Congress of the United States

Washington, DC 20515

December 13, 2023

Richard A. Gonzalez
Chairman and CEO
AbbVie Inc.
1 N Waukegan Road
North Chicago, IL 60064

Dear Mr. Gonzalez:

We write today regarding the Federal Trade Commission's (FTC) November 7, 2023 letter indicating that "certain patents have been improperly or inaccurately listed in the Orange Book with regard to AbbVie Inc.'s Restasis Multidose product."[1] These are deeply troubling allegations, indicating that AbbVie has been abusing the patent system to profit at patients' and taxpayers' expense by charging exorbitant prices for medication that relieves symptoms of chronic dry eyes.[2] Accordingly, we write to ask that you address the improper behavior identified by the FTC by December 16, 2023.

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."[3] The FTC's 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.[4] 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.[5] Powerful Big Pharma players are therefore incentivized to strategically list sham patents in the Orange Book to hold off generic competition — increasing drug and health care costs for patients and driving up insurance premiums.[6]

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[1] Letter from U.S. Federal Trade Commission to AbbVie Inc., November 7, 2023, https://www.ftc.gov/system/files/ftc_gov/pdf/abbvie-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.

[2] RxList, "Restasis Multidose," updated December 6, 2022, https://www.rxlist.com/restasis-multidose-drug.htm.

[3] 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.

[4] 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.

[5] 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.

[6] U.S. Federal Trade Commission, "Federal Trade Commission Statement Concerning Brand Drug Manufacturers' Improper Listing of Patents in the Orange Book," p. 4,

The FTC pledged to scrutinize companies that engage in these practices for violating Section 5 of the *Federal Trade Commission Act*,[7] and in November issued a warning letter to AbbVie that appears to conclude that the company may be violating federal law with regard to its drug listings. Given these concerns, we urge you to voluntarily de-list the four patents named in the FTC's letter that you have listed in the Orange Book with regard to AbbVie's Restasis Multidose product, and any other patents you have listed that unfairly block competition.[8] As FTC noted, AbbVie bears the burden of ensuring its Orange Book listings are accurate and comply with all relevant statutory and regulatory requirements.[9]

The practices that FTC has highlighted in its warning letter are a prime example of how pharmaceutical companies — including AbbVie — regularly employ anticompetitive tactics to extend their government-granted monopolies, insulate themselves from generic and biosimilar competition, and keep prices artificially high.[10] 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.[11] And the Medicare Part D program spent more than $1.6 billion on a single formulation of Restasis in 2021 alone, making it the 19th costliest drug in overall Medicare spending that year.[12]

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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/.

[7] *Id.*

[8] Letter from U.S. Federal Trade Commission to AbbVie Inc., November 7, 2023, https://www.ftc.gov/system/files/ftc_gov/pdf/abbvie-orange-book.pdf.

[9] *Id*.

[10] National Library of Medicine, "Patents and Regulatory Exclusivities on Inhalers for Asthma and COPD," William Feldman, Doni Bloomfield, Reed Beall, and Aaron Kesselheim, May 17, 2022, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10328096/; Washington Post, "How the makers of inhalers keep prices so high," William B. Feldman and Aaron S. Kesselheim, June 1, 2023, https://www.washingtonpost.com/opinions/2023/06/01/inhaler-cost-drug-company-prices/.

[11] 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.

[12] Centers for Medicare & Medicaid Services, "Medicare Part D Spending by Drug," 2021, 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.[13] FDA has acknowledged these Orange Book-related issues[14] 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."[15] In September 2023, we encouraged the FTC to declare the listing of sham patents in the Orange Book as an unfair method of competition.[16]

Now, in light of FTC's notice disputing several of your company's patent listings, we request that you to voluntarily de-list all of AbbVie's improperly and inaccurately listed Orange Book patents by December 16, 2023 and provide responses to the following questions by no later than January 15, 2024.

1. FTC identified four patents for Restasis that have been improperly or inaccurately listed in the Orange Book.
    a. Has AbbVie 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. Has AbbVie voluntarily de-listed the four patents listed in the Orange Book with regard to the Restasis Multidose product that the FTC has disputed as being improperly or inaccurately listed?
    a. Please specify which ones you have de-listed.
    b. Please specify when you will de-list them if you have not done so yet.

[13] 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.

[14] 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.

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

[16] 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.

3. Will AbbVie 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

December 13, 2023

Chirag Patel
President and Co-CEO
Amneal Pharmaceuticals
400 Crossing Blvd
Bridgewater, NJ 08807

Chintu Patel
Co-CEO
Amneal Pharmaceuticals
400 Crossing Blvd
Bridgewater, NJ 08807

Dear Mr. Patel and Mr. Patel:

We write today regarding the Federal Trade Commission's (FTC) November 7, 2023 letter indicating that "certain patents have been improperly or inaccurately listed in the Orange Book with regard to Impax Laboratories LLC's – which is now owned by Amneal Pharmaceuticals[1] – Adrenaclick product."[2] These are deeply troubling allegations, indicating that Impax Laboratories has been abusing the patent system to profit at patients' and taxpayers' expense by charging exorbitant prices for lifesaving epinephrine injectors used to treat severe asthma attacks and allergic reactions.[3] Accordingly, we write to ask that you address the improper behavior identified by the FTC by December 16, 2023.

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 FTC's 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 FDA is barred from approving a generic version of the drug for 30 months.[6] Powerful Big Pharma players are therefore incentivized to strategically list sham patents in the Orange

[1] Amneal, "Amneal and Impax Complete Business Combination," press release, May 7, 2018, https://investors.amneal.com/news/press-releases/press-release-details/2018/Amneal-and-Impax-Complete-Business-Combination/default.aspx.

[2] Letter from U.S. Federal Trade Commission to Impax Laboratories LLC., November 7, 2023, https://www.ftc.gov/system/files/ftc_gov/pdf/impax-labs-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.

[3] RxList, "Adrenaclick," October 25, 2022, https://www.rxlist.com/adrenaclick-drug.htm.

[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.

[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.

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 November issued a warning letter to Impax Laboratories that appears to conclude that the company may be violating federal law with regard to its drug listings. Given these concerns, we urge you to voluntarily de-list the two patents named in the FTC's letter that you have listed in the Orange Book with regard to Impax Laboratories' Adrenaclick product, and any other patents you have listed that unfairly block competition.[9] As FTC noted, Impax Laboratories bears the burden of ensuring its Orange Book listings are accurate and comply with all relevant statutory and regulatory requirements.[10]

The practices that FTC has highlighted in its warning letter are a prime example of how pharmaceutical companies — including Impax Laboratories — regularly employ anticompetitive tactics to extend their government-granted monopolies, insulate themselves from generic and biosimilar competition, and keep prices artificially high.[11] 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 $40.7 billion on pharmaceutical products "as a result of antitrust violations by the pharmaceutical industry" in 2019.[12]

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[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] 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] Letter from U.S. Federal Trade Commission to Impax Laboratories LLC., November 7, 2023, https://www.ftc.gov/system/files/ftc_gov/pdf/impax-labs-orange-book.pdf.

[10] *Id*.

[11] National Library of Medicine, "Patents and Regulatory Exclusivities on Inhalers for Asthma and COPD," William Feldman, Doni Bloomfield, Reed Beall, and Aaron Kesselheim, Jun 2022, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10328096/; Washington Post, "How the makers of inhalers keep prices so high," William B. Feldman and Aaron S. Kesselheim, June 1, 2023, https://www.washingtonpost.com/opinions/2023/06/01/inhaler-cost-drug-company-prices/.

[12] 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.

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.[13] FDA has acknowledged these Orange Book-related issues[14] 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."[15] In September 2023, we encouraged the FTC to declare the listing of sham patents in the Orange Book as an unfair method of competition.[16]

Now, in light of FTC's notice disputing several of your company's patent listings, we request that you to voluntarily de-list all of Impax Laboratories' improperly and inaccurately listed Orange Book patents by December 16, 2023 and provide responses to the following questions by no later than January 15, 2024.

1. FTC identified two patents for Adrenaclick that have been improperly or inaccurately listed in the Orange Book.
    a. Has Impax Laboratories 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. Has Impax Laboratories voluntarily de-listed the two patents listed in the Orange Book with regard to the Adrenaclick product that the FTC has disputed as being improperly or inaccurately listed?
    a. Please specify which ones you have de-listed.
    b. Please specify when you will de-list them if you have not done so yet.

[13] 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.

[14] 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.

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3. Will Impax Laboratories 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

December 13, 2023

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) November 7, 2023 letter indicating that "certain patents have been improperly or inaccurately listed in the Orange Book with regard to Astrazeneca LP's Symbicort product."[1] These are deeply troubling allegations, indicating that AstraZeneca has been abusing the patent system to profit at patients' and taxpayers' expense by charging exorbitant prices for lifesaving inhaler products used to prevent and control symptoms caused by asthma.[2] Accordingly, we write to ask that you address the improper behavior identified by the FTC by December 16, 2023.

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."[3] The FTC's 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.[4] 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.[5] Powerful Big Pharma players are therefore incentivized to strategically list sham patents in the Orange

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[1] Letter from U.S. Federal Trade Commission to AstraZeneca LP, November 7, 2023, https://www.ftc.gov/system/files/ftc_gov/pdf/astrazeneca-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.

[2] RxList, "Symbicort," May 22, 2023, https://www.rxlist.com/symbicort-drug.htm.

[3] 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.

[4] 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.

[5] 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.

Book to hold off generic competition — increasing drug and health care costs for patients and driving up insurance premiums.[6]

The FTC pledged to scrutinize companies that engage in these practices for violating Section 5 of the *Federal Trade Commission Act*,[7] and in November issued a warning letter to AstraZeneca that appears to conclude that the company may be violating federal law with regard to its drug listings. Given these concerns, we urge you to voluntarily de-list the ten patents named in the FTC's letter that you have listed in the Orange Book with regard to AstraZeneca's Symbicort product, and any other patents you have listed that unfairly block competition.[8] As FTC noted, AstraZeneca bears the burden of ensuring its Orange Book listings are accurate and comply with all relevant statutory and regulatory requirements.[9]

The practices that FTC has highlighted in its warning letter are a prime example of how pharmaceutical companies — including AstraZeneca — regularly employ anticompetitive tactics to extend their government-granted monopolies, insulate themselves from generic and biosimilar competition, and keep prices artificially high.[10] 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 $40.7 billion on pharmaceutical products "as a result of antitrust violations by the pharmaceutical industry" in 2019.[11] And the Medicare Part D program spent nearly $2 billion on a single formulation of Symbicort in 2021 alone, making it the 15th costliest drug in overall Medicare spending that year.[12]

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[6] 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/.

[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] Letter from U.S. Federal Trade Commission to AstraZeneca LP, November 7, 2023, https://www.ftc.gov/system/files/ftc_gov/pdf/astrazeneca-orange-book.pdf.

[9] *Id*.

[10] National Library of Medicine, "Patents and Regulatory Exclusivities on Inhalers for Asthma and COPD," William Feldman, Doni Bloomfield, Reed Beall, and Aaron Kesselheim, Jun 2022, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10328096/; Washington Post, "How the makers of inhalers keep prices so high," William B. Feldman and Aaron S. Kesselheim, June 1, 2023, https://www.washingtonpost.com/opinions/2023/06/01/inhaler-cost-drug-company-prices/.

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[12] Centers for Medicare & Medicaid Services, "Medicare Part D Spending by Drug," 2021, 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.[13] FDA has acknowledged these Orange Book-related issues[14] 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."[15] In September 2023, we encouraged the FTC to declare the listing of sham patents in the Orange Book as an unfair method of competition.[16]

Now, in light of FTC's notice disputing several of your company's patent listings, we request that you to voluntarily de-list all of AstraZeneca's improperly and inaccurately listed Orange Book patents by December 16, 2023 and provide responses to the following questions by no later than January 15, 2024.

1. FTC identified five patents for Symbicort that have been improperly or inaccurately listed in the Orange Book.
    a. Has AstraZeneca 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. Has AstraZeneca voluntarily de-listed the ten patents listed in the Orange Book with regard to the Symbicort product that the FTC has disputed as being improperly or inaccurately listed?
    a. Please specify which ones you have de-listed.
    b. Please specify when you will de-list them if you have not done so yet.

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[14] 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.

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

[16] 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.

3. Will AstraZeneca 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

December 13, 2023

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) November 7, 2023 letter indicating that "certain patents have been improperly or inaccurately listed in the Orange Book with regard to Boehringer Ingelheim Pharmaceuticals, Inc. products."[1] These are deeply troubling allegations, indicating that Boehringer Ingelheim has been abusing the patent system to profit at patients' and taxpayers' expense by charging exorbitant prices for lifesaving inhaler products used to prevent and control symptoms caused by asthma.[2] Accordingly, we write to ask that you address the improper behavior identified by the FTC by December 16, 2023.

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."[3] The FTC's 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.[4] 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.[5] Powerful Big Pharma players are therefore incentivized to strategically list sham patents in the Orange

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[1] 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.

[2] RxList, "Atrovent HFA," September 29, 2020, https://www.rxlist.com/atrovent-hfa-drug.htm; RxList, "Combivent," June 5, 2023, https://www.rxlist.com/combivent-drug.htm; RxList, "Spiriva," October 20, 2020, https://www.rxlist.com/spiriva-drug.htm; RxList, "Spiriva Respimat," July 13, 2023, https://www.rxlist.com/spiriva-respimat-drug.htm.

[3] 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.

[4] 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.

[5] 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.

Book to hold off generic competition — increasing drug and health care costs for patients and driving up insurance premiums.[6]

The FTC pledged to scrutinize companies that engage in these practices for violating Section 5 of the *Federal Trade Commission Act*,[7] and in November issued a warning letter to Boehringer Ingelheim that appears to conclude that the company may be violating federal law with regard to its drug listings. Given these concerns, we urge you to voluntarily de-list the 22 patents named in the FTC's letter that you have listed in the Orange Book with regard to Boehringer Ingelheim's Atrovent HFA, Combivent Respimat, Spiriva, and Spiriva Respimat products, and any other patents you have listed that unfairly block competition.[8] As FTC noted, Boehringer Ingelheim bears the burden of ensuring its Orange Book listings are accurate and comply with all relevant statutory and regulatory requirements.[9]

The practices that FTC has highlighted in its warning letter are a prime example of how pharmaceutical companies — including Boehringer Ingelheim — regularly employ anticompetitive tactics to extend their government-granted monopolies, insulate themselves from generic and biosimilar competition, and keep prices artificially high.[10] 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 $40.7 billion on pharmaceutical products "as a result of antitrust violations by the pharmaceutical industry" in 2019.[11] And the Medicare Part D program spent $2.5 billion on these inhaler-related products in 2021 alone.[12]

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[6] 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/.

[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] 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.

[9] *Id*.

[10] National Library of Medicine, "Patents and Regulatory Exclusivities on Inhalers for Asthma and COPD," William Feldman, Doni Bloomfield, Reed Beall, and Aaron Kesselheim, Jun 2022, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10328096/; Washington Post, "How the makers of inhalers keep prices so high," William B. Feldman and Aaron S. Kesselheim, June 1, 2023, https://www.washingtonpost.com/opinions/2023/06/01/inhaler-cost-drug-company-prices/.

[11] 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.

[12] Centers for Medicare & Medicaid Services, "Medicare Part D Spending by Drug," 2021, 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.[13] FDA has acknowledged these Orange Book-related issues 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."[14] In September 2023, we encouraged the FTC to declare the listing of sham patents in the Orange Book as an unfair method of competition.[15]

Now, in light of FTC's notice disputing several of your company's patent listings, we request that you to voluntarily de-list all of Boehringer Ingelheim's improperly and inaccurately listed Orange Book patents by December 16, 2023 and provide responses to the following questions by no later than January 15, 2024.

1. FTC identified fifteen patents for Boehringer Ingelheim's 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. Has Boehringer Ingelheim voluntarily de-listed the 22 patents listed in the Orange Book with regard to the inhaler-related products that the FTC has disputed as being improperly or inaccurately listed?
    a. Please specify which ones you have de-listed.
    b. Please specify when you will de-list them if you have not done so yet.

[13] 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.

[14] 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. Patent and Trademark Office, "USPTO – FDA Collaboration Initiatives," https://www.uspto.gov/initiatives/fda-collaboration; Federal Register, "Listing of Patent Information in the Orange Book; Establishment of a Public Docket; Request for Comments," U.S. Food and Drug Administration, 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.

[15] 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.

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

Congress of the United States

Washington, DC 20515

December 13, 2023

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

Maya Martinez-Davis
President of U.S. Pharmaceuticals
GlaxoSmithKline
2929 Walnut Street
Philadelphia, PA 19104

Dear Ms. Walmsley and Ms. Martinez-Davis:

We write today regarding the Federal Trade Commission's (FTC) November 7, 2023 letter indicating that "certain patents have been improperly or inaccurately listed in the Orange Book" with regard to GlaxoSmithKline's Arnuity Ellipta, Ventolin HFA, Advair HFA, and Flovent HFA products.[1] These are deeply troubling allegations, indicating that GlaxoSmithKline has been abusing the patent system to profit at patients' and taxpayers' expense charging exorbitant prices for lifesaving inhaler products used to prevent and control symptoms caused by asthma.[2] Accordingly, we write to ask that you address the improper behavior identified by the FTC by December 16, 2023.

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."[3] The FTC's 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.[4] 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.[5] Powerful Big Pharma players are therefore incentivized to strategically list sham patents in the Orange

[1] Letter from U.S. Federal Trade Commission to GlaxoSmithKline Intellectual, 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; 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.

[2] GlaxoSmithKline, "Arnuity Ellipta," https://arnuity.com/; GlaxoSmithKline, "Ventolin HFA," https://www.ventolin.com/; GlaxoSmithKline, "Advair HFA," https://www.advair.com/; GlaxoSmithKline, "Flovent HFA," https://www.flovent.com/.

[3] 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.

[4] 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.

[5] 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.

Book to hold off generic competition — increasing drug and health care costs for patients and driving up insurance premiums.[6]

The FTC pledged to scrutinize companies that engage in these practices for violating Section 5 of the *Federal Trade Commission Act*,[7] and in November issued a warning letter to GlaxoSmithKline that appears to conclude that the company may be violating federal law with regard to its drug listings. Given these concerns, we urge you to voluntarily de-list the 14 patents named in the FTC's letter that you have listed in the Orange Book with regard to GlaxoSmithKline's Advair HFA, Flovent HFA, Arnuity Ellipta, Ventolin HFA, and any other patents you have listed that unfairly block competition.[8] As FTC noted, GlaxoSmithKline bears the burden of ensuring its Orange Book listings are accurate and comply with all relevant statutory and regulatory requirements.[9]

The practices that FTC has highlighted in its warning letter 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.[10] 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 $40.7 billion on pharmaceutical products "as a result of antitrust violations by the pharmaceutical industry" in 2019.[11] And the Medicare Part D program spent more than $1 billion on these inhaler-related products in 2021 alone.[12]

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[6] 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/.

[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] Letter from U.S. Federal Trade Commission to GlaxoSmithKline Intellectual, 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.

[9] *Id*.

[10] National Library of Medicine, "Patents and Regulatory Exclusivities on Inhalers for Asthma and COPD," William Feldman, Doni Bloomfield, Reed Beall, and Aaron Kesselheim, Jun 2022, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10328096/; Washington Post, "How the makers of inhalers keep prices so high," William B. Feldman and Aaron S. Kesselheim, June 1, 2023, https://www.washingtonpost.com/opinions/2023/06/01/inhaler-cost-drug-company-prices/.

[11] 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.

[12] Centers for Medicare & Medicaid Services, "Medicare Part D Spending by Drug," 2021, 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.[13] FDA has acknowledged these Orange Book-related issues[14] 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."[15] In September 2023, we encouraged the FTC to declare the listing of sham patents in the Orange Book as an unfair method of competition.[16]

Now, in light of FTC's notice disputing several of your company's patent listings, we request that you to voluntarily de-list all of GlaxoSmithKline's improperly and inaccurately listed Orange Book patents by December 16, 2023 and provide responses to the following questions by no later than January 15, 2024.

1. FTC identified seven patents for GlaxoSmithKline's 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. Has GlaxoSmithKline voluntarily de-listed the 14 patents listed in the Orange Book with regard to the inhaler-related products that the FTC has disputed as being improperly or inaccurately listed?
    a. Please specify which ones you have de-listed.
    b. Please specify when you will de-list them if you have not done so yet.

[13] 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.

[14] 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.

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

[16] 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.

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

Congress of the United States

Washington, DC 20515

December 13, 2023

Michael Wells
Chairman and CEO
Kaléo Inc.
111 Virginia Street
Richmond, VA 23225

Dear Mr. Wells:

We write today regarding the Federal Trade Commission's (FTC) November 7, 2023 letter indicating that "certain patents have been improperly or inaccurately listed in the Orange Book with regard to Kaléo Inc.'s AUVI-Q product."[1] These are deeply troubling allegations, indicating that Kaléo has been abusing the patent system to profit at patients' and taxpayers' expense by charging exorbitant prices for lifesaving epinephrine injectors used to treat severe asthma attacks and allergic reactions.[2] Accordingly, we write to ask that you address the improper behavior identified by the FTC by December 16, 2023.

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."[3] The FTC's 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.[4] 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.[5] Powerful Big Pharma players are therefore incentivized to strategically list sham patents in the Orange Book to hold off generic competition — increasing drug and health care costs for patients and driving up insurance premiums.[6]

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[1] Letter from U.S. Federal Trade Commission to Kaléo Inc., November 7, 2023, https://www.ftc.gov/system/files/ftc_gov/pdf/kaleo-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.

[2] Kaelo, Inc., "Auvi-Q" https://www.auvi-q.com/.

[3] 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.

[4] 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.

[5] 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.

[6] U.S. Federal Trade Commission, "Federal Trade Commission Statement Concerning Brand Drug Manufacturers' Improper Listing of Patents in the Orange Book," p. 4,

The FTC pledged to scrutinize companies that engage in these practices for violating Section 5 of the *Federal Trade Commission Act*,[7] and in November issued a warning letter to Kaléo that appears to conclude that the company may be violating federal law with regard to its drug listings. Given these concerns, we urge you to voluntarily de-list the eight patents named in the FTC's letter that you have listed in the Orange Book with regard to Kaléo's AUVI-Q product, and any other patents you have listed that unfairly block competition.[8] As FTC noted, Kaléo bears the burden of ensuring its Orange Book listings are accurate and comply with all relevant statutory and regulatory requirements.[9]

The practices that FTC has highlighted in its warning letter are a prime example of how pharmaceutical companies — including Kaléo — regularly employ anticompetitive tactics to extend their government-granted monopolies, insulate themselves from generic and biosimilar competition, and keep prices artificially high.[10] 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 $40.7 billion on pharmaceutical products "as a result of antitrust violations by the pharmaceutical industry" in 2019.[11] And the Medicare Part D program spent nearly $3.1 million on a single formulation of AUVI-Q in 2021 alone.[12]

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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/.

[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] Letter from U.S. Federal Trade Commission to Kaelo Inc., November 7, 2023, https://www.ftc.gov/system/files/ftc_gov/pdf/kaleo-orange-book.pdf.

[9] *Id*.

[10] National Library of Medicine, "Patents and Regulatory Exclusivities on Inhalers for Asthma and COPD," William Feldman, Doni Bloomfield, Reed Beall, and Aaron Kesselheim, Jun 2022, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10328096/; Washington Post, "How the makers of inhalers keep prices so high," William B. Feldman and Aaron S. Kesselheim, June 1, 2023, https://www.washingtonpost.com/opinions/2023/06/01/inhaler-cost-drug-company-prices/.

[11] 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.

[12] Centers for Medicare & Medicaid Services, "Medicare Part D Spending by Drug," 2021, 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.[13] FDA has acknowledged these Orange Book-related issues[14] 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."[15] In September 2023, we encouraged the FTC to declare the listing of sham patents in the Orange Book as an unfair method of competition.[16]

Now, in light of FTC's notice disputing several of your company's patent listings, we request that you to voluntarily de-list all of Kaléo's improperly and inaccurately listed Orange Book patents by December 16, 2023 and provide responses to the following questions by no later than January 15, 2024.

1. FTC identified eight patents for AUVI-Q that have been improperly or inaccurately listed in the Orange Book.
    a. Has Kaléo 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. Has Kaléo voluntarily de-listed the eight patents listed in the Orange Book with regard to the AUVI-Q product that the FTC has disputed as being improperly or inaccurately listed?
    a. Please specify which ones you have de-listed.
    b. Please specify when you will de-list them if you have not done so yet.

[13] 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.

[14] 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.

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

[16] 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.

3. Will Kaléo 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

December 13, 2023

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

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

Dear Mr. Francis:

We write today regarding the Federal Trade Commission's (FTC) November 7, 2023 letter indicating that "certain patents have been improperly or inaccurately listed in the Orange Book" with regard to Norton (Waterford) Limited's and Teva Branded Pharmaceutical Products R&D, Inc's QVAR RediHaler, QVAR 40, ProAir HFA, and ProAir DigiHaler products.[1] These are deeply troubling allegations, indicating that Teva has been abusing the patent system to profit at patients' and taxpayers' expense by charging exorbitant prices for lifesaving inhaler products used to prevent and control symptoms caused by asthma or chronic obstructive pulmonary disease.[2] Accordingly, we write to ask that you address the improper behavior identified by the FTC by December 16, 2023.

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."[3] The FTC's 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.[4] If a brand-name drug company sues a generic manufacturer for infringing on a patent listed in the Orange

[1] 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; Letter from U.S. Federal Trade Commission to Teva Branded Pharmaceutical Products R&D, Inc., November 7, 2023, https://www.ftc.gov/system/files/ftc_gov/pdf/teva-branded-pharma-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.

[2] RxList, "QVAR RediHaler," March 16, 2022, https://www.rxlist.com/qvar-redihaler-drug.htm#indications; RxList, "ProAir," February 23, 2021, https://www.rxlist.com/proair-drug.htm; RxList, "ProAir DigiHaler," February 9, 2022, https://www.rxlist.com/proair-digihaler-drug.htm.

[3] 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.

[4] 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.

Book, the FDA is barred from approving a generic version of the drug for 30 months.[5] Powerful Big Pharma players are therefore incentivized to strategically list sham patents in the Orange Book to hold off generic competition — increasing drug and health care costs for patients and driving up insurance premiums.[6]

The FTC pledged to scrutinize companies that engage in these practices for violating Section 5 of the *Federal Trade Commission Act*,[7] and in November issued a warning letter to Norton Limited and Teva that appears to conclude that the company may be violating federal law with regard to its drug listings. Given these concerns, we urge you to voluntarily de-list the 42 patents named in the FTC's letter that you have listed in the Orange Book with regard to Norton Limited's QVAR RediHaler product and Teva's QVAR 40, ProAir HFA, and ProAir DigiHaler products, and any other patents you have listed that unfairly block competition.[8] As FTC noted, Norton Limited and Teva bears the burden of ensuring its Orange Book listings are accurate and comply with all relevant statutory and regulatory requirements.[9]

The practices that FTC has highlighted in its warning letter are a prime example of how pharmaceutical companies — including Norton Limited and Teva — regularly employ anticompetitive tactics to extend their government-granted monopolies, insulate themselves from generic and biosimilar competition, and keep prices artificially high.[10] 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 $40.7 billion on pharmaceutical products "as a result of antitrust violations by the pharmaceutical industry" in 2019.[11] And the Medicare Part D program spent

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[5] 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.

[6] 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/.

[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] 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; Letter from U.S. Federal Trade Commission to Teva Branded Pharmaceutical Products R&D, Inc., November 7, 2023, https://www.ftc.gov/system/files/ftc_gov/pdf/teva-branded-pharma-orange-book.pdf.

[9] *Id*.

[10] National Library of Medicine, "Patents and Regulatory Exclusivities on Inhalers for Asthma and COPD," William Feldman, Doni Bloomfield, Reed Beall, and Aaron Kesselheim, Jun 2022, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10328096/; Washington Post, "How the makers of inhalers keep prices so high," William B. Feldman and Aaron S. Kesselheim, June 1, 2023, https://www.washingtonpost.com/opinions/2023/06/01/inhaler-cost-drug-company-prices/.

[11] 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.

roughly $52.8 million, $70 million, and $282,000 on single formulations of the QVAR RediHaler, ProAir HFA, and ProAir DigiHaler products respectively in 2021 alone.[12]

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.[13] FDA has acknowledged these Orange Book-related issues[14] 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."[15] In September 2023, we encouraged the FTC to declare the listing of sham patents in the Orange Book as an unfair method of competition.[16]

Now, in light of FTC's notice disputing several of your company's patent listings, we request that you to voluntarily de-list all of Norton Limited's and Teva's improperly and inaccurately listed Orange Book patents by December 16, 2023 and provide responses to the following questions by no later than January 15, 2024.

1. FTC identified 42 patents for the QVAR RediHaler, QVAR 40, ProAir HFA, and ProAir DigiHaler products that have been improperly or inaccurately listed in the Orange Book.
    a. Has Teva or Norton Limited 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. Have Teva and Norton Limited voluntarily de-listed the 42 patents listed in the Orange Book with regard to the QVAR RediHaler, QVAR 40, ProAir HFA, and ProAir DigiHaler products that the FTC has disputed as being improperly or inaccurately listed?
    a. Please specify which ones you have de-listed.
    b. Please specify when you will de-list them if you have not done so yet.

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[12] Centers for Medicare & Medicaid Services, "Medicare Part D Spending by Drug," 2021, https://data.cms.gov/summary-statistics-on-use-and-payments/medicare-medicaid-spending-by-drug/medicare-part-d-spending-by-drug//data.

[13] 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.

[14] 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.

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

[16] 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.

3. Will Teva and Norton Limited 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

December 13, 2023

Rajiv Malik
President
Viatris Inc.
1000 Mylan Blvd.
Canonsburg, PA 15322

Scott A. Smith
CEO
Viatris Inc.
1000 Mylan Blvd.
Canonsburg, PA 15322

Dear Mr. Malik and Mr. Scott:

We write today regarding the Federal Trade Commission's (FTC) November 7, 2023 letter indicating that "certain patents have been improperly or inaccurately listed in the Orange Book with regard to Mylan Specialty LP's – which is now part of Viatris[1] – EPIPEN and EPIPEN JR. products."[2] These are deeply troubling allegations, indicating that Mylan Specialty has been abusing the patent system to profit at patients' and taxpayers' expense by charging exorbitant prices for lifesaving epinephrine injectors used to treat severe asthma attacks and allergic reactions.[3] Accordingly, we write to ask that you address the improper behavior identified by the FTC by December 16, 2023.

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 FTC's 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 FDA is barred from approving a generic version of the drug for 30 months.[6] Powerful Big Pharma players are therefore incentivized to strategically list sham patents in the Orange

[1] Mylan, https://www.mylan.com/.

[2] Letter from U.S. Federal Trade Commission to Mylan Specialty Inc., November 7, 2023, https://www.ftc.gov/system/files/ftc_gov/pdf/mylan-specialty-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.

[3] Mylan, "EpiPen," https://www.epipen.com/en.

[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.

[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.

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 November issued a warning letter to Mylan Specialty that appears to conclude that the company may be violating federal law with regard to its drug listings. Given these concerns, we urge you to voluntarily de-list the eight patents named in the FTC's letter that you have listed in the Orange Book with regard to Mylan Specialty's EPIPEN and EPIPEN JR. products, and any other patents you have listed that unfairly block competition.[9] As FTC noted, Mylan Specialty bears the burden of ensuring its Orange Book listings are accurate and comply with all relevant statutory and regulatory requirements.[10]

The practices that FTC has highlighted in its warning letter are a prime example of how pharmaceutical companies — including Mylan Specialty — regularly employ anticompetitive tactics to extend their government-granted monopolies, insulate themselves from generic and biosimilar competition, and keep prices artificially high.[11] 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 $40.7 billion on pharmaceutical products "as a result of antitrust violations by the pharmaceutical industry" in 2019.[12] And the Medicare Part D program spent over $1.6 million and $18,000 on a single formulation of EPIPEN and EPIPEN JR, respectively.[13]

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[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] 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] Letter from U.S. Federal Trade Commission to Mylan Specialty Inc., November 7, 2023, https://www.ftc.gov/system/files/ftc_gov/pdf/mylan-specialty-orange-book.pdf.

[10] *Id*.

[11] National Library of Medicine, "Patents and Regulatory Exclusivities on Inhalers for Asthma and COPD," William Feldman, Doni Bloomfield, Reed Beall, and Aaron Kesselheim, Jun 2022, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10328096/; Washington Post, "How the makers of inhalers keep prices so high," William B. Feldman and Aaron S. Kesselheim, June 1, 2023, https://www.washingtonpost.com/opinions/2023/06/01/inhaler-cost-drug-company-prices/.

[12] 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.

[13] Centers for Medicare & Medicaid Services, "Medicare Part D Spending by Drug," 2021, 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.[14] FDA has 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 listing of sham patents in the Orange Book as an unfair method of competition.[17]

Now, in light of FTC's notice disputing several of your company's patent listings, we request that you to voluntarily de-list all of Mylan Specialty's improperly and inaccurately listed Orange Book patents by December 16, 2023 and provide responses to the following questions by no later than January 15, 2024.

1. FTC identified eight patents for EPIPEN and EPIPEN JR that have been improperly or inaccurately listed in the Orange Book.
    a. Has Mylan Specialty 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. Has Mylan Specialty voluntarily de-listed the eight patents listed in the Orange Book with regard to the EPIPEN and EPIPEN JR products that the FTC has disputed as being improperly or inaccurately listed?
    a. Please specify which ones you have de-listed.
    b. Please specify when you will de-list them if you have not done so yet.

[14] 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.

[15] 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.

[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.

3. Will Mylan Specialty 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