Congress of the United States

Washington, DC 20515

February 22, 2023

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 regarding recent reports that Merck is seeking to extend its patent monopoly on the $165,000 cancer drug Keytruda.[1] If the company is successful, it will result in billions of dollars in new profits from this lifesaving drug -- at extraordinary expense to patients and taxpayers.[2]

These efforts by Merck appear to be part of a long-standing pattern of drug manufacturers' abuse of the patent system.[3] In the case of Keytruda, the company had – as of October 2021 – "filed 129 patents linked to Keytruda, which could extend the period of exclusivity to 2036 and beyond,"[4] nearly a decade past its expected end date.[5]

Last year, we wrote to you regarding our concerns about the pharmaceutical industry's broad use of anti-competitive practices, noting that pharmaceutical companies use "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."[6] We appreciate your December 27, 2022 response, which outlined steps the United States Patent and Trademark Office (USPTO) is taking to address the high cost of medications and biologic treatments, including

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[1] The Initiative for Medicines, Access & Knowledge, "Overpatented, Overpriced: Keytruda's Patent Wall," May 2021, https://www.i-mak.org/wp-content/uploads/2021/05/i-mak.keytruda.report-2021-05-06F.pdf.

[2] The Campaign for Sustainable Rx Pricing, "Big Pharma Watch: Merck Plots to Further Block Competition and Extend Monopoly Pricing on Blockbuster Cancer Drug Keytruda," December 2, 2022, https://www.csrxp.org/big-pharma-watch-merck-plots-to-further-block-competition-and-extend-monopoly-pricing-on-blockbuster-cancer-drug-keytruda/.

[3] Financial Times, "Merck on deals hunt as patent cliff looms for top cancer drug," October, 6, 2021, https://www.ft.com/content/a9688ef3-42ad-4600-ac19-6b22783922c3.

[4] *Id.*

[5] Reuters, "Merck could keep its patent edge by shifting Keytruda cancer drug to a simple shot," Michael Erman, December 2, 2022, https://www.reuters.com/business/healthcare-pharmaceuticals/merck-could-keep-its-patent-edge-by-shifting-keytruda-cancer-drug-simple-shot-2022-12-02/.

[6] Letter from Sen. Warren and Rep. Jayapal to USPTO Director Kathy Vidal, December 5, 2022, https://www.warren.senate.gov/imo/media/doc/Warren-Jayapal%20Follow%20Up%20Letter%20to%20USPTO%20re%20Patent%20Abuse%20and%20Drug%20Pricing%20-%2012.5.22.pdf.

collaboration with the U.S. Food and Drug Administration (FDA).[7] Merck's attempts to extend the Keytruda patent will be an important test of your agency's ability to meet these goals.

Keytruda is a biologic treatment used to treat cancer.[8] First approved in September 2014 for melanoma,[9] it is now used to treat eighteen types of advanced cancer.[10] The drug is Merck's biggest seller,[11] bringing in $5.4 billion in sales in the third quarter of 2022, and Merck has aggressively used the patent system to protect its monopoly on this drug.[12] The company has 53 granted patents for Keytruda, with another 129 applications pending as of 2021.[13] Fifty percent of those applications were filed after Keytruda received initial FDA approval, and seventy-four percent cover different indications and formulations of the drug, not the key antibody.[14] Absent further USPTO approvals, the original key patents on Keytruda will begin to expire in 2028, opening the door to cheaper biosimilars.[15] However, should the USPTO approve new patent applications for the drug, biosimilar competitors could be shut out of the market until 2036, giving Merck a total period of nearly 35 years of patent protection for Keytruda[16] – monopoly protection that extends well beyond the intent of the Drug Price Restoration and Patent Term Restoration Act (Hatch-Waxman)[17] and the Biologics Price Competition and Innovation Act.[18]

One particular concern is Merck's attempt "to patent a new formulation of … Keytruda that can be injected under the skin."[19] According to Merck CFO Caroline Litchfield, "We believe that subcutaneous formulation has the potential to be novel, non-obvious and useful, which means we would get a new patent for it."[20] If approved, Merck's patent application for its subcutaneous formulation of Keytruda could shield the drug from competition for many years, according to Tahir Amin, co-founder of drug patents watchdog group Initiative for Medicines, Access & Knowledge.[21]

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[7] USPTO Response to Sen. Warren and Rep. Jayapal, Dec. 27, 2022. On File with the Office of Senator Elizabeth Warren.

[8] The Initiative for Medicines, Access & Knowledge, "Overpatented, Overpriced: Keytruda's Patent Wall," May 2021, https://www.i-mak.org/wp-content/uploads/2021/05/i-mak.keytruda.report-2021-05-06F.pdf.

[9] *Id.*

[10] *Id.*

[11] FiercePharma, The top 20 drugs by worldwide sales in 2021, May 31, 2022, https://www.fiercepharma.com/special-reports/top-20-drugs-worldwide-sales-2021.

[12] Reuters, "Merck lifts full-year forecast as Keytruda sales soar," Michael Erman and Leroy Leo, Oct. 27, 2022, https://www.reuters.com/business/healthcare-pharmaceuticals/merck-third-quarter-earnings-climb-lifts-full-year-outlook-2022-10-27/; *See,* e.g, The Initiative for Medicines, Access & Knowledge, "Overpatented, Overpriced: Keytruda's Patent Wall," May 2021, https://www.i-mak.org/wp-content/uploads/2021/05/i-mak.keytruda.report-2021-05-06F.pdf.

[13] The Initiative for Medicines, Access & Knowledge, "Overpatented, Overpriced: Keytruda's Patent Wall," May 2021, https://www.i-mak.org/wp-content/uploads/2021/05/i-mak.keytruda.report-2021-05-06F.pdf.

[14] *Id*.

[15] *Id*.

[16] *Id.*

[17] Drug Price Restoration and Patent Term Restoration Act, P.L. 98-417.

[18] Biologics Price Competition and Innovation Act, P.L. 111-148, § 7001-7003.

[19] Reuters, "Merck could keep its patent edge by shifting Keytruda cancer drug to a simple shot," Michael Erman, December 2, 2022, https://www.reuters.com/business/healthcare-pharmaceuticals/merck-could-keep-its-patent-edge-by-shifting-keytruda-cancer-drug-simple-shot-2022-12-02.

[20] *Id.*

[21] *Id.*

But it is not at all clear that Merck is doing anything other than extending its monopoly power over the drug. This approach – and Merck's use of dozens of patents to fend off Keytruda competitors – appear to be an example of the anti-competitive business practices, including double-patenting, patent thicketing, product hopping, and evergreening, that we have long been concerned about.[22] Subcutaneous injection for delivery of treatments and medications is not novel, but an obvious use: medications have been injected under the skin since Insulin was discovered in 1921.[23] Furthermore, physicians appear to be skeptical about whether the new route of administration represents a significant enough clinical improvement over intravenous infusions to justify a new patent: Dr. Shailender Bhatia, an oncologist at the Fred Hutchinson Cancer Center in Seattle, stated "I don't think it's going to improve the safety or the effectiveness of the drug."[24]

In your July 6, 2022 letter to FDA Commissioner Dr. Robert Califf, you recognized that the high cost of patent litigation is a significant challenge for generic and biosimilar entrants.[25] 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 for a single patent[26] – and blockbuster drugs are typically protected by dozens of patents.[27] One analysis of the twelve top-grossing drugs in 2017 revealed, on average, 125 patents were filed per drug.[28] Yet, no matter how weak some patent applications may be, challenging them is nevertheless estimated to cost millions per patent in a thicket.[29]

Abusive patent practices reduce competition and result in significant financial strain for patients. The non-discounted annual price of Keytruda is $165,308, and that price has increased 147% in the five years since Keytruda was launched – in large part because of limited competition.[30] As you stated in your July letter to Commissioner Califf, "we must make sure our system as a whole does not unnecessarily delay getting generic, biosimilar and more affordable versions of

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[22] Letter from Sen. Warren and Rep. Jayapal to USPTO Director Kathy Vidal, December 5, 2022, https://www.warren.senate.gov/imo/media/doc/Warren-Jayapal%20Follow%20Up%20Letter%20to%20USPTO%20re%20Patent%20Abuse%20and%20Drug%20Pricing%20-%2012.5.22.pdf.

[23] The American Diabetes Association, "The History of a Wonderful Thing We Call Insulin," July 1, 2019. https://diabetes.org/blog/history-wonderful-thing-we-call-insulin.

[24] Reuters, "Merck could keep its patent edge by shifting Keytruda cancer drug to a simple shot," Michael Erman, December 2, 2022, https://www.reuters.com/business/healthcare-pharmaceuticals/merck-could-keep-its-patent-edge-by-shifting-keytruda-cancer-drug-simple-shot-2022-12-02/.

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

[26] 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-intellectualproperty-patents-a5dd5a7d415e7bae6878c87656e90112.

[27] The Initiative for Medicines, Access & Knowledge, "Overpatented, Overprices: How Excessive Pharmaceutical Patenting is Extending Monopolies and Driving Up Drug Prices," p.2, August 2018, https://www.i-mak.org/wp-content/uploads/2018/08/I-MAK-Overpatented-Overpriced-Report.pdf.

[28] *Id.,* p.11.

[29] Biosimilars Council, "Failure to Launch, Patent Abuse Blocks Access to Biosimilars for America's Patients," June 2019, p. 8, https://www.biosimilarscouncil.org/wp-content/uploads/2019/06/Biosimilars-Council-White-Paper-Failure-to-Launch-June-2019.pdf.

[30] The Initiative for Medicines, Access & Knowledge, "Overpatented, Overpriced: Keytruda's Patent Wall," May 2021, https://www.i-mak.org/wp-content/uploads/2021/05/i-mak.keytruda.report-2021-05-06F.pdf.

those drugs into the hands of Americans who need them."[31] You also outlined USPTO's intention to "further the Biden-Harris Administration's goal of facilitating access to affordable drugs." [32] Your response to Merck's request for new patents with Keytruda is an opportunity to follow through on these commitments. USPTO should give close scrutiny to any of Merck's requests for new patents for Keytruda, and reject those that do not clearly meet the agency's standards of novelty, utility, and non-obviousness.

We also request answers to the following inquiries by March 8, 2023:

1. What actions will USPTO take to ensure that Merck's attempt to seek dozens of patents "does not unnecessarily delay getting generic, biosimilar and more affordable versions of those drugs into the hands of Americans who need them?"[33]

2. From 2014 to the present, how many patents related to Keytruda has Merck applied for?
    a. How many of these have been approved?
    b. How many have been denied?
    c. Please provide a list of all patents for which Merck has applied and been approved, and all that have been denied.

3. What is the status of pending Keytruda patent requests?
    a. How many Keytruda-related patents are pending?
    b. Please provide a list of all such patents, and the expected date of a USPTO decision for each patent.

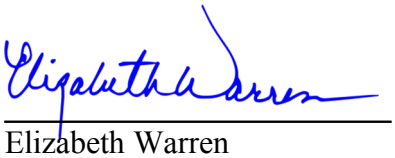
4. What specific recourse does USPTO have to address companies that are engaging in abuses of the patent system in ways that hurt patients and providers?

5. How is USPTO collaborating with the FDA on its decision making about these new patent requests for Keytruda?

6. Your December 2022 response made reference to a joint listening session the USPTO and FDA would be having regarding patent issues in January 2023.[34]
    a. Who attended the listening session?
    b. What were the key takeaways from the conversation?

[31] USPTO Response to FDA, July 6, 2022, p. 1, https://www.uspto.gov/sites/default/files/documents/PTO-FDA-nextsteps-7-6-2022.pdf.
[32] *Id.*, p. 2.
[33] *Id.*, p. 1.
[34] USPTO Response to Senator Warren and Representative Jayapal, December 27, 2022, p. 3. On File with the Office of Senator Elizabeth Warren.

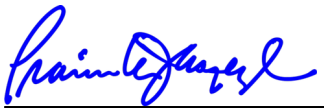
Sincerely,



Elizabeth Warren
United States Senator

Katie Porter
Member of Congress

Bernard Sanders
United States Senator



Pramila Jayapal
Member of Congress