreviated pathways. … We invite USPTO to collaboratively engage with us in these efforts and in any complementary activities under your purview that can advance competition and access in the marketplace."

Letter Exchange

USPTO response to FDA:

"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."

Letter Exchange

USPTO's response outlined areas for collaboration:

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

Request for Comments

Seeking public input on improving procedures for obtaining a patent to ensure that the USPTO issues **robust and reliable patents**, including:

- Sources of prior art
- Patent claim support and continuation practice
- Request for continuing examination (RCE) practice
- Restriction, divisional, rejoinder, and non-statutory double patenting practice

Request for Comments

Seeking public input on **USPTO-FDA Collaboration**, including:

- Publicly available FDA resources that should be searched by patent examiners
- Mechanisms to identify inconsistent statements to USPTO and FDA
- Opportunities and challenges to using PTAB proceedings to address patentability of claims asserted in Hatch-Waxman and BPCIA disputes
- Enhancement to information exchange related to requests for patent term extension
- Additional transparency on patent term extension applications
- Policy considerations on method of use patents and FDA use codes
- Policy considerations on patenting of REMS
- Other steps to address concerns about potential misuse of patents to improperly delay competition

Joint Public Listening Session

- Held January 19, 2023
- 20 speakers:
  - Patient advocates (Generation Patient, T1International, Patients for Affordable Drugs)
  - Non-profits (I-MAK, U.S. PIRG)
  - Industry and legal associations (Biosimilars Forum, PhRMA, BIO, AIPLA)
  - Industry (Novartis, Fresenius Kabi)
  - Academics

USPTO – FDA Cross Training

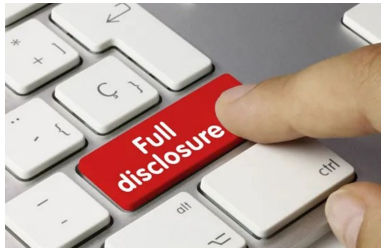
USPTO-led training held on September 16, 2022

- Covered examiner searching and use of FDA documents in PTAB proceedings

FDA-led training happening this Spring

- Will cover FDA's publicly accessible databases and other FDA policies and practices.

Federal Register Notice on Duty of Disclosure and Duty of Reasonable Inquiry



- Published July 29, 2022
- To clarify existing duties to disclose documents material to patentability and statements made to other agencies that are inconsistent with positions taken before the USPTO
- Virtual panel discussion to address stakeholder questions scheduled for February 23, 2023

Publication of PTE Application and Grant Information

- Responsive to stakeholder input
- Increased transparency on PTE application filings
- Provided up-to-date information on PTE grants

Further enhancements coming soon

https://www.uspto.gov/patents/laws/patent-term-extension/patent-terms-extended-under-35-usc-156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