

United States Senate  
WASHINGTON, DC 20510

January 18, 2024

Kathleen Collins  
Vice President & Head US Regulatory Affairs  
Boehringer Ingelheim  
900 Ridgebury Road  
Ridgefield, CT 06877  
[kathleen.collins@boehringer-ingelheim.com](mailto:kathleen.collins@boehringer-ingelheim.com)

Dear Ms. Collins:

On November 7, 2023, the Federal Trade Commission (FTC) sent you a warning letter that identified 22 patents covering four products that are improperly or inaccurately listed in the Orange Book. Two months later, those patents remain listed in the Orange Book. At least three warning letter recipients have taken steps to remove the patents the FTC concluded were improperly listed from the Orange Book, but Boehringer Ingelheim has not. I urge Boehringer Ingelheim to remove all patents identified by the FTC by the end of the month or provide me with a written explanation of why you believe each patent identified by the FTC is properly listed.

As you know, improperly listing a patent in the Orange Book can harm consumers, raise prices, and stifle competition by preventing cheaper generic drugs from entering the market for up to 30 months and drives up the cost of entry by generic drug manufacturers by pushing them into expensive litigation before entering the market. Patients in the United States pay more for prescription drugs than those in any other developed nation. The reasons for this are many, but one reason is the continued abuse of patent rights to extend monopoly control over a drug.

I have fought to end these abuses of our patent system. For example, with Senator Chuck Grassley, I have passed the *Preserving Access to Affordable Generics and Biosimilars Act* and the *Stop STALLING Act* out of the Judiciary Committee to limit anticompetitive “pay-for-delay” deals that prevent or delay the introduction of affordable follow-on versions of branded pharmaceutical and deter pharmaceutical companies from filing sham petitions with the Food and Drug Administration in order to interfere with the approval of generic and biosimilar medicines. These practices—like the improper listing of patents in the Orange Book—serve only

to deter generic competition, raise prices, and pad drug companies' bottom lines at the expense of consumers.

While your inventions that benefit consumers deserve strong patent protections, those patents should not be used to box out generic drug competition long after legitimate patent protections have expired. I call on you to remove all remaining patents identified in the FTC's November 7 letter as quickly as possible.

Sincerely,

A handwritten signature in black ink that reads "Amy Klobuchar". The signature is fluid and cursive, with the first name "Amy" written in a larger, more prominent script than the last name "Klobuchar".

Amy Klobuchar  
United States Senator

CC: Bridget Walsh, [bridget.walsh@boehringer-ingenelheim.com](mailto:bridget.walsh@boehringer-ingenelheim.com)

United States Senate  
WASHINGTON, DC 20510

January 18, 2024

Robert MacRae  
General Counsel, U.S. Commercial  
GSK  
2929 Walnut St  
Philadelphia, PA 19104  
Rob.R.Macrae@gsk.com

Dear Mr. MacRae:

On November 7, 2023, the Federal Trade Commission (FTC) sent two of your subsidiaries warning letters that identified 14 patents covering four products that are improperly or inaccurately listed in the Orange Book. While I appreciate that you have taken steps to remove most of these patents from the Orange Book, reports indicate that you have not removed all of those identified by the FTC. I urge GSK to remove all patents identified by the FTC by the end of the month or provide me with a written explanation of why you believe each patent identified by the FTC is properly listed.

As you know, improperly listing a patent in the Orange Book can harm consumers, raise prices, and stifle competition by preventing cheaper generic drugs from entering the market for up to 30 months and drives up the cost of entry by generic drug manufacturers by pushing them into expensive litigation before entering the market. Patients in the United States pay more for prescription drugs than those in any other developed nation. The reasons for this are many, but one reason is the continued abuse of patent rights to extend monopoly control over a drug.

I have fought to end these abuses of our patent system. For example, with Senator Chuck Grassley, I have passed the *Preserving Access to Affordable Generics and Biosimilars Act* and the *Stop STALLING Act* out of the Judiciary Committee to limit anticompetitive “pay-for-delay” deals that prevent or delay the introduction of affordable follow-on versions of branded pharmaceutical and deter pharmaceutical companies from filing sham petitions with the Food and Drug Administration in order to interfere with the approval of generic and biosimilar medicines. These practices—like the improper listing of patents in the Orange Book—serve only to deter generic competition, raise prices, and pad drug companies’ bottom lines at the expense of consumers.

While your inventions that benefit consumers deserve strong patent protections, those patents should not be used to box out generic drug competition long after legitimate patent protections have expired. I call on you to remove all remaining patents identified in the FTC's November 7 letter as quickly as possible.

Sincerely,

A handwritten signature in black ink that reads "Amy Klobuchar". The signature is fluid and cursive, with the first name "Amy" written in a larger, more prominent script than the last name "Klobuchar".

Amy Klobuchar  
United States Senator

CC: Michael J. Calvo, Michael.J.Calvo@gsk.com

United States Senate  
WASHINGTON, DC 20510

January 18, 2024

Brian Savage  
General Counsel  
Teva Pharmaceuticals USA, Inc.,  
400 Interpace Pkwy, Suite 3  
Parsippany, NJ 07054  
[brian.savage@tevapharm.com](mailto:brian.savage@tevapharm.com)

Dear Mr. Savage:

On November 7, 2023, the Federal Trade Commission (FTC) sent you and your subsidiary, Norton (Waterford) Limited, two warning letters that identified 42 patents covering four products that are improperly or inaccurately listed in the Orange Book. Two months later, those patents remain listed in the Orange Book. At least three warning letter recipients have taken steps to remove the patents the FTC concluded were improperly listed from the Orange Book, but Teva Pharmaceuticals and Norton (Waterford) Limited have not. I urge Teva and Norton to remove all patents identified by the FTC by the end of the month or provide me with a written explanation of why you believe each patent identified by the FTC is properly listed.

As you know, improperly listing a patent in the Orange Book can harm consumers, raise prices, and stifle competition by preventing cheaper generic drugs from entering the market for up to 30 months, and drives up the cost of entry by generic drug manufacturers by pushing them into expensive litigation before entering the market. Patients in the United States pay more for prescription drugs than those in any other developed nation. The reasons for this are many, but one reason is the continued abuse of patent rights to extend monopoly control over a drug.

I have fought to end these abuses of our patent system. For example, with Senator Chuck Grassley, I have passed the *Preserving Access to Affordable Generics and Biosimilars Act* and the *Stop STALLING Act* out of the Judiciary Committee to limit anticompetitive “pay-for-delay” deals that prevent or delay the introduction of affordable follow-on versions of branded pharmaceutical and deter pharmaceutical companies from filing sham petitions with the Food and Drug Administration in order to interfere with the approval of generic and biosimilar medicines. These practices—like the improper listing of patents in the Orange Book—serve only to deter generic competition, raise prices, and pad drug companies’ bottom lines at the expense of consumers.

While your inventions that benefit consumers deserve strong patent protections, those patents should not be used to box out generic drug competition long after legitimate patent protections have expired. I call on you to remove all remaining patents identified in the FTC's November 7 letter as quickly as possible.

Sincerely,

A handwritten signature in black ink that reads "Amy Klobuchar". The signature is fluid and cursive, with a large loop under the "y" and a distinct "K" for the first letter of the last name.

Amy Klobuchar  
United States Senator

CC: Michael Brzica, [Michael.Brzica@tevapharm.com](mailto:Michael.Brzica@tevapharm.com)

United States Senate  
WASHINGTON, DC 20510

January 18, 2024

Brian Roman  
Global General Counsel  
Viatris Inc.  
1000 Mylan Blvd.  
Canonsburg, PA 15322  
Brian.Roman@viatris.com

Dear Mr. Roman:

On November 7, 2023, the Federal Trade Commission (FTC) sent you a warning letter that identified four patents covering two products that are improperly or inaccurately listed in the Orange Book. Two months later, those patents remain listed in the Orange Book. At least three warning letter recipients have taken steps to remove the patents the FTC concluded were improperly listed from the Orange Book, but Viatris has not. I urge Viatris to remove all patents identified by the FTC by the end of the month or provide me with a written explanation of why you believe each patent identified by the FTC is properly listed.

As you know, improperly listing a patent in the Orange Book can harm consumers, raise prices, and stifle competition by preventing cheaper generic drugs from entering the market for up to 30 months and drives up the cost of entry by generic drug manufacturers by pushing them into expensive litigation before entering the market. Patients in the United States pay more for prescription drugs than those in any other developed nation. The reasons for this are many, but one reason is the continued abuse of patent rights to extend monopoly control over a drug.

I have fought to end these abuses of our patent system. For example, with Senator Chuck Grassley, I have passed the *Preserving Access to Affordable Generics and Biosimilars Act* and the *Stop STALLING Act* out of the Judiciary Committee to limit anticompetitive “pay-for-delay” deals that prevent or delay the introduction of affordable follow-on versions of branded pharmaceutical and deter pharmaceutical companies from filing sham petitions with the Food and Drug Administration in order to interfere with the approval of generic and biosimilar medicines. These practices—like the improper listing of patents in the Orange Book—serve only to deter generic competition, raise prices, and pad drug companies’ bottom lines at the expense of consumers.

While your inventions that benefit consumers deserve strong patent protections, those patents should not be used to box out generic drug competition long after legitimate patent protections have expired. I call on you to remove all remaining patents identified in the FTC's November 7 letter as quickly as possible.

Sincerely,

A handwritten signature in black ink that reads "Amy Klobuchar". The signature is fluid and cursive, with the first name "Amy" written in a larger, more prominent script than the last name "Klobuchar".

Amy Klobuchar  
United States Senator

CC: Peter Wallace, [Peter.Wallace@viatris.com](mailto:Peter.Wallace@viatris.com)



United States Senate  
WASHINGTON, DC 20510

January 18, 2024

Perry C. Siatis  
General Counsel, EVP  
Abbvie Inc.  
1 North Waukegan Road  
North Chicago, IL 60064  
Perry.Siatis@abbvie.com

Dear Mr. Siatis Counsel:

On November 7, 2023, the Federal Trade Commission (FTC) sent you a warning letter that identified four patents that are improperly or inaccurately listed in the Orange Book. Two months later, those patents remain listed in the Orange Book. At least three warning letter recipients have taken steps to remove the patents the FTC concluded were improperly listed from the Orange Book, but Abbvie has not. I urge Abbvie to remove all patents identified by the FTC by the end of the month or provide me with a written explanation of why you believe each patent identified by the FTC is properly listed.

As you know, improperly listing a patent in the Orange Book can harm consumers, raise prices, and stifle competition by preventing cheaper generic drugs from entering the market for up to 30 months, and drives up the cost of entry by generic drug manufacturers by pushing them into expensive litigation before entering the market. Patients in the United States pay more for prescription drugs than those in any other developed nation. The reasons for this are many, but one reason is the continued abuse of patent rights to extend monopoly control over a drug.

I have fought to end these abuses of our patent system. For example, with Senator Chuck Grassley, I have passed the *Preserving Access to Affordable Generics and Biosimilars Act* and the *Stop STALLING Act* out of the Judiciary Committee to limit anticompetitive “pay-for-delay” deals that prevent or delay the introduction of affordable follow-on versions of branded pharmaceutical and deter pharmaceutical companies from filing sham petitions with the Food and Drug Administration in order to interfere with the approval of generic and biosimilar medicines. These practices—like the improper listing of patents in the Orange Book—serve only to deter generic competition, raise prices, and pad drug companies’ bottom lines at the expense of consumers.

While your inventions that benefit consumers deserve strong patent protections, those patents should not be used to box out generic drug competition long after legitimate patent protections have expired. I call on you to remove all remaining patents identified in the FTC's November 7 letter as quickly as possible.

Sincerely,

A handwritten signature in black ink that reads "Amy Klobuchar". The signature is fluid and cursive, with the first name "Amy" written in a larger, more prominent script than the last name "Klobuchar".

Amy Klobuchar  
United States Senator

CC: Daniel Bachner, [dan.bachner@abbvie.com](mailto:dan.bachner@abbvie.com)

United States Senate  
WASHINGTON, DC 20510

January 18, 2024

Jeff Pott  
General Counsel, AstraZeneca  
1 Francis Crick Avenue  
Cambridge CB2 0AA  
United Kingdom  
[jeffrey.pott@astrazeneca.com](mailto:jeffrey.pott@astrazeneca.com)

Dear Mr. Pott:

On November 7, 2023, the Federal Trade Commission (FTC) sent you a warning letter that identified 10 patents that are improperly or inaccurately listed in the Orange Book. Two months later, those patents remain listed in the Orange Book. At least three warning letter recipients have taken steps to remove the patents the FTC concluded were improperly listed from the Orange Book, but AstraZeneca has not. I urge AstraZeneca to remove all patents identified by the FTC by the end of the month or provide me with a written explanation of why you believe each patent identified by the FTC is properly listed.

As you know, improperly listing a patent in the Orange Book can harm consumers, raise prices, and stifle competition by preventing cheaper generic drugs from entering the market for up to 30 months, and drives up the cost of entry by generic drug manufacturers by pushing them into expensive litigation before entering the market. Patients in the United States pay more for prescription drugs than those in any other developed nation. The reasons for this are many, but one reason is the continued abuse of patent rights to extend monopoly control over a drug.

I have fought to end these abuses of our patent system. For example, with Senator Chuck Grassley, I have passed the *Preserving Access to Affordable Generics and Biosimilars Act* and the *Stop STALLING Act* out of the Judiciary Committee to limit anticompetitive “pay-for-delay” deals that prevent or delay the introduction of affordable follow-on versions of branded pharmaceutical and deter pharmaceutical companies from filing sham petitions with the Food and Drug Administration in order to interfere with the approval of generic and biosimilar medicines. These practices—like the improper listing of patents in the Orange Book—serve only to deter generic competition, raise prices, and pad drug companies’ bottom lines at the expense of consumers.

While your inventions that benefit consumers deserve strong patent protections, those patents should not be used to box out generic drug competition long after legitimate patent protections have expired. I call on you to remove all remaining patents identified in the FTC's November 7 letter as quickly as possible.

Sincerely,

A handwritten signature in black ink that reads "Amy Klobuchar". The signature is fluid and cursive, with the first name "Amy" written in a larger, more prominent script than the last name "Klobuchar".

Amy Klobuchar  
United States Senator

CC: Sarah Arbes, [sarah.arbes@astrazeneca.com](mailto:sarah.arbes@astrazeneca.com)