Congress of the United States

Washington, DC 20515

February 15, 2024

Dr. Robert M. Califf, M.D.
Commissioner of Food and Drugs
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20903

Dear Commissioner Califf:

We have worked hard to fight drug manufacturers' abusive patent practices in order to reduce drug costs for consumers, and were pleased to see the Food and Drug Administration (FDA) announce in January that the agency intends to establish new guidance this year on "*Submission of Patent Information for Listing in the Orange Book*."[1]

Last year, we wrote to you and to the Federal Trade Commission (FTC) seeking action to "address[] the anti-competitive business practices that pharmaceutical companies use to keep drug prices high,"[2] and appreciate that both FDA and FTC are moving forward to do so. In December 2023, the FTC took an important step on behalf of consumers, writing to 10 drug manufacturers and "challeng[ing] more than 100 patents held by manufacturers of brand-name asthma inhalers, epinephrine autoinjectors, and other drug products as improperly or inaccurately listed" in the Orange Book.[3]

Soon after FTC's announcement, we wrote to these same manufacturers, asking them a series of questions and urging them to withdraw any improperly listed patents as rapidly as possible.[4] We have received answers to our questions, and are attaching them here in order to assist FDA as the agency develops its new Orange Book guidance.

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[1] FDA, "CDER Guidance Agenda: New, Revised Draft and Immediately in Effect Guidances Planned for Publication in Calendar Year 2024," January 2024, https://www.fda.gov/media/134778/download.

[2] Letter from Sen. Warren and Rep. Jayapal to Dr. Robert Califf, FDA Commissioner, August 28, 2023, https://www.warren.senate.gov/imo/media/doc/2023.08.28%20Letter%20to%20FDA%20re%20drug%20patents.pdf; Letter from Sen. Warren and Rep. Jayapal to Lina Kahn, FTC Commissioner, September 13, 2023, https://www.warren.senate.gov/imo/media/doc/2023.09.13%20Letter%20to%20FTC%20re%20Orange%20Book.pdf.

[3] Federal Trade Commissioner, "FTC Challenges More Than 100 Patents as Improperly Listed in the FDA's Orange Book," press release, November 7, 2023, https://www.ftc.gov/news-events/news/press-releases/2023/11/ftc-challenges-more-100-patents-improperly-listed-fdas-orange-book.

[4] Sen. Elizabeth Warren, "Warren, Jayapal Blast Big Pharma's Sham Patent Claims, Urge Companies to End Abusive Patent Practices that Cost Patients Billions," press release, December 14, 2023, https://www.warren.senate.gov/newsroom/press-releases/warren-jayapal-blast-big-pharmas-sham-patent-claims-urge-companies-to-end-abusive-patent-practices-that-cost-patients-billions.

The response to FTC's challenges was rapid, and significant. Two of the manufacturers, Kaléo[5] and Amneal,[6] indicated they would be delisting every patent challenged by FTC, plus five additional patents (three for Kaléo and two for Amneal). GlaxoSmithKline (GSK) indicated that the company would be delisting 12 of 14 patents identified by FTC, plus an additional five more "in light of evolving policies and developments in the law regarding the listing of drug-device combinations."[7]

This was a remarkable success for FTC, with drug manufacturers announcing the withdrawal of 27 challenged patents within weeks of being asked to do so. At the same time, this rapid response reveals the extent to which drug manufacturers have been blatantly misusing the patent system and gaming FDA's Orange Book policies, demonstrating that more work remains. For example, GSK did not delist all of its challenged patents, and Boehringer Ingelheim,[8] AbbVie,[9] Teva,[10] AstraZeneca,[11] and Viatris[12] indicated that they would not be delisting any of their challenged patents.

FTC and FDA should fight these companies' efforts to misuse the Orange Book to discourage competition, and FDA's new guidance provides an opportunity to clarify the rules. The manufacturers' responses indicated that such clarification would be useful: GSK, for example, indicated that "GSK and others in the industry have requested that the FDA provide specific guidance to help them make listing decisions regarding such patents," and that the agency "has failed to provide more specific guidance related to, for example, patents covering only the approved device or components integral to the use of the approved device."[13] Teva indicated that the current "underlying statute and regulatory guidance support the appropriateness of listing the challenged patents,"[14] And AstraZeneca indicated that the company will "incorporate any change in the applicable FDA guidance."[15]

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[5] Letter from Ned Ruffin, Chief Legal and Compliance Officer, Kaléo, to Sen. Warren and Rep. Jayapal, January 8, 2024, on file with the office of U.S. Senator Elizabeth Warren.

[6] Letter from Maryll W. Toufanian, J.D., Senior Vice President – Regulatory Strategy and Government Affairs, Kaléo, to Sen. Warren and Rep. Jayapal, January 10, 2024, on file with the office of U.S. Senator Elizabeth Warren.

[7] Letter from Amy Chevalier Efantis, Vice President, Government Affairs & Public Policy, GlaxoSmithKline, to Sen. Warren and Rep. Jayapal, January 12, 2024, on file with the office of U.S. Senator Elizabeth Warren.

[8] Letter from Jean-Michel Boers, U.S.Country Managing Director and Chief Executive Officer, Boehringer Ingelheim US Corporation, to Sen. Warren and Rep. Jayapal, January 15, 2024, on file with the office of U.S. Senator Elizabeth Warren.

[9] Letter from Daniel J. Bachner, Vice President, Federal Government Affairs, AbbVie, to Sen. Warren and Rep. Jayapal, Jan. 15, 2024, on file with the office of U.S. Senator Elizabeth Warren.

[10] Letter from Dov Bergwerk, Acting Chief Legal Officer and Corporate Secretary, Teva, to Sen. Warren and Rep. Jayapal, Jan. 15, 2024, on file with the office of U.S. Senator Elizabeth Warren.

[11] Letter from Daniel M. Wygal, Vice President, US Corporate & Government Affairs, AstraZeneca, to Sen. Warren and Rep. Jayapal, February 7, 2024, on file with the office of U.S. Senator Elizabeth Warren.

[12] Letter from Brian S. Roman, Global General Counsel, Viatris, to Sen. Warren and Rep. Jayapal, January 12, 2024, on file with the office of U.S. Senator Elizabeth Warren.

[13] Letter from Amy Chevalier Efantis, Vice President, Government Affairs & Public Policy, GlaxoSmithKline, to Sen. Warren and Rep. Jayapal, January 12, 2024, on file with the office of U.S. Senator Elizabeth Warren.

[14] Letter from Dov Bergwerk, Acting Chief Legal Officer and Corporate Secretary, Teva, to Sen. Warren and Rep. Jayapal, Jan. 15, 2024, on file with the office of U.S. Senator Elizabeth Warren.

[15] Letter from Daniel M. Wygal, Vice President, US Corporate & Government Affairs, AstraZeneca, to Sen. Warren and Rep. Jayapal, February 7, 2024, on file with the office of U.S. Senator Elizabeth Warren.

Our August 2023 letter to FDA asked that you update the guidance and rules for listing patents in the Orange Book and develop a review and validation system to remove improperly-listed patents.[16] The new information on drug manufacturers' patent withdrawals described in this letter provides an important update that we hope will inform FDA as you develop these new rules.

We thank you for your efforts to end drug manufacturers' patent abuse and lower drug costs for all Americans.

Sincerely,

Elizabeth Warren
United States Senator

Pramila Jayapal
Member of Congress

cc: Lina Khan, Chair, Federal Trade Commission

[16] Letter from Sen. Warren and Rep. Jayapal to Dr. Robert Califf, FDA Commissioner, August 28, 2023, https://www.warren.senate.gov/imo/media/doc/2023.08.28%20Letter%20to%20FDA%20re%20drug%20patents.pdf.