United States Senate

WASHINGTON, DC 20510

May 25, 2022

Kathi Vidal
Director
U.S. Patent and Trademark Office
600 Dulany Street
Alexandra, VA 22314

Dr. Robert M. Califf
Administrator
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20903

Dear Ms. Vidal and Dr. Califf,

The lack of coordination between the Patent and Trademark Office (PTO) and Food and Drug Administration (FDA) has allowed the pharmaceutical industry to obtain patents of questionable validity. Through these patents, drug manufacturers are able to delay the entry of generic drugs and extend monopoly prices. We request information on the extent to which the PTO seeks, obtains, and considers FDA information when reviewing pharmaceutical-related patent applications.

Drug manufacturers are increasingly relying on patent thickets—dense webs of overlapping patents protecting a single drug—to evade competition. Between 2005 and 2015, 78% of drugs associated with new patents were not new drugs, but existing ones, and the number of drugs with three or more patents added to them in one year doubled.[1] These thickets can preserve a drug company's monopoly and block the launch of generic drugs for years or even decades after the expiration of the drug's original patent. In the intervening period, patients are deprived of significant savings: drug prices drop by as much as 20% when the first generic enters the market and as much as 85% when multiple generics enter the market.[2]

Lack of coordination between the PTO and the FDA may help these patent thickets grow by enabling manufacturers to obtain patents that do not meet all of the Patent Act's requirements.[3] For example, under the Act, a manufacturer cannot obtain a patent on a manufacturing process it used more than a year before submitting the application.[4] However, the PTO has granted these patents to drug manufacturers that disclosed the manufacturing process to the FDA more than a year before submitting the patent application. In other instances, statements made by manufacturers to the FDA (e.g., a product is the same as another one already on the market) contradict statements they made to the PTO.[5] This suggests the PTO examiners were unaware of the applicants' disclosures to the FDA, and puts into question the validity of these patents.

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[1] Robin Feldman, "May Your Drug Price be Evergreen," *Journal of Law and the Biosciences* 5, no. 3 (December 2018): 590–647. https://doi.org/10.1093/jlb/lsy022
[2] Ibid.
[3] Arti K. Rai, and W. Nicholson Price II, "An Administrative Fix for Manufacturing Process Patent Thickets," *Nature Biotechnology* 39 (January 2021): 20-22. https://www.nature.com/articles/s41587-020-00780-9
[4] Ibid.
[5] Senator Patrick Leahy and Senator Thom Tillis to Mr. Andrew Hirshfeld, September 9, 2021.

Fortunately, the FDA and the PTO are already able to coordinate with one another. Under section 372(b) of the Federal Food, Drug, and Cosmetic Act, the FDA is authorized to share information with the PTO.[6] However, the lines of communication between the agencies appear not to be working. With better inter-agency coordination, many of these patent applications would have likely been denied. We therefore request that you provide answers to the following questions by June 24, 2022:

1. How does the PTO determine whether an application is connected to pharmaceutical product(s) (small molecule drugs or biologics)?

2. In the past five years, how many patent applications connected to pharmaceutical products did the PTO review?

3. Did the PTO request information from the FDA during the patent application review of the cases in question 2? If so,

    a. Did the FDA provide the PTO with information?

    b. Was the FDA information adequate to guide the PTO's analysis?

4. Do the PTO and the FDA have a process to collaborate when the PTO reviews pharmaceutical-related patent applications?

    a. If not, when will the agencies establish a process?

    b. If so, what actions are the agencies taking to improve it, and what is the timeline for implementing these improvements?

Thank you for your attention. We look forward to working with you to improve communication between the PTO and the FDA in order to ensure appropriate oversight of pharmaceutical patent applications.

Maggie Hassan

Margaret Wood Hassan
United States Senator

Bill Cassidy, M.D.

Bill Cassidy, M.D.
United States Senator

[6] *See also Public Health Service Act*, U.S. Code 42, § 262(j).