Congress of the United States

Washington, DC 20515

December 5, 2022

Ms. Kathi Vidal
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office
600 Dulany Street
Alexandria, VA 22314

Dear Director Vidal,

We are writing to follow up on our June 2021 correspondence with the U.S. Patent and Trademark Office (USPTO or the Office) about its efforts to hold pharmaceutical companies accountable for anti-competitive business practices, and about USPTO's July 2022 response to the U.S. Food and Drug Administration (FDA) regarding its actions to tackle the high cost of prescription drugs in the United States.[1]

On June 30, 2021, we wrote to the USPTO to bring attention to the persistent practices that pharmaceutical companies have engaged in that have made life-saving medications inaccessible and unaffordable to millions of Americans nationwide.[2] Our letter described how pharmaceutical companies use anti-competitive tactics such as patent evergreening, patent thickets, and product hopping to abuse our patent system and unfairly prolong government-granted monopoly rights for some drugs.[3] In addition to our request for relevant patent data, we asked the USPTO to (1) conduct a systemic review of its patent quality guidance; (2) more closely scrutinize pharmaceutical companies' requests for patent term extensions; (3) allow examiners more time to complete reviews of patent applications; and (4) reexamine the Office's fee and bonus structures.[4]

On August 13, 2021, we received the USPTO's response.[5] Although the response addressed some of our questions, the Office overlooked critical aspects of our letter. For example, instead of recognizing the harms of evergreening, patent thickets or product hopping, the USPTO referenced what it believes is a "widespread misconception that continuation patents (i.e., secondary and tertiary patents) can extend the 20-year term of a parent patent (i.e., the original patent)" throughout its response.[6] The USPTO's refrain from recognizing the predatory practices pharmaceutical companies use to maintain a chokehold on the prescription drug market, raises questions about whether the Office is fully cognizant of the ways in which evergreening, patent

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[1] USPTO Response to FDA, July 6, 2022, https://www.uspto.gov/sites/default/files/documents/PTO-FDA-nextsteps-7-6-2022.pdf.
[2] Letter from Senator Elizabeth Warren and Representative Pramila Jayapal to USPTO Commissioner Hirshfeld, June 30, 2021 (On file with the Office of Senator Elizabeth Warren).
[3] *Id.*
[4] *Id.*
[5] Letter from Director Hirshfeld to Senator Elizabeth Warren and Representative Jayapal, August 13, 2021 (On file with the Office of Senator Elizabeth Warren).
[6] *Id.*

thickets, and product hopping undermine the legitimacy of our patent system or whether it views such practices as legitimate.[7]

Our letter also raised the need for the USPTO to "apply greater scrutiny to pharmaceutical companies' requests for patent term extension, which drives up drug costs when granted improperly."[8] Your response focused on the agency's purported "high accuracy rate" for conducting patent term extension (PTE) evaluations[9] but did not address what the USPTO is doing to fulfill its responsibility to scrutinize PTEs to determine whether they are even justified in the first place, whether the product is actually eligible for PTE under relevant statue and regulations, or whether the PTE applicant complied with the USPTO's duty of disclosure.[10]

Since the last time we wrote to the USPTO, the cost of prescription drugs has continued to climb, leaving Americans to pay the price for corporate greed. This year, more than 3,000 drugs had a list price increase.[11] In January 2022, pharmaceutical companies hiked prices by $150 per drug roughly representing almost 10 percent increase, and in July 2022 prices increased by $250 or 7.8 percent.[12] A 2021 GoodRx survey found that almost 40% of people had difficulty affording their medications in 2021, while a quarter of Americans could not afford basic necessities because of high medication costs.[13] While the *Inflation Reduction Act* will provide relief from these high prices in some cases, and, for the first time, allow Medicare to negotiate with drug manufacturers for lower prices, there are still important actions that USPTO and other administration agencies can and should take.[14]

In addition to your correspondence with our offices, you have also communicated with the FDA on these matters. On September 10, 2021, FDA Commissioner Robert Califf sent you a letter regarding the FDA's concerns that "certain uses of the patent system … have been criticized as allowing companies to inappropriately impede competition from generic, biosimilar, and interchangeable biological products," and "offer[ing] …ideas for the USPTO's consideration" to address those concerns.[15]" Specifically, the FDA called for a partnership with the USPTO to improve the patent examination process, a review of the misuses of the patent system (i.e. patent thickets, product hopping, and evergreening), adequate time and resources for PTO examiners,

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[7] *Id.*
[8] Letter from Senator Elizabeth Warren and Representative Pramila Jayapal to USPTO Commissioner Hirshfeld, June 30, 2021 (On file with the Office of Senator Elizabeth Warren).
[9] *Id.*
[10] 37 CFR §1.765, Duty of disclosure in patent term extension proceedings.
[11] The American Association of Retired Persons, "Prices of Hundreds of Drugs Outpace Inflation," Peter Urban, October 4, 2022, https://www.aarp.org/health/drugs-supplements/info-2022/drug-prices-and-inflation.html#:~:text=Drug%20price%20report%20highlights&text=Among%20its%20key%20findings%3A,7.8%20percent)%20in%20July%202022.
[12] *Id.*
[13] GoodRX, "Survey: Medication Costs Force Americans to Dip Into Savings and Cut Back on Basic Necessities," Amanda Brooks, May 9, 2022, https://www.goodrx.com/healthcare-access/research/medication-debt-survey-2021.
[14] Department of Health and Human Services, New HHS Reports Illustrate Potential Positive Impact of Inflation Reduction Act on Prescription Drug Prices, September 30, 2022, https://www.hhs.gov/about/news/2022/09/30/new-hhs-reports-illustrate-potential-positive-impact-inflation-reduction-act-prescription-drug-prices.html.
[15] Letter from Acting Commissioner of the FDA to USPTO, September 10, 2022, https://www.uspto.gov/sites/default/files/documents/EO14036-FDALettertoPTO.pdf.

and Patent and Trial Appeal Board (PTAB) data regarding the Post Grant Review and Inter Partes Review process.[16] On July 6, 2022, you sent a public response to the FDA.[17]

Your response acknowledged the importance of ensuring "our [patent] 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,"[18] and provided a detailed description of the ways in which the USPTO can collaborate with the FDA to improve drug accessibility. Of particular interest to us was the information you provided in section 2(f) "Revisit obviousness-type double patenting practice."[19] We are glad that the USPTO is committed to evaluating how obvious type double patenting is contributing to the high cost of prescription drugs and we are interested in learning about the changes you will make to ensure this type of abuse ceases.

As your response letter also recognizes, one challenge that arises for generic and biosimilar entrants is the high cost of patent litigation. The American Intellectual Property Lawyer's Association's bi-annual survey of IP-related costs found that patent litigation costs can be as high as $4 million per case – and blockbuster drugs are typically protected by dozens of patents.[20] One analysis of the twelve top-grossing drugs in 2017 revealed that, on average, 125 patents were filed per drug.[21] Yet, no matter how weak some patent applications may be, challenging them is nevertheless estimated to cost roughly $3 million per patent in a thicket.[22]

Although we are pleased with the USPTO's efforts to collaborate with the FDA, we have ongoing concerns with the high cost of prescription drugs in America and the persistence of anti-competitive abuses of our patent system and remain concerned that USPTO is not moving quickly or aggressively enough to combat abuses of the patent system. We write to seek additional information on the status of the USPTO's initiatives to address the shortcomings of our patent system, and are therefore requesting answers to the following inquiries by December 19, 2022:

1. Please provide an update on the collaborative efforts that have taken place between the FDA and USPTO since your July 6, 2022 letter was issued.

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[16] *Id.*

[17] USPTO Response to FDA, July 6, 2022, https://www.uspto.gov/sites/default/files/documents/PTO-FDA-nextsteps-7-6-2022.pdf.

[18] *Id.*

[19] *Id.* at page 6.

[20] Associated Press, "Current Patent Litigation Costs Are Between $2.3 to 4M - from the BlueIron Blog," Russ Krajec, July 10, 2020, https://apnews.com/press-release/news-direct-corporation/technology-business-intellectual-property-patents-a5dd5a7d415e7bae6878c87656e90112.

[21] The Initiative for Medicines, Access & Knowledge, "Overpatented, Overprices: How Excessive Pharmaceutical Patenting is Extending Monopolies and Driving Up Drug Prices," p.11, August 2018 http://www.i-mak.org/wp-content/uploads/2018/08/I-MAK-Overpatented-Overpriced-Report.pdf.

[22] Biosimilars Council, "Failure to Launch, Patent Abuse Blocks Access to Biosimilars for America's Patients," June 2019, https://www.biosimilarscouncil.org/wp-content/uploads/2019/06/Biosimilars-Council-White-Paper-Failure-to-Launch-June-2019.pdf.

2. Your response to the FDA makes reference to a process the USPTO has "put in place…for the PTAB to share feedback as it relates to ex parte appeals…[23]" Please share the data points that have been collected from this partnership to date.

    a. Is the PTAB sharing information about the patent examiners issuing patents that are later invalidated by the PTAB? Have you noticed any patterns?

    b. What systems are in place to hold USPTO employees who repeatedly issue invalid patents accountable for their persistent errors?

3. The USPTO also stated its intent to "introduce more examining time into the patent examination system". How much extra time will be provided to examiners and what rationale did the USPTO use to reach this number?[24]

4. Does the USPTO collect data relating to the frequency of obviousness-type double patenting rejections and compliance rates with its requirement to file terminal disclaimers? If so, we request that you share that data with us. If not, will the USPTO commit to collect this data?

5. What steps has the USPTO taken since its July 6 correspondence with the FDA to "revisit obviousness type double patenting practice"[25]? Please describe what the USPTO has learned about this practice and what changes it will implement to reduce this abuse of the patent system?

6. Is the USPTO enforcing the "duty of disclosure" as required by statute?[26] How is the agency doing so?

7. Please share any data or commitments the USPTO is taking to ensure that it will apply more scrutiny in its review of PTE applications.

8. Our June 30, 2021 letter to the USPTO, discussed concerns with the Office's current funding structure –one dependent on fees which may incentivize the approval of non-meritorious patents[27].

    a. Does the USPTO acknowledge any issue with the Office's funding structure?

[23] USPTO Response to FDA, July 6, 2022, pp. 5-6, https://www.uspto.gov/sites/default/files/documents/PTO-FDA-nextsteps-7-6-2022.pdf.
[24] USPTO Response to FDA, July 6, 2022, https://www.uspto.gov/sites/default/files/documents/PTO-FDA-nextsteps-7-6-2022.pdf.
[25] *Id.*
[26] 35 U.S.C. 156 (d)(2)(B)(4).
[27] Letter from Senator Elizabeth Warren and Representative Pramila Jayapal to USPTO Commissioner Hirshfeld, June 30, 2021 (On file with the Office of Senator Elizabeth Warren).

b. How can the USPTO impartially evaluate its own system for reviewing continuation application, particularly in large patent families, and make an adequate determination on what additional scrutiny it may apply to repeat players whose fees help fund the daily operations of the Office?

c. How can Congress support the USPTO in this endeavor?

Sincerely,

Elizabeth Warren
United States Senator

Pramila Jayapal
Member of Congress