Congress of the United States

Washington, DC 20515

June 6, 2024

Jack Zhang
Chief Executive Officer, President, Chief
Scientific Officer, and Director
Amphastar Pharmaceuticals
11570 6th Street
Rancho Cucamonga, CA 91730

Dear Mr. Zhang:

We write today regarding the Federal Trade Commission's (FTC) April 30, 2024 letter indicating that "certain patents [may] have been improperly or inaccurately listed in the Orange Book with regard to Amphastar Pharmaceuticals Inc.'s Baqsimi."[1] This is an indication from FTC that Amphastar has been abusing the patent system to profit at patients' and taxpayers' expense by charging exorbitant prices –for a glucagon nasal spray to treat severe hypoglycemia in type-1 diabetics.[2] We applaud the FTC's leadership in challenging "junk" patent listings that, together with other anticompetitive conduct, cost consumers and the U.S. health care system billions of dollars each year.[3] Accordingly, we write to ask that you address the improper behavior identified by the FTC by June 8, 2024.

In September 2023, the FTC issued a policy statement that "improper patent listings may unlawfully delay generic competition for years and disincentivize generic manufacturers from trying to come to market with lower cost alternatives."[4] The Orange Book contains a list of drugs approved by the Food and Drug Administration (FDA) and related patent and exclusivity information, covering drug substances, drug products, and method of use.[5] If a brand-name drug company sues a generic manufacturer for infringing on a patent listed in the Orange Book, the

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[1] Letter from U.S. Federal Trade Commission to Novartis Pharmaceuticals Corp., April 30, 2024, p. 1, https://www.ftc.gov/system/files/ftc_gov/pdf/amphastar-baqsimi-4302024.pdf ; U.S. Federal Trade Commission, "FTC Expands Patent Listing Challenges, Targeting More Than 300 Junk Listings for Diabetes, Weight Loss, Asthma and COPD Drugs," press release, April 30, 2024, https://www.ftc.gov/news-events/news/press-releases/2024/04/ftc-expands-patent-listing-challenges-targeting-more-300-junk-listings-diabetes-weight-loss-asthma.

[2] RxList, "BAQSIMI,"NEOHALER," last updated December 18, 2023, https://www.rxlist.com/baqsimi-drug.htm.

[3] American Economic Liberties Project, "The Costs of Pharma Cheating," May 2023, p. 2, https://www.economicliberties.us/wp-content/uploads/2023/05/AELP_052023_PharmaCheats_Report_FINAL.pdf.

[4] U.S. Federal Trade Commission, "FTC Issues Policy Statement on Brand Pharmaceutical Manufacturers' Improper Listing of Patents in the Food and Drug Administration's 'Orange Book'," press release, September 14, 2023, https://www.ftc.gov/news-events/news/press-releases/2023/09/ftc-issues-policy-statement-brand-pharmaceutical-manufacturers-improper-listing-patents-food-drug.

[5] U.S. Food and Drug Administration, "Approved Drug Products with Therapeutic Equivalence Evaluations | Orange Book," updated December 8, 2023, https://www.fda.gov/drugs/drug-approvals-and-databases/approved-drug-products-therapeutic-equivalence-evaluations-orange-book.

FDA is barred from approving a generic version of the drug for 30 months.[6] Powerful Big Pharma players are therefore incentivized to strategically use sham patent listings in the Orange Book to hold off generic competition — increasing drug and health care costs for patients and driving up insurance premiums.[7]

The FTC pledged to scrutinize companies that engage in these practices for violating Section 5 of the *Federal Trade Commission Act*,[8] and in April issued a warning letter to Amphastar that appears to conclude that the company may be violating federal law with regard to a drug listing for Baqsimi.[9] Given these concerns, we urge you to voluntarily de-list the patent named in the FTC's letter, and any other patents you have listed that unfairly block competition.[10] As the FTC noted, Amphastar "bears the burden of listing patents in the Orange Book accurately and in accordance with all relevant statutory and regulatory requirements."[11]

The practices that FTC has highlighted in its warning letter are a prime example of how pharmaceutical companies — including Amphastar — regularly employ anticompetitive tactics to extend their government-granted monopolies, insulate themselves from generic and biosimilar competition, and keep prices artificially high.[12] Drug manufacturers' patent gaming tactics can drive up drug prices, contribute to higher premiums and out-of-pocket costs for patients, and increase costs for Medicare and Medicaid. For example, U.S. patients and payers spent an additional $40.07 billion on pharmaceutical products "as a result of antitrust violations by the pharmaceutical industry" in 2019.[13] And the Medicare Part D program spent over $19 million on Baqsimi in 2022 alone.[14]

We have long been concerned by these and other pharmaceutical industry abuses of the patent system to stifle competition, prolong drug monopolies, and price-gouge patients.[15] FDA has

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[6] United States District Court for the District of Delaware, "Federal Trade Commission's Brief as *Amicus Curiae*," November 10, 2022, p. 1, https://www.ftc.gov/system/files/ftc_gov/pdf/P163500JazzPharmaAmicusBrief.pdf.

[7] U.S. Federal Trade Commission, "Federal Trade Commission Statement Concerning Brand Drug Manufacturers' Improper Listing of Patents in the Orange Book," p. 4, https://www.ftc.gov/system/files/ftc_gov/pdf/p239900orangebookpolicystatement092023.pdf; Center for American Progress, "Following the Money: Untangling U.S. Prescription Drug Financing," Sam Hughes and Nicole Rapfogel, October 12, 2023, https://www.americanprogress.org/article/following-the-money-untangling-u-s-prescription-drug-financing/.

[8] *Id.;* 15 U.S.C. §§ 41-58.

[9] Letter from U.S. Federal Trade Commission to Novartis Pharmaceuticals Corp., April 30, 2024, https://www.ftc.gov/system/files/ftc_gov/pdf/amphastar-baqsimi-4302024.pdf.

[10] *Id*.

[11] *Id*.

[12] National Library of Medicine, "Patents and Regulatory Exclusivities on Inhalers for Asthma and COPD, 1986-2020," William Feldman, Doni Bloomfield, Reed Beall, and Aaron Kesselheim, May 17, 2022, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10328096/; American Economic Liberties Project, "The Costs of Pharma Cheating," May 2023 https://www.economicliberties.us/wp-content/uploads/2023/05/AELP_052023_PharmaCheats_Report_FINAL.pdf.

[13] American Economic Liberties Project and Initiative for Medicines, Access, and Knowledge (I-MAK), "The Costs of Pharma Cheating," May 2023, p. 2, https://www.economicliberties.us/wp-content/uploads/2023/05/AELP_052023_PharmaCheats_Report_FINAL.pdf.

[14] Centers for Medicare & Medicaid Services, "Medicare Part D Spending by Drug," 2022, https://data.cms.gov/summary-statistics-on-use-and-payments/medicare-medicaid-spending-by-drug/medicare-part-d-spending-by-drug//data.

acknowledged these Orange Book-related issues[16] and taken some steps to "ensure[] our system, as a whole, is not used to improperly delay getting more affordable drugs and biosimilars into the hands of Americans who need them."[17] In September 2023, we encouraged the FTC to declare sham patent listings in the Orange Book as an unfair method of competition, and in December 2023, we wrote to eight companies identified by the FTC as potentially violating the *Federal Trade Commission Act*, urging them to delist these improperly-listed patents.[18]

Now, in light of FTC's notice disputing several of your company's patent listings, we request that you voluntarily de-list all of Amphastar's improperly- and inaccurately-listed Orange Book patents by June 8, 2024 and provide responses to the following questions by no later than June 20, 2024.

1. In its April 2024 letter, the FTC identified one patent for the Baqsimi product that has been improperly or inaccurately listed in the Orange Book.
    a. Has Amphastar ever taken action to enforce this patent against any other drug manufacturer? If so, please list all such actions, and their outcome.
    b. During the time period in which you were challenging this patent, or in the ensuing 30-month period in which you were granted a stay that delayed approval of a generic competitor to one of this drug, what were total sales (in dollars) of these drugs? What were total sales to Medicare and Medicaid?
2. Will Amphastar voluntarily de-list the one patent you have listed in the Orange Book with regard to Baqsimi that the FTC has disputed as being improperly or inaccurately listed?

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[15] Letters from Senator Warren and Representative Jayapal to AbbVie, AstraZeneca, Boehringer Ingelheim Pharmaceuticals, GlaxoSmithKline, Amneal Pharmaceuticals (Impax), Kaléo, Viatris (Mylan), and Teva/Norton, December 13, 2023, https://www.warren.senate.gov/imo/media/doc/orange%20book_combinedpdf.pdf; Office of U.S. Senator Elizabeth Warren, "Warren, Jayapal Call on Patent Office to Take Critical Steps to Lower Drug Prices and Fight Big Pharma's Patent Abuse," press release, April 27, 2023, https://www.warren.senate.gov/oversight/letters/warren-jayapal-call-on-patent-office-to-take-critical-steps-to-lower-drug-prices-and-fight-big-pharmas-patent-abuse; Office of U.S. Senator Elizabeth Warren, "Senator Warren, Representative Jayapal Urge FDA to Hold Big Pharma Accountable for Abuse of Patent System, Profiteering at Patients' Expense," press release, August 29, 2023, https://www.warren.senate.gov/oversight/letters/senator-warren-representative-jayapal-urge-fda-to-hold-big-pharma-accountable-for-abuse-of-patent-system-profiteering-at-patients-expense.

[16] U.S. Food and Drug Administration, "The Listing of Patent Information in the Orange Book," January 5, 2022, pp. 21-22, https://www.fda.gov/media/155200/download; U.S. Food and Drug Administration, Federal Register Notice, "Listing of Patent Information in the Orange Book; Establishment of a Public Docket; Request for Comments," June 1, 2020, https://www.federalregister.gov/documents/2020/06/01/2020-11684/listing-of-patent-information-in-the-orangebook-establishment-of-a-public-docket-request-for.

[17] U.S. Patent and Trademark Office, "USPTO – FDA Collaboration Initiatives," https://www.uspto.gov/initiatives/fda-collaboration.

[18] Office of U.S. Senator Elizabeth Warren, "Warren, Jayapal Urge FTC to Rein in Big Pharma Abuses of Patent System," press release, September 14, 2023, https://www.warren.senate.gov/oversight/letters/warren-jayapal-urge-ftc-to-rein-in-big-pharma-abuses-of-patent-system; Letters from Senator Warren and Representative Jayapal to AbbVie, AstraZeneca, Boehringer Ingelheim Pharmaceuticals, GlaxoSmithKline, Amneal Pharmaceuticals (Impax), Kaléo, Viatris (Mylan), and Teva/Norton, December 13, 2023, https://www.warren.senate.gov/imo/media/doc/orange%20book_combinedpdf.pdf.

a. What is your specific timeline for doing so?

3. Will Amphastar voluntarily review and de-list additional patents the company has listed in the Orange Book that are improperly or inaccurately listed?

   a. Please specify which ones you will de-list.

   b. What is your specific timeline for doing so?

Sincerely,

Elizabeth Warren
United States Senator

Pramila Jayapal
Member of Congress

Congress of the United States

Washington, DC 20515

June 6, 2024

Pascal Soriot
Executive Director and CEO
AstraZeneca
1 Francis Crick Avenue
Cambridge CB2 0AA
United Kingdom

Dear Mr. Soriot:

We write today regarding the Federal Trade Commission's (FTC) April 30, 2024 letter indicating that "certain patents [may] have been improperly or inaccurately listed in the Orange Book with regard to Astrazeneca AB's Bydureon Pen."[1] This is another indication from FTC that AstraZeneca AB has been abusing the patent system to profit at patients' and taxpayers' expense by charging exorbitant prices – this time for medication that helps provide consistent control of blood sugar.[2] We applaud the FTC's leadership in challenging "junk" patent listings that, together with other anticompetitive conduct, cost consumers and the U.S. health care system billions of dollars each year.[3]

This is the second time in the past six months that the FTC has written to you regarding sham patent listings listed in the Orange Book.[4] After a similar set of letters from FTC directed at inhaler medications in November 2023, we urged you to delist AstraZeneca LP's Symbicort product and all other improper and inaccurate listings.[5] Several other companies delisted their patents following FTC and congressional scrutiny, but you have refused to do so – delaying the approval of generic versions of the patents listed, and potentially violating the law.[6]

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[1] Letter from U.S. Federal Trade Commission to AstraZeneca AB, April 30, 2024, https://www.ftc.gov/system/files/ftc_gov/pdf/astrazeneca-ab-bydureon-pen-4302024.pdf; U.S. Federal Trade Commission, "FTC Expands Patent Listing Challenges, Targeting More Than 300 Junk Listings for Diabetes, Weight Loss, Asthma and COPD Drugs," press release, April 30, 2024, https://www.ftc.gov/news-events/news/press-releases/2024/04/ftc-expands-patent-listing-challenges-targeting-more-300-junk-listings-diabetes-weight-loss-asthma.

[2] Bydureon BCise, "Say hello to BYDUREON BCise®," https://www.bydureon.com/bydureon-bcise.html.

[3] American Economic Liberties Project, "The Costs of Pharma Cheating," May 2023, p. 2, https://www.economicliberties.us/wp-content/uploads/2023/05/AELP_052023_PharmaCheats_Report_FINAL.pdf.

[4] Letter from FTC to Astrazeneca LP, November 7, 2023, https://www.ftc.gov/system/files/ftc_gov/pdf/astrazeneca-orange-book.pdf.

[5] Letters from Senator Warren and Representative Jayapal to AbbVie, AstraZeneca, Boehringer Ingelheim Pharmaceuticals, GlaxoSmithKline, Amneal Pharmaceuticals (Impax), Kaléo, Viatris (Mylan), and Teva/Norton, December 13, 2023, https://www.warren.senate.gov/imo/media/doc/orange%20book_combinedpdf.pdf.

[6] FDA Law Blog, "Drugs Companies Clap Back at Congress…Then Get Sued," Sara W. Koblitz, March 13, 2024, https://www.thefdalawblog.com/2024/03/drugs-companies-clap-back-at-congressthen-get-sued/; Food and Drug Administration, "Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations," https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm.

Accordingly, we again write to ask that you address the improper behavior identified by the FTC by June 8, 2024.

In September 2023, the FTC issued a policy statement that "improper patent listings may unlawfully delay generic competition for years and disincentivize generic manufacturers from trying to come to market with lower cost alternatives."[7] The Orange Book contains a list of drugs approved by the Food and Drug Administration (FDA) and related patent and exclusivity information, covering drug substances, drug products, and method of use.[8] If a brand-name drug company sues a generic manufacturer for infringing on a patent listed in the Orange Book, the FDA is barred from approving a generic version of the drug for 30 months.[9] Powerful Big Pharma players are therefore incentivized to strategically use sham patent listings in the Orange Book to hold off generic competition — increasing drug and health care costs for patients and driving up insurance premiums.[10]

The FTC pledged to scrutinize companies that engage in these practices for violating Section 5 of the *Federal Trade Commission Act*,[11] and in April issued a warning letter to AstraZeneca AB that appears to conclude that the company may be violating federal law with regard to eight drug listings for Bydureon Pen and other insulin medications.[12] Given these concerns, we again urge you to voluntarily de-list the eight patents named in the FTC's letter, and any other patents you have listed that unfairly block competition.[13] As the FTC noted, AstraZeneca AB "bears the burden of listing patents in the Orange Book accurately and in accordance with all relevant statutory and regulatory requirements."[14]

The practices that FTC has highlighted in its warning letters are a prime example of how pharmaceutical companies — including AstraZeneca AB — regularly employ anticompetitive tactics to extend their government-granted monopolies, insulate themselves from generic and biosimilar competition, and keep prices artificially high.[15] Drug manufacturers' patent gaming

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[7] U.S. Federal Trade Commission, "FTC Issues Policy Statement on Brand Pharmaceutical Manufacturers' Improper Listing of Patents in the Food and Drug Administration's 'Orange Book'," press release, September 14, 2023, https://www.ftc.gov/news-events/news/press-releases/2023/09/ftc-issues-policy-statement-brand-pharmaceutical-manufacturers-improper-listing-patents-food-drug.

[8] U.S. Food and Drug Administration, "Approved Drug Products with Therapeutic Equivalence Evaluations | Orange Book," updated December 8, 2023, https://www.fda.gov/drugs/drug-approvals-and-databases/approved-drug-products-therapeutic-equivalence-evaluations-orange-book.

[9] United States District Court for the District of Delaware, "Federal Trade Commission's Brief as *Amicus Curiae*," November 10, 2022, p. 1, https://www.ftc.gov/system/files/ftc_gov/pdf/P163500JazzPharmaAmicusBrief.pdf.

[10] U.S. Federal Trade Commission, "Federal Trade Commission Statement Concerning Brand Drug Manufacturers' Improper Listing of Patents in the Orange Book," p. 4, https://www.ftc.gov/system/files/ftc_gov/pdf/p239900orangebookpolicystatement092023.pdf; Center for American Progress, "Following the Money: Untangling U.S. Prescription Drug Financing," Sam Hughes and Nicole Rapfogel, October 12, 2023, https://www.americanprogress.org/article/following-the-money-untangling-u-s-prescription-drug-financing/.

[11] *Id.;* 15 U.S.C. §§ 41-58.

[12] Letter from U.S. Federal Trade Commission to AstraZeneca AB, April 30, 2024, https://www.ftc.gov/system/files/ftc_gov/pdf/astrazeneca-ab-bydureon-pen-4302024.pdf.

[13] *Id*.

[14] *Id*.

[15] National Library of Medicine, "Patents and Regulatory Exclusivities on Inhalers for Asthma and COPD, 1986-2020," William Feldman, Doni Bloomfield, Reed Beall, and Aaron Kesselheim, May 17, 2022, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10328096/; American Economic Liberties Project, "The Costs of

tactics can drive up drug prices, contribute to higher premiums and out-of-pocket costs for patients, and increase costs for Medicare and Medicaid. For example, U.S. patients and payers spent an additional $40.07 billion on pharmaceutical products "as a result of antitrust violations by the pharmaceutical industry" in 2019.[16] And the Medicare Part D program spent more than $600,000on the Bydureon Pen in 2022 alone.[17]

We have long been concerned by these and other pharmaceutical industry abuses of the patent system to stifle competition, prolong drug monopolies, and price-gouge patients.[18] FDA has acknowledged these Orange Book-related issues[19] and taken some steps to "ensure[] our system, as a whole, is not used to improperly delay getting more affordable drugs and biosimilars into the hands of Americans who need them."[20] In September 2023, we encouraged the FTC to declare the listing of sham patent listings in the Orange Book an unfair method of competition, and in December 2023, we wrote to eight companies identified by the FTC as potentially violating the *Federal Trade Commission Act* (including AstraZeneca,) urging them to delist these improperly-listed patents.[21]

Now, in light of FTC's second notice disputing several of your company's patent listings, we request that you voluntarily de-list all of AstraZeneca AB's improperly- and inaccurately-listed

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Pharma Cheating," May 2023 https://www.economicliberties.us/wp-content/uploads/2023/05/AELP_052023_PharmaCheats_Report_FINAL.pdf.

[16] American Economic Liberties Project and Initiative for Medicines, Access, and Knowledge (I-MAK), "The Costs of Pharma Cheating," May 2023, p. 2, https://www.economicliberties.us/wp-content/uploads/2023/05/AELP_052023_PharmaCheats_Report_FINAL.pdf.

[17] Centers for Medicare & Medicaid Services, "Medicare Part D Spending by Drug," 2022, https://data.cms.gov/summary-statistics-on-use-and-payments/medicare-medicaid-spending-by-drug/medicare-part-d-spending-by-drug//data.

[18] Letters from Senator Warren and Representative Jayapal to AbbVie, AstraZeneca, Boehringer Ingelheim Pharmaceuticals, GlaxoSmithKline, Amneal Pharmaceuticals (Impax), Kaléo, Viatris (Mylan), and Teva/Norton, December 13, 2023, https://www.warren.senate.gov/imo/media/doc/orange%20book_combinedpdf.pdf; Office of U.S. Senator Elizabeth Warren, "Warren, Jayapal Call on Patent Office to Take Critical Steps to Lower Drug Prices and Fight Big Pharma's Patent Abuse," press release, April 27, 2023, https://www.warren.senate.gov/oversight/letters/warren-jayapal-call-on-patent-office-to-take-critical-steps-to-lower-drug-prices-and-fight-big-pharmas-patent-abuse; Office of U.S. Senator Elizabeth Warren, "Senator Warren, Representative Jayapal Urge FDA to Hold Big Pharma Accountable for Abuse of Patent System, Profiteering at Patients' Expense," press release, August 29, 2023, https://www.warren.senate.gov/oversight/letters/senator-warren-representative-jayapal-urge-fda-to-hold-big-pharma-accountable-for-abuse-of-patent-system-profiteering-at-patients-expense.

[19] U.S. Food and Drug Administration, "The Listing of Patent Information in the Orange Book," January 5, 2022, pp. 21-22, https://www.fda.gov/media/155200/download; U.S. Food and Drug Administration, Federal Register Notice, "Listing of Patent Information in the Orange Book; Establishment of a Public Docket; Request for Comments," June 1, 2020, https://www.federalregister.gov/documents/2020/06/01/2020-11684/listing-of-patent-information-in-the-orangebook-establishment-of-a-public-docket-request-for.

[20] U.S. Patent and Trademark Office, "USPTO – FDA Collaboration Initiatives," https://www.uspto.gov/initiatives/fda-collaboration.

[21] Office of U.S. Senator Elizabeth Warren, "Warren, Jayapal Urge FTC to Rein in Big Pharma Abuses of Patent System," press release, September 14, 2023, https://www.warren.senate.gov/oversight/letters/warren-jayapal-urge-ftc-to-rein-in-big-pharma-abuses-of-patent-system; Letters from Senator Warren and Representative Jayapal to AbbVie, AstraZeneca, Boehringer Ingelheim Pharmaceuticals, GlaxoSmithKline, Amneal Pharmaceuticals (Impax), Kaléo, Viatris (Mylan), and Teva/Norton, December 13, 2023, https://www.warren.senate.gov/imo/media/doc/orange%20book_combinedpdf.pdf.

Orange Book patents by June 8, 2024 and provide responses to the following questions by no later than June 20, 2024.

1. In its April 2024 letter, the FTC identified eight patents for the Bydureon Pen that have been improperly or inaccurately listed in the Orange Book.
    a. Has AstraZeneca AB ever taken action to enforce any of these patents against any other drug manufacturer? If so, please list all such actions, and their outcome.
    b. During the time period in which you were challenging these patents, or in the ensuing 30-month period in which you were granted a stay that delayed approval of a generic competitor to one of these drugs, what were total sales (in dollars) of these drugs? What were total sales to Medicare and Medicaid?
2. Will AstraZeneca AB voluntarily de-list the eight patents you have listed in the Orange Book with regard to the Bydureon Pen products that the FTC has disputed as being improperly or inaccurately listed?
    a. Please specify which ones you will de-list.
    b. What is your specific timeline for doing so?
3. Will AstraZeneca AB voluntarily review and de-list additional patents the company has listed in the Orange Book that are improperly or inaccurately listed?
    a. Please specify which ones you will de-list.
    b. What is your specific timeline for doing so?

Sincerely,

Elizabeth Warren
United States Senator

Pramila Jayapal
Member of Congress

Congress of the United States

Washington, DC 20515

June 6, 2024

Hubertus von Baumbach
Chairman and CEO
Boehringer Ingelheim Pharmaceuticals
900 Ridgebury Road
Ridgefield, CT 06877

Jean-Michel Boers
U.S. Managing Director, President, and CEO
Boehringer Ingelheim Pharmaceuticals
900 Ridgebury Road
Ridgefield, CT 06877

Dear Mr. von Baumbach and Mr. Boers:

We write today regarding the Federal Trade Commission's (FTC) April 30, 2024 letter indicating that "certain patents [may] have been improperly or inaccurately listed in the Orange Book with regard to Boehringer Ingelheim Pharmaceuticals, Inc.'s Striverdi and Stiolto Respimat products."[1] This is another indication from FTC that Boehringer Ingelheim has been abusing the patent system to profit at patients' and taxpayers' expense by charging exorbitant prices — this time for inhalation spray medication that helps control symptoms in adults with chronic obstructive pulmonary disease.[2] We applaud the FTC's leadership in challenging "junk" patent listings that, together with other anticompetitive conduct, cost consumers and the U.S. health care system billions of dollars each year.[3]

This is the second time in the past six months that the FTC has written to you regarding sham patent listings in the Orange Book.[4] After a similar set of letter from FTC directed at inhaler medications in November 2023, we urged you to de-list Boehringer Ingelheim**'s** Atrovent HFA, Combivent Respimat, Spiriva, and Spiriva Respimat products and all other improper and inaccurate listings.[5] Several other companies de-listed their patents following FTC and congressional scrutiny, but you have refused to do so, delaying the approval of generic versions

[1] Letter from U.S. Federal Trade Commission to Boehringer Ingelheim, April 30, 2024, p. 1, https://www.ftc.gov/system/files/ftc_gov/pdf/boehringer-striverdi-stiolto-4302024.pdf ; U.S. Federal Trade Commission, "FTC Expands Patent Listing Challenges, Targeting More Than 300 Junk Listings for Diabetes, Weight Loss, Asthma and COPD Drugs," press release, April 30, 2024, https://www.ftc.gov/news-events/news/press-releases/2024/04/ftc-expands-patent-listing-challenges-targeting-more-300-junk-listings-diabetes-weight-loss-asthma.

[2] RxList, STRIVERDI RESPIMAT, last updated November 10, 2021, https://www.rxlist.com/striverdi-respimat-drug.htm; RxList, STIOLTO RESPIMAT, last updated July 13, 2021, https://www.rxlist.com/stiolto-respimat-drug.htm .

[3] American Economic Liberties Project, "The Costs of Pharma Cheating," May 2023, https://www.economicliberties.us/wp-content/uploads/2023/05/AELP_052023_PharmaCheats_Report_FINAL.pdf.

[4] Letter from U.S. Federal Trade Commission to Boehringer Ingelheim Pharmaceuticals, Inc., November 7, 2023, https://www.ftc.gov/system/files/ftc_gov/pdf/boehringer-ingelheim-orange-book.pdf ; U.S. Federal Trade Commission, "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.

[5] Letters from Senator Warren and Representative Jayapal to AbbVie, AstraZeneca, Boehringer Ingelheim, GlaxoSmithKline, Amneal Pharmaceuticals (Impax), Kaleo, Viatris (Mylan), and Teva/Norton, December 13, 2023, https://www.warren.senate.gov/imo/media/doc/orange%20book_combinedpdf.pdf.

of the patents listed, and potentially violating the law.[6] Accordingly, we again write to ask that you address the improper behavior identified by the FTC by June 8, 2024.

In September 2023, the FTC issued a policy statement that "improper patent listings may unlawfully delay generic competition for years and disincentivize generic manufacturers from trying to come to market with lower cost alternatives."[7] The Orange Book contains a list of drugs approved by the Food and Drug Administration (FDA) and related patent and exclusivity information, covering drug substances, drug products, and method of use.[8] If a brand-name drug company sues a generic manufacturer for infringing on a patent listed in the Orange Book, the FDA is barred from approving a generic version of the drug for 30 months.[9] Powerful Big Pharma players are therefore incentivized to strategically use sham patent listings in the Orange Book to hold off generic competition — increasing drug and health care costs for patients and driving up insurance premiums.[10]

The FTC pledged to scrutinize companies that engage in these practices for violating Section 5 of the *Federal Trade Commission Act*,[11] and in April issued a second warning letter to Boehringer Ingelheim that appears to conclude that the company may be violating federal law with regard to ten more drug listings for Striverdi and Stiolto Respimat products.[12] Given these concerns, we again urge you to voluntarily de-list the ten patents named in the FTC's letter, and any other patents you have listed that unfairly block competition.[13] As the FTC noted, Boehringer Ingelheim "bears the burden of listing patents in the Orange Book accurately and in accordance with all relevant statutory and regulatory requirements."[14]

The practices that FTC has highlighted in its warning letters are a prime example of how pharmaceutical companies — including Boehringer Ingelheim — regularly employ anticompetitive tactics to extend their government-granted monopolies, insulate themselves from

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[6] FDA Law Blog, "Drugs Companies Clap Back at Congress…Then Get Sued," Sara W. Koblitz, March 13, 2024, https://www.thefdalawblog.com/2024/03/drugs-companies-clap-back-at-congressthen-get-sued/; Food and Drug Administration, "Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations," https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm.

[7] U.S. Federal Trade Commission, "FTC Issues Policy Statement on Brand Pharmaceutical Manufacturers' Improper Listing of Patents in the Food and Drug Administration's 'Orange Book'," press release, September 14, 2023, https://www.ftc.gov/news-events/news/press-releases/2023/09/ftc-issues-policy-statement-brand-pharmaceutical-manufacturers-improper-listing-patents-food-drug.

[8] U.S. Food and Drug Administration, "Approved Drug Products with Therapeutic Equivalence Evaluations | Orange Book," updated December 8, 2023, https://www.fda.gov/drugs/drug-approvals-and-databases/approved-drug-products-therapeutic-equivalence-evaluations-orange-book.

[9] United States District Court for the District of Delaware, "Federal Trade Commission's Brief as *Amicus Curiae*," November 10, 2022, p. 1, https://www.ftc.gov/system/files/ftc_gov/pdf/P163500JazzPharmaAmicusBrief.pdf.

[10] U.S. Federal Trade Commission, "Federal Trade Commission Statement Concerning Brand Drug Manufacturers' Improper Listing of Patents in the Orange Book," p. 4, https://www.ftc.gov/system/files/ftc_gov/pdf/p239900orangebookpolicystatement092023.pdf; Center for American Progress, "Following the Money: Untangling U.S. Prescription Drug Financing," Sam Hughes and Nicole Rapfogel, October 12, 2023, https://www.americanprogress.org/article/following-the-money-untangling-u-s-prescription-drug-financing/.

[11] *Id.;* 15 U.S.C. §§ 41-58.

[12] Letter from U.S. Federal Trade Commission to Boehringer Ingelheim, April 30, 2024, https://www.ftc.gov/system/files/ftc_gov/pdf/boehringer-striverdi-stiolto-4302024.pdf.

[13] *Id*.

[14] *Id*.

generic and biosimilar competition, and keep prices artificially high.[15] Drug manufacturers' patent gaming tactics can drive up drug prices, contribute to higher premiums and out-of-pocket costs for patients, and increase costs for Medicare and Medicaid. For example, U.S. patients and payers spent an additional $40.07 billion on pharmaceutical products "as a result of antitrust violations by the pharmaceutical industry" in 2019.[16] And the Medicare Part D program spent nearly $400 million on Stiolto Respimat products and $5 million on Striverdi products in 2022 alone.[17]

We have long been concerned by these and other pharmaceutical industry abuses of the patent system to stifle competition, prolong drug monopolies, and price-gouge patients.[18] FDA has acknowledged these Orange Book-related issues[19] and taken some steps to "ensure[] our system, as a whole, is not used to improperly delay getting more affordable drugs and biosimilars into the hands of Americans who need them."[20] In September 2023, we encouraged the FTC to declare sham patent listings in the Orange Book an unfair method of competition, and in December 2023, we wrote to eight companies identified by the FTC as potentially violating the *Federal Trade Commission Act* (including Boehringer Ingelheim), urging them to de-list these improperly-listed patents.[21]

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[15] National Library of Medicine, "Patents and Regulatory Exclusivities on Inhalers for Asthma and COPD, 1986-2020," William Feldman, Doni Bloomfield, Reed Beall, and Aaron Kesselheim, May 17, 2022, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10328096/; American Economic Liberties Project, "The Costs of Pharma Cheating," May 2023 https://www.economicliberties.us/wp-content/uploads/2023/05/AELP_052023_PharmaCheats_Report_FINAL.pdf.

[16] American Economic Liberties Project and Initiative for Medicines, Access, and Knowledge (I-MAK), "The Costs of Pharma Cheating," May 2023, p. 2, https://www.economicliberties.us/wp-content/uploads/2023/05/AELP_052023_PharmaCheats_Report_FINAL.pdf.

[17] Centers for Medicare & Medicaid Services, "Medicare Part D Spending by Drug," 2022, https://data.cms.gov/summary-statistics-on-use-and-payments/medicare-medicaid-spending-by-drug/medicare-part-d-spending-by-drug//data.

[18] Letters from Senator Warren and Representative Jayapal to AbbVie, AstraZeneca, Boehringer Ingelheim Pharmaceuticals, GlaxoSmithKline, Amneal Pharmaceuticals (Impax), Kaléo, Viatris (Mylan), and Teva/Norton, December 13, 2023, https://www.warren.senate.gov/imo/media/doc/orange%20book_combinedpdf.pdf; Office of U.S. Senator Elizabeth Warren, "Warren, Jayapal Call on Patent Office to Take Critical Steps to Lower Drug Prices and Fight Big Pharma's Patent Abuse," press release, April 27, 2023, https://www.warren.senate.gov/oversight/letters/warren-jayapal-call-on-patent-office-to-take-critical-steps-to-lower-drug-prices-and-fight-big-pharmas-patent-abuse; Office of U.S. Senator Elizabeth Warren, "Senator Warren, Representative Jayapal Urge FDA to Hold Big Pharma Accountable for Abuse of Patent System, Profiteering at Patients' Expense," press release, August 29, 2023, https://www.warren.senate.gov/oversight/letters/senator-warren-representative-jayapal-urge-fda-to-hold-big-pharma-accountable-for-abuse-of-patent-system-profiteering-at-patients-expense.

[19] U.S. Food and Drug Administration, "The Listing of Patent Information in the Orange Book," January 5, 2022, pp. 21-22, https://www.fda.gov/media/155200/download; U.S. Food and Drug Administration, Federal Register Notice, "Listing of Patent Information in the Orange Book; Establishment of a Public Docket; Request for Comments," June 1, 2020, https://www.federalregister.gov/documents/2020/06/01/2020-11684/listing-of-patent-information-in-the-orangebook-establishment-of-a-public-docket-request-for.

[20] U.S. Patent and Trademark Office, "USPTO – FDA Collaboration Initiatives," https://www.uspto.gov/initiatives/fda-collaboration.

[21] Office of U.S. Senator Elizabeth Warren, "Warren, Jayapal Urge FTC to Rein in Big Pharma Abuses of Patent System," press release, September 14, 2023, https://www.warren.senate.gov/oversight/letters/warren-jayapal-urge-ftc-to-rein-in-big-pharma-abuses-of-patent-system; Letters from Senator Warren and Representative Jayapal to AbbVie, AstraZeneca, Boehringer Ingelheim Pharmaceuticals, GlaxoSmithKline, Amneal Pharmaceuticals (Impax), Kaléo, Viatris (Mylan), and Teva/Norton, December 13, 2023,

Now, in light of FTC's second notice disputing several of your company's patent listings, we request that you voluntarily de-list all of Boehringer Ingelheim's improperly- and inaccurately-listed Orange Book patents by June 8, 2024 and provide responses to the following questions by no later than June 8, 2024.

1. In its April 2024 letter, the FTC identified ten patents for the Striverdi and Stiolto Respimat products that have been improperly or inaccurately listed in the Orange Book.
    a. Has Boehringer Ingelheim ever taken action to enforce any of these patents against any other drug manufacturer? If so, please list all such actions, and their outcome.
    b. During the time period in which you were challenging these patents, or in the ensuing 30-month period in which you were granted a stay that delayed approval of a generic competitor to one of these drugs, what were total sales (in dollars) of these drugs? What were total sales to Medicare and Medicaid?
2. Will Boehringer Ingelheim voluntarily de-list the ten patents you have listed in the Orange Book with regard to the Striverdi and Stiolto Respimat products that the FTC has disputed as being improperly or inaccurately listed?
    a. Please specify which ones you will de-list.
    b. What is your specific timeline for doing so?
3. Will Boehringer Ingelheim voluntarily review and de-list additional patents the company has listed in the Orange Book that are improperly or inaccurately listed?
    a. Please specify which ones you will de-list.
    b. What is your specific timeline for doing so?

Sincerely,

Elizabeth Warren
United States Senator

Pramila Jayapal
Member of Congress

https://www.warren.senate.gov/imo/media/doc/orange%20book_combinedpdf.pdf.

Congress of the United States

Washington, DC 20515

June 6, 2024

Michael Porter
Chief Executive Officer
Covis Pharmaceuticals, Inc.
1513 Walnut Street, Suite 270
Cary, NC 27511

Dear Mr. Porter:

We write today regarding the Federal Trade Commission's (FTC) April 30, 2024 letter indicating that "certain patents [may] have been improperly or inaccurately listed in the Orange Book with regard to Covis Pharma's Tudorza and Duaklir Pressair products."[1] This is an indication from FTC that Covis Pharma has been abusing the patent system to profit at patients' and taxpayers' expense by charging exorbitant prices –for chronic obstructive pulmonary disease (COPD) inhalers.[2] We applaud the FTC's leadership in challenging "junk" patent listings that, together with other anticompetitive conduct, cost consumers and the U.S. health care system billions of dollars each year.[3] Accordingly, we write to ask that you address the improper behavior identified by the FTC by June 8, 2024.

In September 2023, the FTC issued a policy statement that "improper patent listings may unlawfully delay generic competition for years and disincentivize generic manufacturers from trying to come to market with lower cost alternatives."[4] The Orange Book contains a list of drugs approved by the Food and Drug Administration (FDA) and related patent and exclusivity information, covering drug substances, drug products, and method of use.[5] If a brand-name drug company sues a generic manufacturer for infringing on a patent listed in the Orange Book, the

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[1] Letter from U.S. Federal Trade Commission to Covis Pharma, April 30, 2024, p. 1, https://www.ftc.gov/system/files/ftc_gov/pdf/covis-pharma-tudorza-and-duaklir-4302024.pdf ; U.S. Federal Trade Commission, "FTC Expands Patent Listing Challenges, Targeting More Than 300 Junk Listings for Diabetes, Weight Loss, Asthma and COPD Drugs," press release, April 30, 2024, https://www.ftc.gov/news-events/news/press-releases/2024/04/ftc-expands-patent-listing-challenges-targeting-more-300-junk-listings-diabetes-weight-loss-asthma.

[2] RxList, "TUDORZA PRESSAIR," last updated August 11, 2023, https://www.rxlist.com/tudorza-pressair-drug.htm ; RxList, "DUAKLIR PRESSAIR," last updated February 21, 2024, https://www.rxlist.com/duaklir-pressair-drug.htm.

[3] American Economic Liberties Project, "The Costs of Pharma Cheating," May 2023, p. 2, https://www.economicliberties.us/wp-content/uploads/2023/05/AELP_052023_PharmaCheats_Report_FINAL.pdf.

[4] U.S. Federal Trade Commission, "FTC Issues Policy Statement on Brand Pharmaceutical Manufacturers' Improper Listing of Patents in the Food and Drug Administration's 'Orange Book'," press release, September 14, 2023, https://www.ftc.gov/news-events/news/press-releases/2023/09/ftc-issues-policy-statement-brand-pharmaceutical-manufacturers-improper-listing-patents-food-drug.

[5] U.S. Food and Drug Administration, "Approved Drug Products with Therapeutic Equivalence Evaluations | Orange Book," updated December 8, 2023, https://www.fda.gov/drugs/drug-approvals-and-databases/approved-drug-products-therapeutic-equivalence-evaluations-orange-book.

FDA is barred from approving a generic version of the drug for 30 months.[6] Powerful Big Pharma players are therefore incentivized to strategically use sham patent listings in the Orange Book to hold off generic competition — increasing drug and health care costs for patients and driving up insurance premiums.[7]

The FTC pledged to scrutinize companies that engage in these practices for violating Section 5 of the *Federal Trade Commission Act*,[8] and in April issued a warning letter to Covis Pharma that appears to conclude that the company may be violating federal law with regard to two drug listings for Tudorza and Duaklir Pressair products.[9] Given these concerns, we urge you to voluntarily de-list the two patents named in the FTC's letter, and any other patents you have listed that unfairly block competition.[10] As the FTC noted, Covis Pharma "bears the burden of listing patents in the Orange Book accurately and in accordance with all relevant statutory and regulatory requirements."[11]

The practices that the FTC has highlighted in its warning letter are a prime example of how pharmaceutical companies — including Covis Pharma — regularly employ anticompetitive tactics to extend their government-granted monopolies, insulate themselves from generic and biosimilar competition, and keep prices artificially high.[12] Drug manufacturers' patent gaming tactics can drive up drug prices, contribute to higher premiums and out-of-pocket costs for patients, and increase costs for Medicare and Medicaid. For example, U.S. patients and payers spent an additional $40.07 billion on pharmaceutical products "as a result of antitrust violations by the pharmaceutical industry" in 2019.[13] And the Medicare Part D program spent nearly $15 million on Tudorza and Duaklir Pressair products in 2022 alone.[14]

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[6] United States District Court for the District of Delaware, "Federal Trade Commission's Brief as *Amicus Curiae*," November 10, 2022, p. 1, https://www.ftc.gov/system/files/ftc_gov/pdf/P163500JazzPharmaAmicusBrief.pdf.

[7] U.S. Federal Trade Commission, "Federal Trade Commission Statement Concerning Brand Drug Manufacturers' Improper Listing of Patents in the Orange Book," p. 4, https://www.ftc.gov/system/files/ftc_gov/pdf/p239900orangebookpolicystatement092023.pdf; Center for American Progress, "Following the Money: Untangling U.S. Prescription Drug Financing," Sam Hughes and Nicole Rapfogel, October 12, 2023, https://www.americanprogress.org/article/following-the-money-untangling-u-s-prescription-drug-financing/.

[8] *Id.;* 15 U.S.C. §§ 41-58.

[9] Letter from U.S. Federal Trade Commission to Covis Pharma, April 30, 2024, https://www.ftc.gov/system/files/ftc_gov/pdf/covis-pharma-tudorza-and-duaklir-4302024.pdf.

[10] *Id*.

[11] *Id*.

[12] National Library of Medicine, "Patents and Regulatory Exclusivities on Inhalers for Asthma and COPD, 1986-2020," William Feldman, Doni Bloomfield, Reed Beall, and Aaron Kesselheim, May 17, 2022, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10328096/; American Economic Liberties Project, "The Costs of Pharma Cheating," May 2023 https://www.economicliberties.us/wp-content/uploads/2023/05/AELP_052023_PharmaCheats_Report_FINAL.pdf..

[13] American Economic Liberties Project and Initiative for Medicines, Access, and Knowledge (I-MAK), "The Costs of Pharma Cheating," May 2023, p. 2, https://www.economicliberties.us/wp-content/uploads/2023/05/AELP_052023_PharmaCheats_Report_FINAL.pdf.

[14] Centers for Medicare & Medicaid Services, "Medicare Part D Spending by Drug," 2022, https://data.cms.gov/summary-statistics-on-use-and-payments/medicare-medicaid-spending-by-drug/medicare-part-d-spending-by-drug//data.

We have long been concerned by these and other pharmaceutical industry abuses of the patent system to stifle competition, prolong drug monopolies, and price-gouge patients.[15] FDA has acknowledged these Orange Book-related issues[16] and taken some steps to "ensure[] our system, as a whole, is not used to improperly delay getting more affordable drugs and biosimilars into the hands of Americans who need them."[17] In September 2023, we encouraged the FTC to declare sham patent listings in the Orange Book an unfair method of competition, and in December 2023, we wrote to eight companies identified by the FTC as potentially violating the *Federal Trade Commission Act*, urging them to delist these improperly-listed patents.[18]

Now, in light of FTC's notice disputing several of your company's patent listings, we request that you voluntarily de-list all of Covis Pharma's improperly- and inaccurately-listed Orange Book patents by June 8, 2024 and provide responses to the following questions by no later than June 20, 2024.

1. In its April 2024 letter, the FTC identified two patents for the Tudorza and Duaklir Pressair products that have been improperly or inaccurately listed in the Orange Book.
    a. Has Covis Pharma ever taken action to enforce any of these patents against any other drug manufacturer? If so, please list all such actions, and their outcome.
    b. During the time period in which you were challenging these patents, or in the ensuing 30-month period in which you were granted a stay that delayed approval of a generic competitor to one of these drugs, what were total sales (in dollars) of these drugs? What were total sales to Medicare and Medicaid?
2. Will Covis Pharma voluntarily de-list the two patents you have listed in the Orange Book with regard to the Tudorza and Duaklir Pressair products that the FTC has disputed as being improperly or inaccurately listed?

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[15] Letters from Senator Warren and Representative Jayapal to AbbVie, AstraZeneca, Boehringer Ingelheim Pharmaceuticals, GlaxoSmithKline, Amneal Pharmaceuticals (Impax), Kaléo, Viatris (Mylan), and Teva/Norton, December 13, 2023, https://www.warren.senate.gov/imo/media/doc/orange%20book_combinedpdf.pdf; Office of U.S. Senator Elizabeth Warren, "Warren, Jayapal Call on Patent Office to Take Critical Steps to Lower Drug Prices and Fight Big Pharma's Patent Abuse," press release, April 27, 2023, https://www.warren.senate.gov/oversight/letters/warren-jayapal-call-on-patent-office-to-take-critical-steps-to-lower-drug-prices-and-fight-big-pharmas-patent-abuse; Office of U.S. Senator Elizabeth Warren, "Senator Warren, Representative Jayapal Urge FDA to Hold Big Pharma Accountable for Abuse of Patent System, Profiteering at Patients' Expense," press release, August 29, 2023, https://www.warren.senate.gov/oversight/letters/senator-warren-representative-jayapal-urge-fda-to-hold-big-pharma-accountable-for-abuse-of-patent-system-profiteering-at-patients-expense.

[16] U.S. Food and Drug Administration, "The Listing of Patent Information in the Orange Book," January 5, 2022, pp. 21-22, https://www.fda.gov/media/155200/download; U.S. Food and Drug Administration, Federal Register Notice, "Listing of Patent Information in the Orange Book; Establishment of a Public Docket; Request for Comments," June 1, 2020, https://www.federalregister.gov/documents/2020/06/01/2020-11684/listing-of-patent-information-in-the-orangebook-establishment-of-a-public-docket-request-for.

[17] U.S. Patent and Trademark Office, "USPTO – FDA Collaboration Initiatives," https://www.uspto.gov/initiatives/fda-collaboration.

[18] Office of U.S. Senator Elizabeth Warren, "Warren, Jayapal Urge FTC to Rein in Big Pharma Abuses of Patent System," press release, September 14, 2023, https://www.warren.senate.gov/oversight/letters/warren-jayapal-urge-ftc-to-rein-in-big-pharma-abuses-of-patent-system; Letters from Senator Warren and Representative Jayapal to AbbVie, AstraZeneca, Boehringer Ingelheim Pharmaceuticals, GlaxoSmithKline, Amneal Pharmaceuticals (Impax), Kaléo, Viatris (Mylan), and Teva/Norton, December 13, 2023, https://www.warren.senate.gov/imo/media/doc/orange%20book_combinedpdf.pdf.

a. Please specify which ones you will de-list.
b. What is your specific timeline for doing so?

3. Will Covis Pharma voluntarily review and de-list additional patents the company has listed in the Orange Book that are improperly or inaccurately listed?
    a. Please specify which ones you will de-list.
    b. What is your specific timeline for doing so?

Sincerely,

Elizabeth Warren
United States Senator

Pramila Jayapal
Member of Congress

Congress of the United States

Washington, DC 20515

June 6, 2024

Emma Walmsley
Chief Executive Officer
GlaxoSmithKline
2929 Walnut Street
Philadelphia, PA 19104

Dear Ms. Walmsley:

We write today regarding the Federal Trade Commission's (FTC) April 30, 2024 and May 2, 2024 letters indicating that "certain patents [may] have been improperly or inaccurately listed in the Orange Book" with regard to GlaxoSmithKline Intellectual Property Development's and Glaxo Group Limited's Anoro, Trelegy, Breo, and Incruse Ellipta products."[1] This is another indication from FTC that GlaxoSmithKline has been abusing the patent system to profit at patients' and taxpayers' expense by charging exorbitant prices – this time for lifesaving inhaler products used to prevent and control symptoms caused by chronic obstructive pulmonary disease (COPD).[2] We applaud the FTC's leadership in challenging "junk" patent listings that, together with other anticompetitive conduct, cost consumers and the U.S. health care system billions of dollars each year.[3]

This is the second time in the past six months that the FTC has written to you regarding sham patent listings in the Orange Book.[4] After a similar set of letters from FTC directed at inhaler medications in November 2023, we urged you to de-list GlaxoSmithKline's Arnuity Ellipta, Ventolin HFA, Advair HFA, and Flovent HFA products and all other improper and inaccurate listings.[5] We appreciate that GlaxoSmithKline has since de-listed its Ventolin HFA, Advair

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[1] Letter from U.S. Federal Trade Commission to GlaxoSmithKline, April 30, 2024, p. 1, https://www.ftc.gov/system/files/ftc_gov/pdf/gsk-intel-prop-dev-anoro-and-trelegy-ellipta-4302024.pdf; Letter from U.S. Federal Trade Commission to Glaxo Group Limited, May 2, 2024, p. 1, https://www.ftc.gov/system/files/ftc_gov/pdf/glaxo-grp-ltd-breo-and-incruse-4302024.pdf; U.S. Federal Trade Commission, "FTC Expands Patent Listing Challenges, Targeting More Than 300 Junk Listings for Diabetes, Weight Loss, Asthma and COPD Drugs," press release, April 30, 2024, https://www.ftc.gov/news-events/news/press-releases/2024/04/ftc-expands-patent-listing-challenges-targeting-more-300-junk-listings-diabetes-weight-loss-asthma.

[2] RxList, "ANORO ELLIPTA," last updated January 3, 2023, https://www.rxlist.com/anoro-ellipta-drug.htm; RxList, "TRELEGY ELLIPTA," last updated August 16, 2023, https://www.rxlist.com/trelegy-ellipta-drug.htm; RxList, "BREO ELLIPTA," June 5, 2023, https://www.rxlist.com/breo-ellipta-drug.htm; RxList, "INCRUSE ELLIPTA," last updated January 8, 2024, https://www.rxlist.com/incruse-ellipta-drug.htm.

[3] American Economic Liberties Project, "The Costs of Pharma Cheating," May 2023, p. 2, https://www.economicliberties.us/wp-content/uploads/2023/05/AELP_052023_PharmaCheats_Report_FINAL.pdf.

[4] Letter from FTC to GlaxoSmithKline, November 7, 2023, https://www.ftc.gov/system/files/ftc_gov/pdf/glaxosmithkline-orange-book.pdf ; Letter from U.S. Federal Trade Commission to Glaxo Group Limited, November 7, 2023, https://www.ftc.gov/system/files/ftc_gov/pdf/glaxo-group-orange-book.pdf.

HFA, and Flovent HFA products.[6] However, Arnuity Ellipta remains listed in the Orange Book– delaying the approval of generic versions of the patents listed, and potentially violating the law.[7] Accordingly, we again write to ask that you address the improper behavior identified by the FTC by June 8, 2024.

In September 2023, the FTC issued a policy statement that "improper patent listings may unlawfully delay generic competition for years and disincentivize generic manufacturers from trying to come to market with lower cost alternatives."[8] The Orange Book contains a list of drugs approved by the Food and Drug Administration (FDA) and related patent and exclusivity information, covering drug substances, drug products, and method of use.[9] If a brand-name drug company sues a generic manufacturer for infringing on a patent listed in the Orange Book, the FDA is barred from approving a generic version of the drug for 30 months.[10] Powerful Big Pharma players are therefore incentivized to strategically use sham patent listings in the Orange Book to hold off generic competition — increasing drug and health care costs for patients and driving up insurance premiums.[11]

The FTC pledged to scrutinize companies that engage in these practices for violating Section 5 of the *Federal Trade Commission Act*,[12] and in April issued warning letters to GlaxoSmithKline and Glaxo Group Limited that appear to conclude that the company may be violating federal law with regard to eleven drug listings for Anoro, Trelegy, Breo, and Incruse Ellipta products.[13] Given these concerns, we again urge you to voluntarily de-list the eleven patents named in the FTC's letter, and any other patents you have listed that unfairly block competition.[14] As the FTC

[5] Letters from Senator Warren and Representative Jayapal to AbbVie, AstraZeneca, Boehringer Ingelheim Pharmaceuticals, GlaxoSmithKline, Amneal Pharmaceuticals (Impax), Kaléo, Viatris (Mylan), and Teva/Norton, December 13, 2023, https://www.warren.senate.gov/imo/media/doc/orange%20book_combinedpdf.pdf.

[6] FDA Law Blog, "Drugs Companies Clap Back at Congress…Then Get Sued," Sara W. Koblitz, March 13, 2024, https://www.thefdalawblog.com/2024/03/drugs-companies-clap-back-at-congressthen-get-sued/; Food and Drug Administration, "Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations," https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm.

[7] *Id*.

[8] U.S. Federal Trade Commission, "FTC Issues Policy Statement on Brand Pharmaceutical Manufacturers' Improper Listing of Patents in the Food and Drug Administration's 'Orange Book'," press release, September 14, 2023, https://www.ftc.gov/news-events/news/press-releases/2023/09/ftc-issues-policy-statement-brand-pharmaceutical-manufacturers-improper-listing-patents-food-drug.

[9] U.S. Food and Drug Administration, "Approved Drug Products with Therapeutic Equivalence Evaluations | Orange Book," updated December 8, 2023, https://www.fda.gov/drugs/drug-approvals-and-databases/approved-drug-products-therapeutic-equivalence-evaluations-orange-book.

[10] United States District Court for the District of Delaware, "Federal Trade Commission's Brief as *Amicus Curiae*," November 10, 2022, p. 1, https://www.ftc.gov/system/files/ftc_gov/pdf/P163500JazzPharmaAmicusBrief.pdf.

[11] U.S. Federal Trade Commission, "Federal Trade Commission Statement Concerning Brand Drug Manufacturers' Improper Listing of Patents in the Orange Book," p. 4, https://www.ftc.gov/system/files/ftc_gov/pdf/p239900orangebookpolicystatement092023.pdf; Center for American Progress, "Following the Money: Untangling U.S. Prescription Drug Financing," Sam Hughes and Nicole Rapfogel, October 12, 2023, https://www.americanprogress.org/article/following-the-money-untangling-u-s-prescription-drug-financing/.

[12] *Id.;* 15 U.S.C. §§ 41-58.

[13] Letter from U.S. Federal Trade Commission to GlaxoSmithKline, April 30, 2024, https://www.ftc.gov/system/files/ftc_gov/pdf/gsk-intel-prop-dev-anoro-and-trelegy-ellipta-4302024.pdf; Letter from U.S. Federal Trade Commission to Glaxo Group Limited, May 2, 2024, https://www.ftc.gov/system/files/ftc_gov/pdf/glaxo-grp-ltd-breo-and-incruse-4302024.pdf.

[14] *Id*.

noted, GlaxoSmithKline "bears the burden of listing patents in the Orange Book accurately and in accordance with all relevant statutory and regulatory requirements."[15]

The practices that FTC has highlighted in its warning letters are a prime example of how pharmaceutical companies — including GlaxoSmithKline — regularly employ anticompetitive tactics to extend their government-granted monopolies, insulate themselves from generic and biosimilar competition, and keep prices artificially high.[16] Drug manufacturers' patent gaming tactics can drive up drug prices, contribute to higher premiums and out-of-pocket costs for patients, and increase costs for Medicare and Medicaid. For example, U.S. patients and payers spent an additional $40.07 billion on pharmaceutical products "as a result of antitrust violations by the pharmaceutical industry" in 2019.[17] And the Medicare Part D program spent nearly $6 billion on Anoro, Trelegy, Breo, and Incruse Ellipta products in 2022 alone.[18]

We have long been concerned by these and other pharmaceutical industry abuses of the patent system to stifle competition, prolong drug monopolies, and price-gouge patients.[19] FDA has acknowledged these Orange Book-related issues[20] and taken some steps to "ensure[] our system, as a whole, is not used to improperly delay getting more affordable drugs and biosimilars into the hands of Americans who need them."[21] In September 2023, we encouraged the FTC to declare sham patent listings in the Orange Book an unfair method of competition, and in December 2023, we wrote to eight companies identified by the FTC as potentially violating the *Federal*

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[15] *Id*.

[16] National Library of Medicine, "Patents and Regulatory Exclusivities on Inhalers for Asthma and COPD, 1986-2020," William Feldman, Doni Bloomfield, Reed Beall, and Aaron Kesselheim, May 17, 2022, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10328096/; American Economic Liberties Project, "The Costs of Pharma Cheating," May 2023 https://www.economicliberties.us/wp-content/uploads/2023/05/AELP_052023_PharmaCheats_Report_FINAL.pdf.

[17] American Economic Liberties Project and Initiative for Medicines, Access, and Knowledge (I-MAK), "The Costs of Pharma Cheating," May 2023, p. 2, https://www.economicliberties.us/wp-content/uploads/2023/05/AELP_052023_PharmaCheats_Report_FINAL.pdf.

[18] Centers for Medicare & Medicaid Services, "Medicare Part D Spending by Drug," 2022, https://data.cms.gov/summary-statistics-on-use-and-payments/medicare-medicaid-spending-by-drug/medicare-part-d-spending-by-drug//data.

[19] Letters from Senator Warren and Representative Jayapal to AbbVie, AstraZeneca, Boehringer Ingelheim Pharmaceuticals, GlaxoSmithKline, Amneal Pharmaceuticals (Impax), Kaléo, Viatris (Mylan), and Teva/Norton, December 13, 2023, https://www.warren.senate.gov/imo/media/doc/orange%20book_combinedpdf.pdf; Office of U.S. Senator Elizabeth Warren, "Warren, Jayapal Call on Patent Office to Take Critical Steps to Lower Drug Prices and Fight Big Pharma's Patent Abuse," press release, April 27, 2023, https://www.warren.senate.gov/oversight/letters/warren-jayapal-call-on-patent-office-to-take-critical-steps-to-lower-drug-prices-and-fight-big-pharmas-patent-abuse; Office of U.S. Senator Elizabeth Warren, "Senator Warren, Representative Jayapal Urge FDA to Hold Big Pharma Accountable for Abuse of Patent System, Profiteering at Patients' Expense," press release, August 29, 2023, https://www.warren.senate.gov/oversight/letters/senator-warren-representative-jayapal-urge-fda-to-hold-big-pharma-accountable-for-abuse-of-patent-system-profiteering-at-patients-expense.

[20] U.S. Food and Drug Administration, "The Listing of Patent Information in the Orange Book," January 5, 2022, https://www.fda.gov/media/155200/download; U.S. Food and Drug Administration, Federal Register Notice, "Listing of Patent Information in the Orange Book; Establishment of a Public Docket; Request for Comments," June 1, 2020, https://www.federalregister.gov/documents/2020/06/01/2020-11684/listing-of-patent-information-in-the-orangebook-establishment-of-a-public-docket-request-for.

[21] U.S. Patent and Trademark Office, "USPTO – FDA Collaboration Initiatives," https://www.uspto.gov/initiatives/fda-collaboration.

Trade Commission Act (including GlaxoSmithKline,) urging them to de-list these improperly-listed patents.[22]

Now, in light of FTC's second notice disputing several of your company's patent listings, we request that you voluntarily de-list all of GlaxoSmithKline's improperly- and inaccurately-listed Orange Book patents by June 8, 2024 and provide responses to the following questions by no later than June 20, 2024.

1. In its April 2024 letter, the FTC identified eleven patents for Anoro, Trelegy, Breo, and Incruse Ellipta products that have been improperly or inaccurately listed in the Orange Book.
    a. Has GlaxoSmithKline ever taken action to enforce any of these patents against any other drug manufacturer? If so, please list all such actions, and their outcome.
    b. During the time period in which you were challenging these patents, or in the ensuing 30-month period in which you were granted a stay that delayed approval of a generic competitor to one of these drugs, what were total sales (in dollars) of these drugs? What were total sales to Medicare and Medicaid?
2. Will GlaxoSmithKline voluntarily de-list the eleven patents you have listed in the Orange Book with regard to the Anoro, Trelegy, Breo, and Incruse Ellipta products that the FTC has disputed as being improperly or inaccurately listed?
    a. Please specify which ones you will de-list.
    b. What is your specific timeline for doing so?
3. Will GlaxoSmithKline voluntarily review and de-list additional patents the company has listed in the Orange Book that are improperly or inaccurately listed?
    a. Please specify which ones you will de-list.
    b. What is your specific timeline for doing so?

Sincerely,

Elizabeth Warren
United States Senator

Pramila Jayapal
Member of Congress

[22] Office of U.S. Senator Elizabeth Warren, "Warren, Jayapal Urge FTC to Rein in Big Pharma Abuses of Patent System," press release, September 14, 2023, https://www.warren.senate.gov/oversight/letters/warren-jayapal-urge-ftc-to-rein-in-big-pharma-abuses-of-patent-system; Letters from Senator Warren and Representative Jayapal to AbbVie, AstraZeneca, Boehringer Ingelheim Pharmaceuticals, GlaxoSmithKline, Amneal Pharmaceuticals (Impax), Kaléo, Viatris (Mylan), and Teva/Norton, December 13, 2023, https://www.warren.senate.gov/imo/media/doc/orange%20book_combinedpdf.pdf.

Congress of the United States

Washington, DC 20515

June 6, 2024

Vasant Narasimhan
Chief Executive Officer
Novartis Pharmaceuticals Corporation
1 Health Plaza
East Hanover, New Jersey 07936

Dear Mr. Narasimhan:

We write today regarding the Federal Trade Commission's (FTC) April 30, 2024 letter indicating that "certain patents [may] have been improperly or inaccurately listed in the Orange Book with regard to Novartis Pharmaceuticals Corp.'s Seebri and Utibron products."[1] This is an indication from FTC that Novartis Pharmaceuticals Corp. has been abusing the patent system to profit at patients' and taxpayers' expense by charging exorbitant prices –for chronic obstructive pulmonary disease (COPD) inhalers.[2] We applaud the FTC's leadership in challenging "junk" patent listings that, together with other anticompetitive conduct, cost consumers and the U.S. health care system billions of dollars each year.[3] Accordingly, we write to ask that you address the improper behavior identified by the FTC by June 8, 2024.

In September 2023, the FTC issued a policy statement that "improper patent listings may unlawfully delay generic competition for years and disincentivize generic manufacturers from trying to come to market with lower cost alternatives."[4] The Orange Book contains a list of drugs approved by the Food and Drug Administration (FDA) and related patent and exclusivity information, covering drug substances, drug products, and method of use.[5] If a brand-name drug company sues a generic manufacturer for infringing on a patent listed in the Orange Book, the

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[1] Letter from U.S. Federal Trade Commission to Novartis Pharmaceuticals Corp., April 30, 2024, p. 1, https://www.ftc.gov/system/files/ftc_gov/pdf/novartis-seebri-and-utibron-4302024.pdf; U.S. Federal Trade Commission, "FTC Expands Patent Listing Challenges, Targeting More Than 300 Junk Listings for Diabetes, Weight Loss, Asthma and COPD Drugs," press release, April 30, 2024, https://www.ftc.gov/news-events/news/press-releases/2024/04/ftc-expands-patent-listing-challenges-targeting-more-300-junk-listings-diabetes-weight-loss-asthma.

[2] RxList, "SEEBRI NEOHALER," last updated June 27, 2022, https://www.rxlist.com/seebri-neohaler-drug.htm; RxList, "UTIBRON NEOHALER," last updated November 18, 2021, https://www.rxlist.com/utibron-neohaler-drug.htm.

[3] American Economic Liberties Project, "The Costs of Pharma Cheating," May 2023, p. 2, https://www.economicliberties.us/wp-content/uploads/2023/05/AELP_052023_PharmaCheats_Report_FINAL.pdf.

[4] U.S. Federal Trade Commission, "FTC Issues Policy Statement on Brand Pharmaceutical Manufacturers' Improper Listing of Patents in the Food and Drug Administration's 'Orange Book'," press release, September 14, 2023, https://www.ftc.gov/news-events/news/press-releases/2023/09/ftc-issues-policy-statement-brand-pharmaceutical-manufacturers-improper-listing-patents-food-drug.

[5] U.S. Food and Drug Administration, "Approved Drug Products with Therapeutic Equivalence Evaluations | Orange Book," updated December 8, 2023, https://www.fda.gov/drugs/drug-approvals-and-databases/approved-drug-products-therapeutic-equivalence-evaluations-orange-book.

FDA is barred from approving a generic version of the drug for 30 months.[6] Powerful Big Pharma players are therefore incentivized to strategically use sham patent listings in the Orange Book to hold off generic competition — increasing drug and health care costs for patients and driving up insurance premiums.[7]

The FTC pledged to scrutinize companies that engage in these practices for violating Section 5 of the *Federal Trade Commission Act*,[8] and in April issued a warning letter to Novartis Pharmaceuticals Corp. that appears to conclude that the company may be violating federal law with regard to two drug listings for Seebri and Utibron products.[9] Given these concerns, we urge you to voluntarily de-list the two patents named in the FTC's letter, and any other patents you have listed that unfairly block competition.[10] As the FTC noted, Novartis Pharmaceuticals Corp. "bears the burden of listing patents in the Orange Book accurately and in accordance with all relevant statutory and regulatory requirements."[11]

The practices that FTC has highlighted in its warning letter are a prime example of how pharmaceutical companies — including Novartis Pharmaceuticals Corp. — regularly employ anticompetitive tactics to extend their government-granted monopolies, insulate themselves from generic and biosimilar competition, and keep prices artificially high.[12] Drug manufacturers' patent gaming tactics can drive up drug prices, contribute to higher premiums and out-of-pocket costs for patients, and increase costs for Medicare and Medicaid. For example, U.S. patients and payers spent an additional $40.07 billion on pharmaceutical products "as a result of antitrust violations by the pharmaceutical industry" in 2019.[13]

We have long been concerned by these and other pharmaceutical industry abuses of the patent system to stifle competition, prolong drug monopolies, and price-gouge patients.[14] FDA has

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[6] United States District Court for the District of Delaware, "Federal Trade Commission's Brief as *Amicus Curiae*," November 10, 2022, p. 1, https://www.ftc.gov/system/files/ftc_gov/pdf/P163500JazzPharmaAmicusBrief.pdf.

[7] U.S. Federal Trade Commission, "Federal Trade Commission Statement Concerning Brand Drug Manufacturers' Improper Listing of Patents in the Orange Book," p. 4, https://www.ftc.gov/system/files/ftc_gov/pdf/p239900orangebookpolicystatement092023.pdf; Center for American Progress, "Following the Money: Untangling U.S. Prescription Drug Financing," Sam Hughes and Nicole Rapfogel, October 12, 2023, https://www.americanprogress.org/article/following-the-money-untangling-u-s-prescription-drug-financing/.

[8] *Id.;* 15 U.S.C. §§ 41-58.

[9] Letter from U.S. Federal Trade Commission to Novartis Pharmaceuticals Corp., April 30, 2024, https://www.ftc.gov/system/files/ftc_gov/pdf/novartis-seebri-and-utibron-4302024.pdf.

[10] *Id*.

[11] *Id*.

[12] National Library of Medicine, "Patents and Regulatory Exclusivities on Inhalers for Asthma and COPD, 1986-2020," William Feldman, Doni Bloomfield, Reed Beall, and Aaron Kesselheim, May 17, 2022, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10328096/; American Economic Liberties Project, "The Costs of Pharma Cheating," May 2023, https://www.economicliberties.us/wp-content/uploads/2023/05/AELP_052023_PharmaCheats_Report_FINAL.pdf..

[13] American Economic Liberties Project and Initiative for Medicines, Access, and Knowledge (I-MAK), "The Costs of Pharma Cheating," May 2023, p. 2, https://www.economicliberties.us/wp-content/uploads/2023/05/AELP_052023_PharmaCheats_Report_FINAL.pdf.

[14] Letters from Senator Warren and Representative Jayapal to AbbVie, AstraZeneca, Boehringer Ingelheim Pharmaceuticals, GlaxoSmithKline, Amneal Pharmaceuticals (Impax), Kaléo, Viatris (Mylan), and Teva/Norton, December 13, 2023, https://www.warren.senate.gov/imo/media/doc/orange%20book_combinedpdf.pdf; Office of U.S. Senator Elizabeth Warren, "Warren, Jayapal Call on Patent Office to Take Critical Steps to Lower Drug Prices

acknowledged these Orange Book-related issues[15] and taken some steps to "ensure[] our system, as a whole, is not used to improperly delay getting more affordable drugs and biosimilars into the hands of Americans who need them."[16] In September 2023, we encouraged the FTC to declare the sham patent listings in the Orange Book as an unfair method of competition, and in December 2023, we wrote to eight companies identified by the FTC as potentially violating the *Federal Trade Commission Act*, urging them to delist these improperly-listed patents.[17]

Now, in light of FTC's notice disputing several of your company's patent listings, we request that you voluntarily de-list all of Novartis Pharmaceuticals Corp.'s improperly- and inaccurately-listed Orange Book patents by June 8, 2024, and provide responses to the following questions by no later than June 20, 2024.

1. In its April 2024 letter, the FTC identified two patents for the Seebri and Utibron products that have been improperly or inaccurately listed in the Orange Book.
    a. Has Novartis Pharmaceuticals Corp. ever taken action to enforce any of these patents against any other drug manufacturer? If so, please list all such actions, and their outcome.
    b. During the time period in which you were challenging these patents, or in the ensuing 30-month period in which you were granted a stay that delayed approval of a generic competitor to one of these drugs, what were total sales (in dollars) of these drugs? What were total sales to Medicare and Medicaid?
2. Will Novartis Pharmaceuticals Corp. voluntarily de-list the two patents you have listed in the Orange Book with regard to the Seebri and Utibron products that the FTC has disputed as being improperly or inaccurately listed?
    a. Please specify which ones you will de-list.
    b. What is your specific timeline for doing so?

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and Fight Big Pharma's Patent Abuse," press release, April 27, 2023, https://www.warren.senate.gov/oversight/letters/warren-jayapal-call-on-patent-office-to-take-critical-steps-to-lower-drug-prices-and-fight-big-pharmas-patent-abuse; Office of U.S. Senator Elizabeth Warren, "Senator Warren, Representative Jayapal Urge FDA to Hold Big Pharma Accountable for Abuse of Patent System, Profiteering at Patients' Expense," press release, August 29, 2023, https://www.warren.senate.gov/oversight/letters/senator-warren-representative-jayapal-urge-fda-to-hold-big-pharma-accountable-for-abuse-of-patent-system-profiteering-at-patients-expense.

[15] U.S. Food and Drug Administration, "The Listing of Patent Information in the Orange Book," January 5, 2022, pp. 21-22https://www.fda.gov/media/155200/download; U.S. Food and Drug Administration, Federal Register Notice, "Listing of Patent Information in the Orange Book; Establishment of a Public Docket; Request for Comments," June 1, 2020, https://www.federalregister.gov/documents/2020/06/01/2020-11684/listing-of-patent-information-in-the-orangebook-establishment-of-a-public-docket-request-for.

[16] U.S. Patent and Trademark Office, "USPTO – FDA Collaboration Initiatives," https://www.uspto.gov/initiatives/fda-collaboration.

[17] Office of U.S. Senator Elizabeth Warren, "Warren, Jayapal Urge FTC to Rein in Big Pharma Abuses of Patent System," press release, September 14, 2023, https://www.warren.senate.gov/oversight/letters/warren-jayapal-urge-ftc-to-rein-in-big-pharma-abuses-of-patent-system; Letters from Senator Warren and Representative Jayapal to AbbVie, AstraZeneca, Boehringer Ingelheim Pharmaceuticals, GlaxoSmithKline, Amneal Pharmaceuticals (Impax), Kaléo, Viatris (Mylan), and Teva/Norton, December 13, 2023, https://www.warren.senate.gov/imo/media/doc/orange%20book_combinedpdf.pdf.

3. Will Novartis Pharmaceuticals Corp. voluntarily review and de-list additional patents the company has listed in the Orange Book that are improperly or inaccurately listed?
    a. Please specify which ones you will de-list.
    b. What is your specific timeline for doing so?

Sincerely,

Elizabeth Warren
United States Senator

Pramila Jayapal
Member of Congress

Congress of the United States

Washington, DC 20515

June 6, 2024

Lars Fruergaard Jørgensen
President and Chief Executive
Novo Nordisk A/S
Novo Alle 1
Bagsværd, Denmark 2880

Dear Mr. Jørgensen:

We write today regarding the Federal Trade Commission's (FTC) April 30, 2024 letter indicating that "certain patents [may] have been improperly or inaccurately listed in the Orange Book with regard to Novo Nordisk Inc.'s Ozempic, Saxenda, and Victoza products."[1] This is an indication from FTC that Novo Nordisk has been abusing the patent system to profit at patients' and taxpayers' expense by charging exorbitant prices for lifesaving obesity and type-2 diabetes injectable drugs.[2] We applaud the FTC's leadership in challenging "junk" patent listings that, together with other anticompetitive conduct, cost consumers and the U.S. health care system billions of dollars each year.[3] Accordingly, we write to ask that you address the improper behavior identified by the FTC by June 8, 2024.

In September 2023, the FTC issued a policy statement that "improper patent listings may unlawfully delay generic competition for years and disincentivize generic manufacturers from trying to come to market with lower cost alternatives."[4] The Orange Book contains a list of drugs approved by the Food and Drug Administration (FDA) and related patent and exclusivity information, covering drug substances, drug products, and method of use.[5] If a brand-name drug company sues a generic manufacturer for infringing on a patent listed in the Orange Book, the

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[1] Letter from U.S. Federal Trade Commission to Novo Nordisk, April 30, 2024, p. 1, https://www.ftc.gov/system/files/ftc_gov/pdf/novo-nordisk-ozempic-saxenda-victoza-_4302024.pdf ; U.S. Federal Trade Commission, "FTC Expands Patent Listing Challenges, Targeting More Than 300 Junk Listings for Diabetes, Weight Loss, Asthma and COPD Drugs," press release, April 30, 2024, https://www.ftc.gov/news-events/news/press-releases/2024/04/ftc-expands-patent-listing-challenges-targeting-more-300-junk-listings-diabetes-weight-loss-asthma.

[2] RxList, "OZEMPIC," last updated October 9, 2023, https://www.rxlist.com/ozempic-drug.htm; RxList, "SAXENDA," last updated May 1, 2023, https://www.rxlist.com/saxenda-drug.htm; RxList, "VICTOZA," last updated January 17, 2024, https://www.rxlist.com/victoza-drug.htm.

[3] American Economic Liberties Project, "The Costs of Pharma Cheating," May 2023, p. 2, https://www.economicliberties.us/wp-content/uploads/2023/05/AELP_052023_PharmaCheats_Report_FINAL.pdf.

[4] U.S. Federal Trade Commission, "FTC Issues Policy Statement on Brand Pharmaceutical Manufacturers' Improper Listing of Patents in the Food and Drug Administration's 'Orange Book'," press release, September 14, 2023, https://www.ftc.gov/news-events/news/press-releases/2023/09/ftc-issues-policy-statement-brand-pharmaceutical-manufacturers-improper-listing-patents-food-drug.

[5] U.S. Food and Drug Administration, "Approved Drug Products with Therapeutic Equivalence Evaluations | Orange Book," updated December 8, 2023, https://www.fda.gov/drugs/drug-approvals-and-databases/approved-drug-products-therapeutic-equivalence-evaluations-orange-book.

FDA is barred from approving a generic version of the drug for 30 months.[6] Powerful Big Pharma players are therefore incentivized to strategically use sham patent listings in the Orange Book to hold off generic competition — increasing drug and health care costs for patients and driving up insurance premiums.[7]

The FTC pledged to scrutinize companies that engage in these practices for violating Section 5 of the *Federal Trade Commission Act*,[8] and in April issued a warning letter to Novo Nordisk that appears to conclude that the company may be violating federal law with regard to thirty-six drug listings for Ozempic, Saxenda, and Victoza products.[9] Given these concerns, we urge you to voluntarily de-list the thirty-six patents named in the FTC's letter, and any other patents you have listed that unfairly block competition.[10] As the FTC noted, Novo Nordisk "bears the burden of listing patents in the Orange Book accurately and in accordance with all relevant statutory and regulatory requirements."[11]

The practices that FTC has highlighted in its warning letter are a prime example of how pharmaceutical companies — including Novo Nordisk — regularly employ anticompetitive tactics to extend their government-granted monopolies, insulate themselves from generic and biosimilar competition, and keep prices artificially high.[12] Drug manufacturers' patent gaming tactics can drive up drug prices, contribute to higher premiums and out-of-pocket costs for patients, and increase costs for Medicare and Medicaid. For example, U.S. patients and payers spent an additional $40.07 billion on pharmaceutical products "as a result of antitrust violations by the pharmaceutical industry" in 2019.[13] And the Medicare Part D program spent almost $5 billion on Ozempic and $1.5 billion on Victoza products in 2022 alone.[14]

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[6] United States District Court for the District of Delaware, "Federal Trade Commission's Brief as *Amicus Curiae*," November 10, 2022, p. 1, https://www.ftc.gov/system/files/ftc_gov/pdf/P163500JazzPharmaAmicusBrief.pdf.

[7] U.S. Federal Trade Commission, "Federal Trade Commission Statement Concerning Brand Drug Manufacturers' Improper Listing of Patents in the Orange Book," p. 4, https://www.ftc.gov/system/files/ftc_gov/pdf/p239900orangebookpolicystatement092023.pdf; Center for American Progress, "Following the Money: Untangling U.S. Prescription Drug Financing," Sam Hughes and Nicole Rapfogel, October 12, 2023, https://www.americanprogress.org/article/following-the-money-untangling-u-s-prescription-drug-financing/.

[8] *Id.;* 15 U.S.C. §§ 41-58.

[9] Letter from U.S. Federal Trade Commission to Novo Nordisk, April 30, 2024, https://www.ftc.gov/system/files/ftc_gov/pdf/novo-nordisk-ozempic-saxenda-victoza-_4302024.pdf.

[10] *Id*.

[11] *Id*.

[12] National Library of Medicine, "Patents and Regulatory Exclusivities on Inhalers for Asthma and COPD, 1986-2020," William Feldman, Doni Bloomfield, Reed Beall, and Aaron Kesselheim, May 17, 2022, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10328096/; American Economic Liberties Project, "The Costs of Pharma Cheating," May 2023, https://www.economicliberties.us/wp-content/uploads/2023/05/AELP_052023_PharmaCheats_Report_FINAL.pdf..

[13] American Economic Liberties Project and Initiative for Medicines, Access, and Knowledge (I-MAK), "The Costs of Pharma Cheating," May 2023, p. 2, https://www.economicliberties.us/wp-content/uploads/2023/05/AELP_052023_PharmaCheats_Report_FINAL.pdf.

[14] Centers for Medicare & Medicaid Services, "Medicare Part D Spending by Drug," 2022, https://data.cms.gov/summary-statistics-on-use-and-payments/medicare-medicaid-spending-by-drug/medicare-part-d-spending-by-drug//data.

We have long been concerned by these and other pharmaceutical industry abuses of the patent system to stifle competition, prolong drug monopolies, and price-gouge patients.[15] FDA has acknowledged these Orange Book-related issues[16] and taken some steps to "ensure[] our system, as a whole, is not used to improperly delay getting more affordable drugs and biosimilars into the hands of Americans who need them."[17] In September 2023, we encouraged the FTC to declare sham patent listings in the Orange Book as an unfair method of competition, and in December 2023, we wrote to eight companies identified by the FTC as potentially violating the *Federal Trade Commission Act*, urging them to de-list these improperly-listed patents.[18]

Now, in light of FTC's notice disputing several of your company's patent listings, we request that you voluntarily de-list all of Novo Nordisk's improperly- and inaccurately-listed Orange Book patents by June 8, 2024 and provide responses to the following questions by no later than June 20, 2024.

1. In its April 2024 letter, the FTC identified thirty-six patents for the Ozempic, Saxenda, and Victoza products that have been improperly or inaccurately listed in the Orange Book.
    a. Has Novo Nordisk ever taken action to enforce any of these patents against any other drug manufacturer? If so, please list all such actions, and their outcome.
    b. During the time period in which you were challenging these patents, or in the ensuing 30-month period in which you were granted a stay that delayed approval of a generic competitor to one of these drugs, what were total sales (in dollars) of these drugs? What were total sales to Medicare and Medicaid?

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[15] Letters from Senator Warren and Representative Jayapal to AbbVie, AstraZeneca, Boehringer Ingelheim Pharmaceuticals, GlaxoSmithKline, Amneal Pharmaceuticals (Impax), Kaléo, Viatris (Mylan), and Teva/Norton, December 13, 2023, https://www.warren.senate.gov/imo/media/doc/orange%20book_combinedpdf.pdf; Office of U.S. Senator Elizabeth Warren, "Warren, Jayapal Call on Patent Office to Take Critical Steps to Lower Drug Prices and Fight Big Pharma's Patent Abuse," press release, April 27, 2023, https://www.warren.senate.gov/oversight/letters/warren-jayapal-call-on-patent-office-to-take-critical-steps-to-lower-drug-prices-and-fight-big-pharmas-patent-abuse; Office of U.S. Senator Elizabeth Warren, "Senator Warren, Representative Jayapal Urge FDA to Hold Big Pharma Accountable for Abuse of Patent System, Profiteering at Patients' Expense," press release, August 29, 2023, https://www.warren.senate.gov/oversight/letters/senator-warren-representative-jayapal-urge-fda-to-hold-big-pharma-accountable-for-abuse-of-patent-system-profiteering-at-patients-expense.

[16] U.S. Food and Drug Administration, "The Listing of Patent Information in the Orange Book," January 5, 2022, pp. 21-22, https://www.fda.gov/media/155200/download; U.S. Food and Drug Administration, Federal Register Notice, "Listing of Patent Information in the Orange Book; Establishment of a Public Docket; Request for Comments," June 1, 2020, https://www.federalregister.gov/documents/2020/06/01/2020-11684/listing-of-patent-information-in-the-orangebook-establishment-of-a-public-docket-request-for.

[17] U.S. Patent and Trademark Office, "USPTO – FDA Collaboration Initiatives," https://www.uspto.gov/initiatives/fda-collaboration.

[18] Office of U.S. Senator Elizabeth Warren, "Warren, Jayapal Urge FTC to Rein in Big Pharma Abuses of Patent System," press release, September 14, 2023, https://www.warren.senate.gov/oversight/letters/warren-jayapal-urge-ftc-to-rein-in-big-pharma-abuses-of-patent-system; Letters from Senator Warren and Representative Jayapal to AbbVie, AstraZeneca, Boehringer Ingelheim Pharmaceuticals, GlaxoSmithKline, Amneal Pharmaceuticals (Impax), Kaléo, Viatris (Mylan), and Teva/Norton, December 13, 2023, https://www.warren.senate.gov/imo/media/doc/orange%20book_combinedpdf.pdf.

2. Will Novo Nordisk voluntarily de-list the thirty-six patents you have listed in the Orange Book with regard to the Ozempic, Saxenda, and Victoza products that the FTC has disputed as being improperly or inaccurately listed?
    a. Please specify which ones you will de-list.
    b. What is your specific timeline for doing so?
3. Will Novo Nordisk voluntarily review and de-list additional patents the company has listed in the Orange Book that are improperly or inaccurately listed?
    a. Please specify which ones you will de-list.
    b. What is your specific timeline for doing so?

Sincerely,

Elizabeth Warren
United States Senator

Pramila Jayapal
Member of Congress

Congress of the United States

Washington, DC 20515

June 6, 2024

Richard Francis
President and CEO
Teva Branded Pharmaceutical Products R&D, Inc.
400 Interpace Parkway, #3
Parsippany, NJ 07054

Norton (Waterford) Limited
Waterford Industrial Park
Unit 301, Cork Rd
Waterford, X91 WK68, Ireland

Dear Mr. Francis:

We write today regarding the Federal Trade Commission's (FTC) April 30, 2024 letters indicating that "certain patents [may] have been improperly or inaccurately listed in the Orange Book" with regard to Teva Pharmaceutical Industries Ltd.'s and Norton (Waterford) Limited's AirDuo and ArmonAir Respiclick, AirDuo and ArmonAir Digihaler, and QVAR RediHaler products.[1] This is another indication from FTC that Teva has been abusing the patent system to profit at patients' and taxpayers' expense by charging exorbitant prices – again for lifesaving inhaler products used to prevent and control symptoms caused by asthma.[2] We applaud the FTC's leadership in challenging "junk" patent listings that, together with other anticompetitive conduct, cost consumers and the U.S. health care system billions of dollars each year.[3]

This is the second time in the past six months that the FTC has written to you regarding sham patent listings listed in the Orange Book.[4] After a similar set of letter from FTC directed at

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[1] Letter from U.S. Federal Trade Commission to Teva, April 30, 2024, https://www.ftc.gov/system/files/ftc_gov/pdf/teva-pharm-industries-digis-and-respiclicks-4302024.pdf; Letter from U.S. Federal Trade Commission to Norton (Waterford) Limited, April 30, 2024, https://www.ftc.gov/system/files/ftc_gov/pdf/teva-norton-qvar-redihaler-4302024.pdf ; U.S. Federal Trade Commission, "FTC Expands Patent Listing Challenges, Targeting More Than 300 Junk Listings for Diabetes, Weight Loss, Asthma and COPD Drugs," press release, April 30, 2024, https://www.ftc.gov/news-events/news/press-releases/2024/04/ftc-expands-patent-listing-challenges-targeting-more-300-junk-listings-diabetes-weight-loss-asthma.

[2] RxList, "AIRDUO RESPICLICK," last updated June 14, 2023, https://www.rxlist.com/airduo-respiclick-drug.htm; RxList, "AIRDUO DIGIHALER," last updated June 14, 2023, https://www.rxlist.com/airduo-digihaler-drug.htm; RxList, "ARMONAIR DIGIHALER," last updated April 25, 2022, https://www.rxlist.com/armonair-digihaler-drug.htm; RxList, "ARMONAIR RESPICLICK," last updated June 15, 2023, https://www.rxlist.com/armonair-respiclick-drug.htm; RxList, "QVAR REDIHALER," last updated March 16, 2022, https://www.rxlist.com/qvar-redihaler-drug.htm.

[3] American Economic Liberties Project, "The Costs of Pharma Cheating," May 2023, p. 2, https://www.economicliberties.us/wp-content/uploads/2023/05/AELP_052023_PharmaCheats_Report_FINAL.pdf.

[4] Letter from U.S. Federal Trade Commission to Teva Pharmaceuticals, Inc., November 7, 2023, https://www.ftc.gov/system/files/ftc_gov/pdf/teva-branded-pharma-orange-book.pdf; Letter from U.S. Federal Trade Commission to Norton (Waterford) Limited, November 7, 2023, https://www.ftc.gov/system/files/ftc_gov/pdf/norton-orange-book.pdf; U.S. Federal Trade Commission, "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.

inhaler medications in November 2023, we urged you to delist Teva's QVAR RediHaler, QVAR 40, ProAir HFA, and ProAir DigiHaler products and all other improper and inaccurate listings.[5] Several other companies delisted their patents following FTC and congressional scrutiny, but you have refused to do so – delaying the approval of generic versions of the patents listed, and potentially violating the law.[6] Accordingly, we again write to ask that you address the improper behavior identified by the FTC by June 8, 2024.

In September 2023, the FTC issued a policy statement that "improper patent listings may unlawfully delay generic competition for years and disincentivize generic manufacturers from trying to come to market with lower cost alternatives."[7] The Orange Book contains a list of drugs approved by the Food and Drug Administration (FDA) and related patent and exclusivity information, covering drug substances, drug products, and method of use.[8] If a brand-name drug company sues a generic manufacturer for infringing on a patent listed in the Orange Book, the FDA is barred from approving a generic version of the drug for 30 months.[9] Powerful Big Pharma players are therefore incentivized to strategically use sham patent listings in the Orange Book to hold off generic competition — increasing drug and health care costs for patients and driving up insurance premiums.[10]

The FTC pledged to scrutinize companies that engage in these practices for violating Section 5 of the *Federal Trade Commission Act*,[11] and in April issued a second warning letter to Teva that appears to conclude that the company may be violating federal law with regard to sixty more drug listings for AirDuo and ArmonAir Respiclick, AirDuo and ArmonAir Digihaler, and QVAR RediHaler products.[12] Given these concerns, we again urge you to voluntarily de-list the sixty

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[5] Letters from Senator Warren and Representative Jayapal to AbbVie, AstraZeneca, Boehringer Ingelheim Pharmaceuticals, GlaxoSmithKline, Amneal Pharmaceuticals (Impax), Kaléo, Viatris (Mylan), and Teva/Norton, December 13, 2023, https://www.warren.senate.gov/imo/media/doc/orange%20book_combinedpdf.pdf.

[6] FDA Law Blog, "Drugs Companies Clap Back at Congress…Then Get Sued," Sara W. Koblitz, March 13, 2024, https://www.thefdalawblog.com/2024/03/drugs-companies-clap-back-at-congressthen-get-sued/; Food and Drug Administration, "Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations," https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm.

[7] U.S. Federal Trade Commission, "FTC Issues Policy Statement on Brand Pharmaceutical Manufacturers' Improper Listing of Patents in the Food and Drug Administration's 'Orange Book'," press release, September 14, 2023, https://www.ftc.gov/news-events/news/press-releases/2023/09/ftc-issues-policy-statement-brand-pharmaceutical-manufacturers-improper-listing-patents-food-drug.

[8] U.S. Food and Drug Administration, "Approved Drug Products with Therapeutic Equivalence Evaluations | Orange Book," updated December 8, 2023, https://www.fda.gov/drugs/drug-approvals-and-databases/approved-drug-products-therapeutic-equivalence-evaluations-orange-book.

[9] United States District Court for the District of Delaware, "Federal Trade Commission's Brief as *Amicus Curiae*," November 10, 2022, p. 1, https://www.ftc.gov/system/files/ftc_gov/pdf/P163500JazzPharmaAmicusBrief.pdf.

[10] U.S. Federal Trade Commission, "Federal Trade Commission Statement Concerning Brand Drug Manufacturers' Improper Listing of Patents in the Orange Book," p. 4, https://www.ftc.gov/system/files/ftc_gov/pdf/p239900orangebookpolicystatement092023.pdf; Center for American Progress, "Following the Money: Untangling U.S. Prescription Drug Financing," Sam Hughes and Nicole Rapfogel, October 12, 2023, https://www.americanprogress.org/article/following-the-money-untangling-u-s-prescription-drug-financing/.

[11] *Id.;* 15 U.S.C. §§ 41-58.

[12] Letter from U.S. Federal Trade Commission to Teva, April 30, 2024, https://www.ftc.gov/system/files/ftc_gov/pdf/teva-pharm-industries-digis-and-respiclicks-4302024.pdf; Letter from U.S. Federal Trade Commission to Norton (Waterford) Limited, April 30, 2024, https://www.ftc.gov/system/files/ftc_gov/pdf/teva-norton-qvar-redihaler-4302024.pdf.

patents named in the FTC's letter, and any other patents you have listed that unfairly block competition.[13] As the FTC noted, Teva "bears the burden of listing patents in the Orange Book accurately and in accordance with all relevant statutory and regulatory requirements."[14]

The practices that FTC has highlighted in its warning letters are a prime example of how pharmaceutical companies — including Teva — regularly employ anticompetitive tactics to extend their government-granted monopolies, insulate themselves from generic and biosimilar competition, and keep prices artificially high.[15] Drug manufacturers' patent gaming tactics can drive up drug prices, contribute to higher premiums and out-of-pocket costs for patients, and increase costs for Medicare and Medicaid. For example, U.S. patients and payers spent an additional $40.07 billion on pharmaceutical products "as a result of antitrust violations by the pharmaceutical industry" in 2019.[16] And the Medicare Part D program spent nearly $300,000on AirDuo Respiclick, over$550,000 on AirDuo Digihaler, and nearly $50 million on QVAR Redihaler products in 2022 alone.[17]

We have long been concerned by these and other pharmaceutical industry abuses of the patent system to stifle competition, prolong drug monopolies, and price-gouge patients.[18] FDA has acknowledged these Orange Book-related issues[19] and taken some steps to "ensure[] our system, as a whole, is not used to improperly delay getting more affordable drugs and biosimilars into the hands of Americans who need them."[20] In September 2023, we encouraged the FTC to declare

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[13] *Id*.

[14] *Id*.

[15] National Library of Medicine, "Patents and Regulatory Exclusivities on Inhalers for Asthma and COPD, 1986-2020," William Feldman, Doni Bloomfield, Reed Beall, and Aaron Kesselheim, May 17, 2022, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10328096/; American Economic Liberties Project, "The Costs of Pharma Cheating," May 2023 https://www.economicliberties.us/wp-content/uploads/2023/05/AELP_052023_PharmaCheats_Report_FINAL.pdf.

[16] American Economic Liberties Project and Initiative for Medicines, Access, and Knowledge (I-MAK), "The Costs of Pharma Cheating," May 2023, p. 2, https://www.economicliberties.us/wp-content/uploads/2023/05/AELP_052023_PharmaCheats_Report_FINAL.pdf.

[17] Centers for Medicare & Medicaid Services, "Medicare Part D Spending by Drug," 2022, https://data.cms.gov/summary-statistics-on-use-and-payments/medicare-medicaid-spending-by-drug/medicare-part-d-spending-by-drug//data.

[18] Letters from Senator Warren and Representative Jayapal to AbbVie, AstraZeneca, Boehringer Ingelheim Pharmaceuticals, GlaxoSmithKline, Amneal Pharmaceuticals (Impax), Kaléo, Viatris (Mylan), and Teva/Norton, December 13, 2023, https://www.warren.senate.gov/imo/media/doc/orange%20book_combinedpdf.pdf; Office of U.S. Senator Elizabeth Warren, "Warren, Jayapal Call on Patent Office to Take Critical Steps to Lower Drug Prices and Fight Big Pharma's Patent Abuse," press release, April 27, 2023, https://www.warren.senate.gov/oversight/letters/warren-jayapal-call-on-patent-office-to-take-critical-steps-to-lower-drug-prices-and-fight-big-pharmas-patent-abuse; Office of U.S. Senator Elizabeth Warren, "Senator Warren, Representative Jayapal Urge FDA to Hold Big Pharma Accountable for Abuse of Patent System, Profiteering at Patients' Expense," press release, August 29, 2023, https://www.warren.senate.gov/oversight/letters/senator-warren-representative-jayapal-urge-fda-to-hold-big-pharma-accountable-for-abuse-of-patent-system-profiteering-at-patients-expense.

[19] U.S. Food and Drug Administration, "The Listing of Patent Information in the Orange Book," January 5, 2022, pp. 21-22, https://www.fda.gov/media/155200/download; U.S. Food and Drug Administration, Federal Register Notice, "Listing of Patent Information in the Orange Book; Establishment of a Public Docket; Request for Comments," June 1, 2020, https://www.federalregister.gov/documents/2020/06/01/2020-11684/listing-of-patent-information-in-the-orangebook-establishment-of-a-public-docket-request-for.

[20] U.S. Patent and Trademark Office, "USPTO – FDA Collaboration Initiatives," https://www.uspto.gov/initiatives/fda-collaboration.

sham patent listings in the Orange Book an unfair method of competition, and in December 2023, we wrote to eight companies identified by the FTC as potentially violating the *Federal Trade Commission Act* (including Teva,) urging them to delist these improperly-listed patents.[21]

Now, in light of FTC's second notice disputing several of your company's patent listings, we request that you voluntarily de-list all of Teva's improperly- and inaccurately-listed Orange Book patents by June 8, 2024 and provide responses to the following questions by no later than June 20, 2024.

1. In its April 2024 letter, the FTC identified sixty patents for the AirDuo and ArmonAir Respiclick, AirDuo and ArmonAir Digihaler, and QVAR RediHaler products that have been improperly or inaccurately listed in the Orange Book.
    a. Has Teva ever taken action to enforce any of these patents against any other drug manufacturer? If so, please list all such actions, and their outcome.
    b. During the time period in which you were challenging these patents, or in the ensuing 30-month period in which you were granted a stay that delayed approval of a generic competitor to one of these drugs, what were total sales (in dollars) of these drugs? What were total sales to Medicare and Medicaid?
2. Will Teva voluntarily de-list the sixty patents you have listed in the Orange Book with regard to the AirDuo and ArmonAir Respiclick, AirDuo and ArmonAir Digihaler, and QVAR RediHaler products that the FTC has disputed as being improperly or inaccurately listed?
    a. Please specify which ones you will de-list.
    b. What is your specific timeline for doing so?
3. Will Teva voluntarily review and de-list additional patents the company has listed in the Orange Book that are improperly or inaccurately listed?
    a. Please specify which ones you will de-list.
    b. What is your specific timeline for doing so?

Sincerely,

Elizabeth Warren
United States Senator

Pramila Jayapal
Member of Congress

[21] Office of U.S. Senator Elizabeth Warren, "Warren, Jayapal Urge FTC to Rein in Big Pharma Abuses of Patent System," press release, September 14, 2023, https://www.warren.senate.gov/oversight/letters/warren-jayapal-urge-ftc-to-rein-in-big-pharma-abuses-of-patent-system; Letters from Senator Warren and Representative Jayapal to AbbVie, AstraZeneca, Boehringer Ingelheim Pharmaceuticals, GlaxoSmithKline, Amneal Pharmaceuticals (Impax), Kaléo, Viatris (Mylan), and Teva/Norton, December 13, 2023, https://www.warren.senate.gov/imo/media/doc/orange%20book_combinedpdf.pdf.