When Agencies Collide: A Discussion of How Coordination Between the FDA and USPTO Could Impact Patent Rights and Policy

May 10, 2023

ACC Association of Corporate Counsel
SAN FRANCISCO BAY AREA

Your Presenters

Arpita Bhattacharyya, Ph.D., Partner
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Denali Therapeutics

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Gilead Sciences

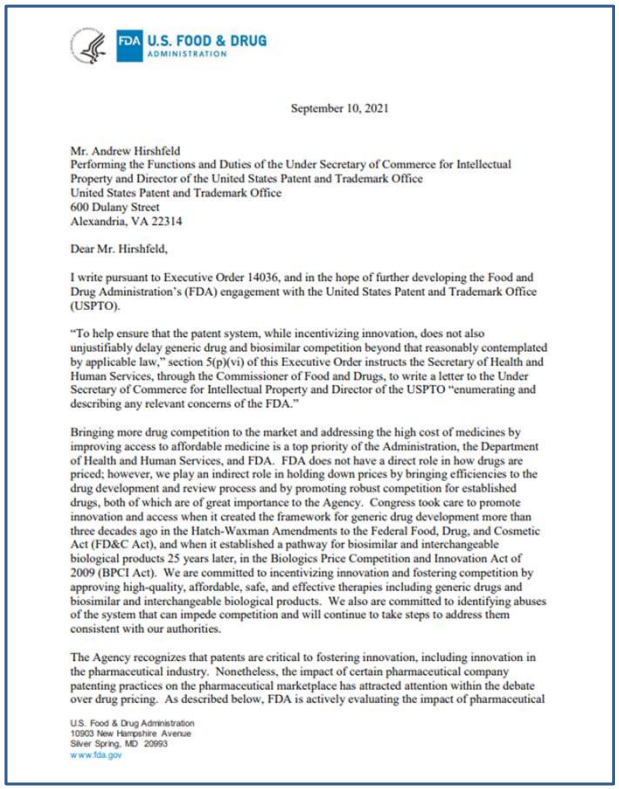
Jeffrey Smyth, Partner
Finnegan

Background of FDA-USPTO Collaboration

"Americans are paying too much for prescription drugs and healthcare services — far more than the prices paid in other countries. Hospital consolidation has left many areas, particularly rural communities, with inadequate or more expensive healthcare options. And 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."

https://www.whitehouse.gov/briefing-room/presidential-actions/2021/07/09/executive-order-on-promoting-competition-in-the-american-economy/

Background of FDA-USPTO Collaboration



U.S. FOOD & DRUG ADMINISTRATION

September 10, 2021

Mr. Andrew Hirshfeld
Performing the Functions and Duties of the Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office
United States Patent and Trademark Office
600 Dulany Street
Alexandria, VA 22314

Dear Mr. Hirshfeld,

I write pursuant to Executive Order 14036, and in the hope of further developing the Food and Drug Administration's (FDA) engagement with the United States Patent and Trademark Office (USPTO).

"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," section 5(p)(vi) of this Executive Order instructs the Secretary of Health and Human Services, through the Commissioner of Food and Drugs, to write a letter to the Under Secretary of Commerce for Intellectual Property and Director of the USPTO "enumerating and describing any relevant concerns of the FDA."

Bringing more drug competition to the market and addressing the high cost of medicines by improving access to affordable medicine is a top priority of the Administration, the Department of Health and Human Services, and FDA. FDA does not have a direct role in how drugs are priced; however, we play an indirect role in holding down prices by bringing efficiencies to the drug development and review process and by promoting robust competition for established drugs, both of which are of great importance to the Agency. Congress took care to promote innovation and access when it created the framework for generic drug development more than three decades ago in the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act (FD&C Act), and when it established a pathway for biosimilar and interchangeable biological products 25 years later, in the Biologics Price Competition and Innovation Act of 2009 (BPCI Act). We are committed to incentivizing innovation and fostering competition by approving high-quality, affordable, safe, and effective therapies including generic drugs and biosimilar and interchangeable biological products. We also are committed to identifying abuses of the system that can impede competition and will continue to take steps to address them consistent with our authorities.

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. As described below, FDA is actively evaluating the impact of pharmaceutical

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

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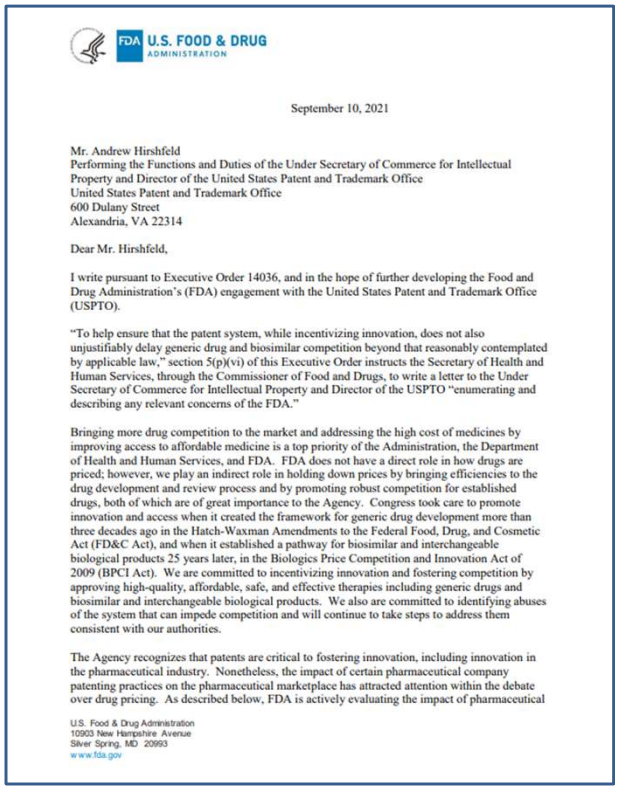
. . .

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."

https://www.uspto.gov/sites/default/files/documents/EO14036-FDALettertoPTO.pdf

Background of FDA-USPTO Collaboration



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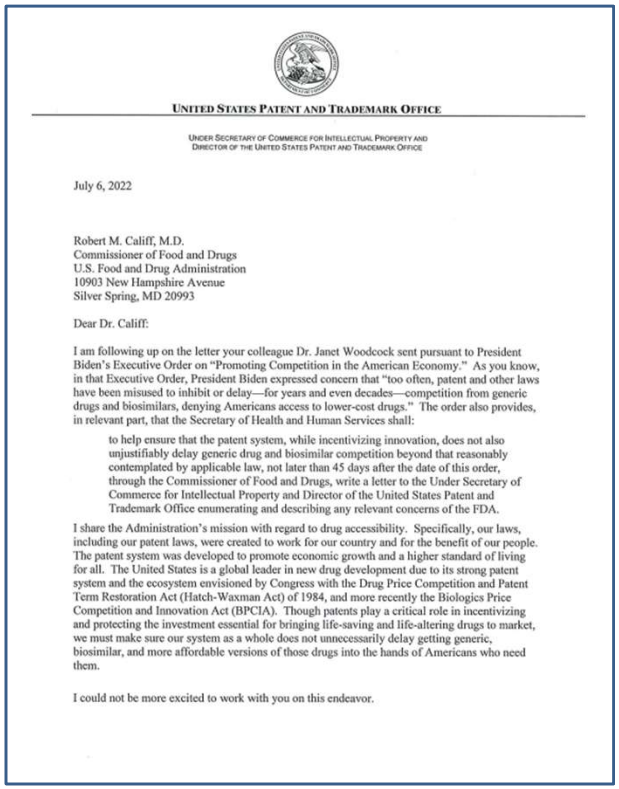
"We invite USPTO to collaboratively engage with us in these efforts and in any complementary activities under your purview that can advance competition and access in the marketplace."

https://www.uspto.gov/sites/default/files/documents/EO14036-FDALettertoPTO.pdf

Background of FDA-USPTO Collaboration



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.

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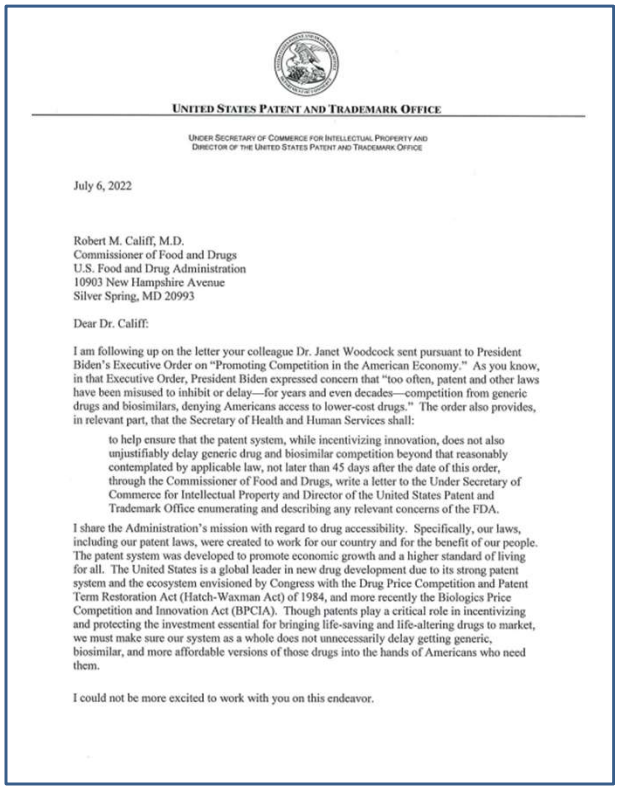
"I'm attaching below the USPTO's current thoughts on what we can do as an agency, and in collaboration with the FDA, to make real progress."

https://www.uspto.gov/sites/default/files/documents/PTO-FDA-nextsteps-7-6-2022.pdf

USPTO Initiatives Resulting From Collaboration



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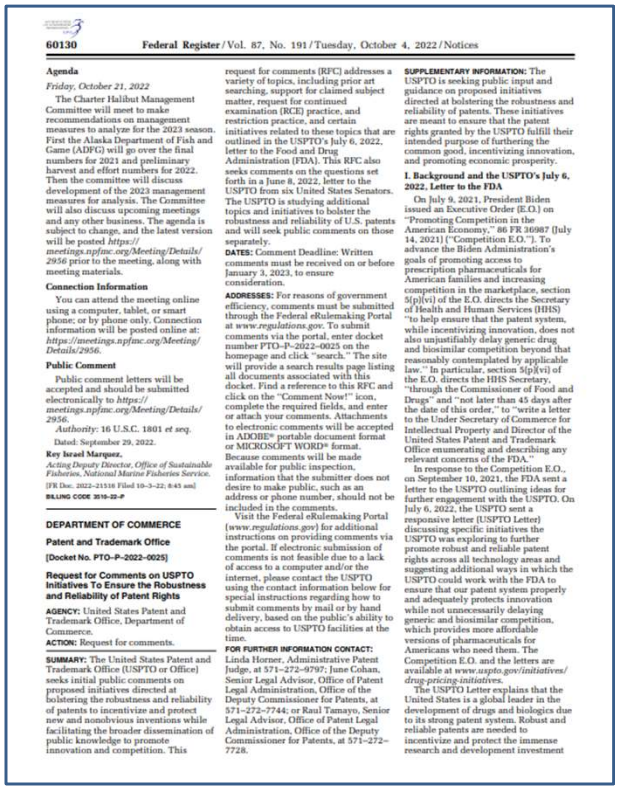
USPTO Initiatives Outlined

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 (America Invents Act 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

https://www.uspto.gov/sites/default/files/documents/EO14036-FDALettertoPTO.pdf

USPTO Initiatives Resulting From Collaboration



60130 Federal Register / Vol. 87, No. 191 / Tuesday, October 4, 2022 / Notices

Agenda

Friday, October 21, 2022

The Charter Halibut Management Committee will meet to make recommendations on management measures to analyze for the 2023 season. First the Alaska Department of Fish and Game (ADFG) will go over the final numbers for 2021 and preliminary harvest and effort numbers for 2022. Then the committee will discuss development of the 2023 management measures for analysis. The Committee will also discuss upcoming meetings and any other business. The agenda is subject to change, and the latest version will be posted *https://meetings.npfmc.org/Meeting/Details/2956* prior to the meeting, along with meeting materials.

Connection Information

You can attend the meeting online using a computer, tablet, or smart phone; or by phone only. Connection information will be posted online at: *https://meetings.npfmc.org/Meeting/Details/2956.*

Public Comment

Public comment letters will be accepted and should be submitted electronically to *https://meetings.npfmc.org/Meeting/Details/2956.*

Authority: 16 U.S.C. 1801 *et seq.*

Dated: September 29, 2022.

Key Israel Marquez,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2022–21516 Filed 10–3–22; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

Patent and Trademark Office

[Docket No. PTO–P–2022–0025]

Request for Comments on USPTO Initiatives To Ensure the Robustness and Reliability of Patent Rights

AGENCY: United States Patent and Trademark Office, Department of Commerce.

ACTION: Request for comments.

SUMMARY: The United States Patent and Trademark Office (USPTO or Office) seeks initial public comments on proposed initiatives directed at bolstering the robustness and reliability of patents to incentivize and protect new and nonobvious inventions while facilitating the broader dissemination of public knowledge to promote innovation and competition. This request for comments (RFC) addresses a variety of topics, including prior art searching, support for claimed subject matter, request for continued examination (RCE) practice, and certain initiatives related to these topics that are outlined in the USPTO's July 6, 2022, letter to the Food and Drug Administration (FDA). This RFC also seeks comments on the questions set forth in a June 8, 2022, letter to the USPTO from six United States Senators. The USPTO is studying additional topics and initiatives to bolster the robustness and reliability of U.S. patents and will seek public comments on those separately.

DATES: Comment Deadline: Written comments must be received on or before January 3, 2023, to ensure consideration.

ADDRESSES: For reasons of government efficiency, comments must be submitted through the Federal eRulemaking Portal at *www.regulations.gov.* To submit comments via the portal, enter docket number PTO–P–2022–0025 on the homepage and click "search." The site will provide a search results page listing all documents associated with this docket. Find a reference to this RFC and click on the "Comment Now!" icon, complete the required fields, and enter or attach your comments. Attachments to electronic comments will be accepted in ADOBE® portable document format or MICROSOFT WORD® format. Because comments will be made available for public inspection, information that the submitter does not desire to make public, such as an address or phone number, should not be included in the comments.

Visit the Federal eRulemaking Portal (*www.regulations.gov*) for additional instructions on providing comments via the portal. If electronic submission of comments is not feasible due to a lack of access to a computer and/or the internet, please contact the USPTO using the contact information below for special instructions regarding how to submit comments by mail or by hand delivery, based on the public's ability to obtain access to USPTO facilities at the time.

FOR FURTHER INFORMATION CONTACT: Linda Horner, Administrative Patent Judge, at 571–272–9797; June Cohan, Senior Legal Advisor, Office of Patent Legal Administration, Office of the Deputy Commissioner for Patents, at 571–272–7744; or Raul Tamayo, Senior Legal Advisor, Office of Patent Legal Administration, Office of the Deputy Commissioner for Patents, at 571–272–7728.

SUPPLEMENTARY INFORMATION: The USPTO is seeking public input and guidance on proposed initiatives directed at bolstering the robustness and reliability of patents. These initiatives are meant to ensure that the patent rights granted by the USPTO fulfill their intended purpose of furthering the common good, incentivizing innovation, and promoting economic prosperity.

I. Background and the USPTO's July 6, 2022, Letter to the FDA

On July 9, 2021, President Biden issued an Executive Order (E.O.) on "Promoting Competition in the American Economy," 86 FR 36987 (July 14, 2021) ("Competition E.O."). To advance the Biden Administration's goals of promoting access to prescription pharmaceuticals for American families and increasing competition in the marketplace, section 5(p)(vi) of the E.O. directs the Secretary of Health and Human Services (HHS) "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." In particular, section 5(p)(vi) of the E.O. directs the HHS Secretary, "through the Commissioner of Food and Drugs" and "not later than 45 days after the date of this order," to "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."

In response to the Competition E.O., on September 10, 2021, the FDA sent a letter to the USPTO outlining ideas for further engagement with the USPTO. On July 6, 2022, the USPTO sent a responsive letter (USPTO Letter) discussing specific initiatives the USPTO was exploring to further promote robust and reliable patent rights across all technology areas and suggesting additional ways in which the USPTO could work with the FDA to ensure that our patent system properly and adequately protects innovation while not unnecessarily delaying generic and biosimilar competition, which provides more affordable versions of pharmaceuticals for Americans who need them. The Competition E.O. and the letters are available at *www.uspto.gov/initiatives/drug-pricing-initiatives.*

The USPTO Letter explains that the United States is a global leader in the development of drugs and biologics due to its strong patent system. Robust and reliable patents are needed to incentivize and protect the immense research and development investment

Request for Comments on USPTO Initiatives To Ensure the Robustness and Reliability of Patent Rights

- Covered four specific topics:
  - (1) Prior Art Searching
  - (2) Support for Patent Claims
  - (3) RCE Practice
  - (4) Restriction, Divisional, Rejoinder, and Non-Statutory Double Patenting Practice
- Included 11 questions for public comment concerning various potential changes to USPTO practice
- USPTO also conducted a public listening session in January

https://www.uspto.gov/sites/default/files/documents/rfc_robust_and_reliable_patents.pdf

https://www.uspto.gov/about-us/events/joint-uspto-fda-public-listening-session-collaboration-initiatives

Audience Poll

Which of the potential changes resulting from the FDA-USPTO collaboration will have the largest impact:

1. Increased information exchange between the two agencies implicating the duties of disclosure and reasonable inquiry
2. New requirements for RCE practice, including new processes triggered once numbers of RCEs reaches certain threshold
3. New requirements for continuation practice, including heightened examination requirements
4. Modifications to non-statutory obviousness type double patenting practice that limit the use of terminal disclaimers
5. Not sure/None of these will have a significant impact

Panel Discussion

Audience Poll — Any change?

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5. Not sure/None of these will have a significant impact

Our Disclaimer

These materials have been prepared solely for educational and informational purposes to contribute to the understanding of U.S. intellectual property law. These materials do not constitute legal advice and are not intended to suggest or establish any form of attorney-client relationship with the authors or Finnegan, Henderson, Farabow, Garrett & Dunner, LLP (including Finnegan Europe LLP, and Fei Han Foreign Legal Affairs Law Firm) ("Finnegan"). Rather, these materials reflect only the personal opinions of the authors, and those views are not necessarily appropriate for every situation they refer to or describe. These materials do not reflect the opinions or views of any of the authors' clients or law firms (including Finnegan) or the opinions or views of any other individual. Specifically, neither Finnegan nor the authors may be bound either philosophically or as representatives of their various present and future clients to the opinions expressed in these materials. While every attempt was made to ensure that these materials are accurate, errors or omissions may be contained therein, for which any liability is disclaimed. All references in this disclaimer to 'authors' refer to Finnegan (including Finnegan personnel) and any other authors, presenters, or law firms contributing to these materials.