IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BRISTOL-MYERS SQUIBB COMPANY AND PFIZER INC.,	)	
Plaintiffs,	)	
v.	)	Civil Action No. 1:17-cv-00407-LPS
SANDOZ INC.,	)	
Defendant.	)	

SANDOZ INC.'S ANSWER, DEFENSES AND COUNTERCLAIMS

Defendant, Sandoz Inc. ("Sandoz"), for its Answer, Defenses and Counterclaims to the Complaint for Patent Infringement of Plaintiffs, Bristol-Myers Squibb Company ("BMS") and Pfizer Inc. ("Pfizer") (collectively "Plaintiffs"), responds as follows. Every allegation not expressly admitted herein is denied.

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, against Defendant Sandoz Inc. ("Sandoz"). This action relates to Abbreviated New Drug Application ("ANDA") No. 209981 filed by Sandoz with the U.S. Food and Drug Administration ("FDA").

ANSWER: Paragraph 1 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Sandoz admits that this action purports to state a claim for alleged patent infringement. Sandoz further admits that it has filed Abbreviated New Drug Application ("ANDA") No. 209981 with the U.S. Food and Drug Administration ("FDA"). Sandoz denies any and all remaining allegations of Paragraph 1.

2. In ANDA No. 209981, Sandoz seeks approval to market 2.5 mg and 5 mg tablets of apixaban, generic versions of Plaintiffs' Eliquis® drug product (the "Sandoz ANDA product"), prior to expiration of U.S. Patent Nos. 6,967,208 (the "'208 patent") and 9,326,945 (the "'945 patent") (collectively, the "patents-in-suit").

ANSWER: Paragraph 2 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Sandoz admits that it has filed ANDA No. 209981 with FDA, seeking approval for Apixaban Tablets, 2.5 mg and 5 mg, prior to the expiration of United States Patent Nos. 6,967,208 (the "'208 patent") and 9,326,945 (the "'945 patent"). Sandoz denies any and all remaining allegations of Paragraph 2.

PARTIES

3. BMS is a corporation organized and existing under the laws of Delaware, having a place of business at Route 206 and Province Line Road, Princeton, New Jersey 08540.

ANSWER: On information and belief, Sandoz admits the allegations of Paragraph 3.

4. Pfizer is a corporation organized and existing under the laws of Delaware, having its principal place of business at 235 East 42nd Street, New York, New York 10017.

ANSWER: On information and belief, Sandoz admits the allegations of Paragraph 4.

5. Plaintiffs are engaged in the business of creating, developing, and bringing to market revolutionary pharmaceutical products to help patients prevail against serious diseases, including treatments for thromboembolic disorders. Plaintiffs sell Eliquis® in this judicial district and throughout the United States.

ANSWER: Paragraph 5 contains allegations to which no answer is required. To the extent an answer is required, Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 5, and therefore denies them.

6. Upon information and belief, Sandoz is a corporation organized and existing under the laws of Colorado, having its principal place of business at 100 College Road West, Princeton, New Jersey 08540.

ANSWER: Paragraph 6 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Sandoz admits that it is a corporation organized and existing under the laws of Colorado with a place of business at 100 College Road West, Princeton, NJ 08540. Sandoz denies any and all remaining allegations of Paragraph 6.

JURISDICTION AND VENUE

7. This action arises under the patent laws of the United States, 35 U.S.C. §§ 100, *et seq.*, and this Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

ANSWER: Paragraph 7 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Sandoz admits that this action purports to state a claim for alleged patent infringement, and that subject matter jurisdiction is proper, if at all, solely for the claims asserted against it under 35 U.S.C. § 271(e)(2)(A). Sandoz denies that subject matter jurisdiction is proper under 35 U.S.C. § 271(a), (b), or (c). Sandoz denies any and all remaining allegations of Paragraph 7.

8. This Court has jurisdiction over Sandoz because, *inter alia*, Sandoz has committed an act of patent infringement under 35 U.S.C. § 271(e)(2) and intends a future course of conduct that includes acts of patent infringement in Delaware. These acts have led and will lead to foreseeable harm and injury to Plaintiffs, both Delaware corporations, in Delaware. For example, on information and belief, following approval of ANDA No. 209981, Sandoz will make, use, import, sell, and/or offer for sale the Sandoz ANDA product in the United States, including in Delaware, prior to the expiration of the patents-in-suit.

ANSWER: Paragraph 8 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, denied. Further answering, Sandoz does not contest personal jurisdiction in this judicial district solely for the limited purposes of this action only.

9. This Court also has jurisdiction over Sandoz because, *inter alia*, this action arises from actions of Sandoz directed toward Delaware, and because Sandoz has purposefully availed itself of the rights and benefits of Delaware law by engaging in systematic and continuous contacts with Delaware. Upon information and belief, Sandoz regularly and continuously transacts business within Delaware, including by selling pharmaceutical products in Delaware. Upon information and belief, Sandoz derives substantial revenue from the sale of those products in Delaware and has availed itself of the privilege of conducting business within Delaware.

ANSWER: Paragraph 9 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, denied. Further answering, Sandoz does not

contest personal jurisdiction in this judicial district solely for the limited purposes of this action only.

10. Sandoz has previously been sued in this judicial district and has availed itself of Delaware courts through the assertion of counterclaims in suits brought in Delaware including *Astellas Pharma Inc. v. Sandoz Inc.*, 1:15-cv-00952-SLR-CJB.

ANSWER: Paragraph 10 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, denied. Further answering, Sandoz admits that it was a named Defendant in *Astellas Pharma Inc. v. Sandoz Inc.*, 1:16-cv-00952-SLR (D. Del.). Sandoz further admits that Sandoz has asserted claims and/or counterclaims in the above action. Sandoz denies any and all remaining allegations of Paragraph 10.

11. Venue is proper in this Court under 28 U.S.C. §§ 1391 and/or 1400(b), including because, *inter alia*, Sandoz is subject to personal jurisdiction in this district, as set forth above, has committed an act of infringement and will commit further acts of infringement in this judicial district, as set forth in more detail in paragraph 8 above, and, upon information and belief, has a regular and established place of business in this judicial district.

ANSWER: Paragraph 11 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, denied. Further answering, Sandoz does not contest venue in this judicial district solely for the limited purposes of this action only.

12. For these reasons, and for other reasons that will be presented to the Court if jurisdiction and/or venue is challenged, the Court has personal jurisdiction over Sandoz, and venue in this judicial district is proper.

ANSWER: Paragraph 12 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, denied. Further answering, Sandoz does not contest personal jurisdiction or venue in this judicial district solely for the limited purposes of this action only.

PATENTS-IN-SUIT

13. On November 22, 2005, the U.S. Patent and Trademark Office duly and legally issued the '208 patent, titled "Lactam-Containing Compounds and Derivatives thereof as Factor Xa Inhibitors." A true and correct copy of the '208 patent is attached hereto as Exhibit A. The claims of the '208 patent are valid, enforceable, and not expired. BMS is the owner of the '208 patent and has the right to enforce it.

ANSWER: Paragraph 13 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Sandoz admits that, according to the online records of the United States Patent and Trademark Office ("PTO"), the '208 patent, which is titled "Lactam-Containing Compounds and Derivatives Thereof as Factor Xa Inhibitors," issued on or about November 22, 2005. Sandoz further admits that what purports to be a copy of the '208 patent is attached to Plaintiffs' Complaint as Exhibit A. Sandoz denies that the '208 patent was duly and legally issued, as well as any suggestion that the '208 patent is valid and enforceable. Sandoz denies any and all remaining allegations of Paragraph 13.

14. On May 3, 2016, the U.S. Patent and Trademark Office duly and legally issued the '945 patent, titled "Apixaban Formulations." A true and correct copy of the '945 patent is attached hereto as Exhibit B. The claims of the '945 patent are valid, enforceable, and not expired. Plaintiffs are the joint owners of the '945 patent and have the right to enforce it.

ANSWER: Paragraph 14 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Sandoz admits that, according to the online records of the PTO, the '945 patent, which is titled "Apixaban Formulations," issued on or about May 3, 2016. Sandoz further admits that what purports to be a copy of the '945 patent is attached to Plaintiffs' Complaint as Exhibit B. Sandoz denies that the '945 patent was duly and legally issued, as well as any suggestion that the '945 patent is valid and enforceable. Sandoz denies any and all remaining allegations of Paragraph 14.

15. BMS is the holder of New Drug Application ("NDA") No. 202155, by which the FDA granted approval for the marketing and sale of 2.5 mg and 5 mg strength apixaban tablets. Plaintiffs market apixaban tablets in the United States, under the trade name "Eliquis®." The FDA's official publication of approved drugs (the "Orange Book")

includes Eliquis® together with the patents-in-suit. Eliquis® is a factor Xa inhibitor indicated: (1) to reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation; (2) for the prophylaxis of deep vein thrombosis ("DVT"), which may lead to pulmonary embolism ("PE"), in patients who have undergone hip or knee replacement surgery; and (3) for the treatment of DVT and PE, and for the reduction in the risk of recurrent DVT and PE following initial therapy. A copy of the complete prescribing information for Eliquis® approved in NDA No. 202155 is attached as Exhibit C.

ANSWER: Paragraph 15 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Sandoz admits that the electronic version of FDA's publication, *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as "the Orange Book"), identifies "BRISTOL-MYERS SQUIBB CO PHARMACEUTICAL RESEARCH INSTITUTE" as the purported "Applicant Holder" for approved New Drug Application ("NDA") No. 202155 for "ELIQUIS" (apixaban tablet; oral, 2.5 mg and 5 mg). Sandoz further admits that the Orange Book lists the '208 and the '945 patents in connection with Eliquis®. Sandoz further admits that the current FDA-approved prescribing information for Eliquis® states that it is indicated "to reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation," "for the prophylaxis of deep vein thrombosis (DVT), which may lead to pulmonary embolism (PE), in patients who have undergone hip or knee replacement surgery," and "for the treatment of DVT and PE, and for the reduction in the risk of recurrent DVT and PE following initial therapy." Sandoz also admits that what purports to be a copy of the July 2016 prescribing information for Eliquis® is attached to Plaintiffs' Complaint as Exhibit C. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 15, and therefore denies them.

INFRINGEMENT BY SANDOZ

16. By letter sent by FedEx Priority Overnight service and Certified Mail on March 9, 2017, Sandoz notified Plaintiffs that Sandoz had submitted ANDA No. 209981 to the FDA under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. §

355(j)) ("the Eliquis Notice Letter"). Plaintiffs received the Eliquis Notice Letter no earlier than March 10, 2017.

ANSWER: Sandoz admits that it sent several copies of a letter, dated March 9, 2017, regarding its submission of ANDA No. 209981 to FDA under Section of 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) ("Sandoz Notice Letter"). Upon information and belief, Plaintiffs received this letter on or about March 10, 2017. Sandoz denies any and all remaining allegations of Paragraph 16.

17. The Eliquis Notice Letter states that Sandoz seeks approval from the FDA to engage in the commercial manufacture, use, and sale of the Sandoz ANDA product before the expiration of the patents-in-suit. Upon information and belief, Sandoz intends to – directly or indirectly – engage in the commercial manufacture, use, and sale of the Sandoz ANDA product promptly upon receiving FDA approval to do so.

ANSWER: Paragraph 17 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Sandoz admits that the Sandoz Notice Letter states that it submitted an ANDA to FDA seeking approval for Apixaban Tablets, 2.5 mg and 5 mg, before the expiration of the '208 and '945 patents. Sandoz denies any and all remaining allegations of Paragraph 17.

18. By filing ANDA No. 209981, Sandoz has necessarily represented to the FDA that the Sandoz ANDA product has the same active ingredient as Eliquis®, has the same dosage form and strength as Eliquis®, and is bioequivalent to Eliquis®.

ANSWER: Paragraph 18 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Sandoz admits that it has filed ANDA No. 209981 with FDA seeking approval for Apixaban Tablets, 2.5 mg and 5 mg and that this ANDA satisfies all statutory and regulatory requirements for an ANDA. Sandoz denies any and all remaining allegations of Paragraph 18.

19. Upon information and belief, Sandoz is seeking approval to market the Sandoz ANDA product for the same approved indications as Eliquis®.

ANSWER: Paragraph 19 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Sandoz admits that it submitted an ANDA to FDA seeking approval for Apixaban Tablets, 2.5 mg and 5 mg with proposed labeling as required by statute and regulation. Sandoz denies any and all remaining allegations of Paragraph 19.

20. In the Eliquis Notice Letter, Sandoz states that its ANDA contains a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the patents-in-suit are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, and sale of the Sandoz ANDA product.

ANSWER: Sandoz admits that the Sandoz Notice Letter notes that it submitted an ANDA to FDA seeking approval for Apixaban Tablets, 2.5 mg and 5 mg, before the expiration of to the '208 and '945 patents, and that Sandoz's ANDA contains a so-called "Paragraph IV Certification" stating that, in Sandoz's opinion and to the best of its knowledge, the '208 and '945 patents are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, sale, offer for sale, and/or importation of the drug products described in Sandoz's ANDA. Sandoz denies any and all remaining allegations of Paragraph 20.

21. In the Eliquis Notice Letter, Sandoz offered confidential access to portions of its ANDA No. 209981 on terms and conditions set forth in the Eliquis Notice Letter ("the Sandoz Offer"). Sandoz requested that Plaintiffs accept the Sandoz Offer before receiving access to Sandoz's ANDA No. 209981. The Sandoz Offer contained unreasonable restrictions well beyond those that would apply under a protective order on who could view the ANDA. For example, the Sandoz Offer contained a broad patent prosecution bar, which, among other things, does not have a carve-out for inter-partes reviews or other adversarial proceedings, and a broad bar on any work related to actions before the FDA. The Sandoz Offer unreasonably restricted the ability of counsel to seek the opinions of outside experts without written permission from Sandoz's designated counsel, and Sandoz had broad authority to reject any request by Plaintiffs to seek outside expert access to the Sandoz ANDA. The restrictions Sandoz has placed on access to ANDA No. 209981 contravene 21 U.S.C. § 355(j)(5)(C)(i)(III), which states that an offer of confidential access "shall contain such restrictions as to persons entitled to access, and on the use and disposition of any information accessed, *as would apply had a protective order been entered for the purpose of protecting trade secrets and other confidential business information*" (emphasis added).

ANSWER: Paragraph 21 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Sandoz admits that the Sandoz Notice Letter contains an appropriate offer of confidential access ("OCA") to Sandoz's ANDA that satisfies all statutory requirements. Sandoz denies any and all remaining allegations of Paragraph 21.

22. This Complaint is being filed before the expiration of forty-five days from the date Plaintiffs received the Eliquis Notice Letter.

ANSWER: Paragraph 22 contains legal conclusions and allegations for which no answer is required. To the extent an answer is required, Sandoz admits that the electronic court records of the United States District Court for the District of Delaware indicate that a Complaint was docketed against Sandoz on or about April 10, 2017. Sandoz denies any and all remaining allegations of Paragraph 22.

COUNT I
(THE '208 PATENT)

23. Each of the preceding paragraphs 1 to 22 is incorporated as if fully set forth herein.

ANSWER: Sandoz restates and incorporates its responses to paragraphs 1-22 as if fully set forth herein.

24. Sandoz's submission of ANDA No. 209981 to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Sandoz ANDA product prior to the expiration of the '208 patent constituted a technical act of infringement of at least one of the claims of the '208 patent, either literally or under the doctrine of equivalents, including but not limited to claims 8, 13, 26-27, and 55-61, under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Denied.

25. Sandoz's commercial manufacture, use, offer to sell, sale, or importation of the Sandoz ANDA product prior to the expiration of the '208 patent, and its inducement of and/or contribution to such conduct, would further infringe, either literally or under the doctrine of equivalents, at least one of the claims of the '208 patent, including but not limited to claims 8, 13, and 26-27, under 35 U.S.C. §§ 271(a), (b) and/or (c).

ANSWER: Denied.

26. Sandoz's commercial manufacture, use, offer to sell, sale, or importation of the Sandoz ANDA product for the same treatment claimed in the '208 patent prior to the expiration of the '208 patent, and its inducement of and/or contribution to such conduct, would further infringe, either literally or under the doctrine of equivalents, at least one of the claims of the '208 patent, including but not limited to claims 55-61, under 35 U.S.C. §§ 271(a), (b) and/or (c).

ANSWER: Denied.

27. Upon FDA approval of Sandoz's ANDA No. 209981, Sandoz will infringe, either literally or under the doctrine of equivalents, at least one of the claims of the '208 patent, including but not limited to claims 8, 13, 26-27, and 55-61, by making, using, offering to sell, and selling the Sandoz ANDA product in the United States and/or importing said product into the United States, or by actively inducing and contributing to infringement of the '208 patent by others, under 35 U.S.C. § 271(a)-(c), unless enjoined by the Court.

ANSWER: Denied.

28. If Sandoz's marketing and sale of the Sandoz ANDA product prior to expiration of the '208 patent and all other relevant exclusivities are not enjoined, BMS will suffer substantial and irreparable harm for which there is no remedy at law.

ANSWER: Denied.

COUNT II
(THE '945 PATENT)

29. Each of the preceding paragraphs 1 to 28 is incorporated as if fully set forth herein.

ANSWER: Sandoz restates and incorporates its responses to paragraphs 1-28 as if fully set forth herein.

30. Sandoz's submission of ANDA No. 209981 to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Sandoz ANDA product prior to the expiration of the '945 patent constituted a technical act of infringement of at least one of the claims of the '945 patent, either literally or under the doctrine of equivalents, including but not limited to claims 1, 9-12, 20-23, 25, 27, 29, 31, 33, 35, and 37, under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Denied.

31. Sandoz's commercial manufacture, use, offer to sell, sale, or importation of the Sandoz ANDA product prior to the expiration of the '945 patent, and its inducement of

and/or contribution to such conduct, would further infringe at least one of the claims of the '945 patent, either literally or under the doctrine of equivalents, including but not limited to claims 1, 9-12, 20-23, 25, 27, 29, 31, 33, 35, and 37, under 35 U.S.C. §§ 271(a), (b) and/or (c).

ANSWER: Denied.

32. Upon FDA approval of Sandoz's ANDA No. 209981, Sandoz will infringe one or more claims of the '945 patent, either literally or under the doctrine of equivalents, including but not limited to claims 1, 9-12, 20-23, 25, 27, 29, 31, 33, 35, and 37, by making, using, offering to sell, and selling the Sandoz ANDA product in the United States and/or importing said product into the United States, or by actively inducing and contributing to infringement of the '945 patent by others, under 35 U.S.C. § 271(a)-(c), unless enjoined by the Court.

ANSWER: Denied.

33. If Sandoz's marketing and sale of the Sandoz ANDA product prior to expiration of the '945 patent and all other relevant exclusivities are not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no remedy at law.

ANSWER: Denied.

* * *

As stated above, Sandoz denies all allegations not expressly admitted herein.

[PLAINTIFFS'] RELIEF SOUGHT

Sandoz denies that Plaintiffs are entitled to the relief requested, or to any relief whatsoever. Sandoz respectfully requests that the Court: (a) dismiss this action with prejudice; (b) enter judgment in favor of Sandoz; (c) award Sandoz its reasonable attorney fees and costs incurred in defending this action pursuant to 35 U.S.C. § 285; and (d) award Sandoz such further relief as the Court deems just and appropriate.

SEPARATE DEFENSES

Without prejudice to the denials set forth in this Answer, without admitting any allegation in the Complaint not otherwise admitted, and without undertaking any of the burdens imposed by law on the Plaintiffs, Defendant Sandoz Inc. ("Sandoz") asserts the following separate defenses:

First Defense

The Complaint fails to state a claim upon which relief can be granted.

Second Defense

The claims of the ’208 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code, and/or for double-patenting.

Third Defense

The claims of the ’945 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code, and/or for double-patenting.

Fourth Defense

The manufacture, use, sale, offer for sale, importation, and/or marketing of the Apixaban Tablet product, that is the subject of ANDA No. 209981 (“Sandoz’s ANDA”), has not infringed, does not infringe, and would not—if made, used, sold, offered for sale, imported or marketed—infringe, either directly or indirectly, any valid and/or enforceable claim of the ’208 patent, either literally or under the doctrine of equivalents.

Fifth Defense

The manufacture, use, sale, offer for sale, importation, and/or marketing of the Apixaban Tablet product, that is the subject of Sandoz’s ANDA, has not infringed, does not infringe, and would not—if made, used, sold, offered for sale, imported or marketed—infringe, either directly or indirectly, any valid and/or enforceable claim of the ’945 patent, either literally or under the doctrine of equivalents.

Sixth Defense

Sandoz has not induced, does not induce, and will not induce infringement of any valid and/or enforceable claim of the ’208 patent.

Seventh Defense

Sandoz has not induced, does not induce, and will not induce infringement of any valid and/or enforceable claim of the ’945 patent.

Eight Defense

Sandoz has not contributed, does not contribute, and will not contribute to infringement of any valid and/or enforceable claim of the ’208 patent.

Ninth Defense

Sandoz has not contributed, does not contribute, and will not contribute to infringement of any valid and/or enforceable claim of the ’945 patent.

Tenth Defense

The Court lacks subject matter jurisdiction over any and all claims asserted under 35 U.S.C. § 271(a), (b), or (c).

Eleventh Defense

The Complaint fails to state a claim for willful infringement and/or exceptional case.

Twelfth Defense

Any additional defenses or counterclaims that discovery may reveal, including unenforceability.

* * *

COUNTERCLAIMS

Defendant/Counterclaim-Plaintiff Sandoz Inc., for its Counterclaims against Plaintiffs/Counterclaim-Defendants Bristol-Myers Squibb Company ("BMS") and Pfizer Inc. ("Pfizer") (collectively "Counterclaim-Defendants"), alleges as follows:

THE PARTIES

1. Sandoz Inc. is a corporation organized and existing under the laws of the State of Colorado, with a place of business at 100 College Road West, Princeton, New Jersey 08540.

2. BMS purports to be a corporation organized and existing under the laws of the State of Delaware with its principal place of business at Route 206 and Province Line Road, Princeton, New Jersey 08540.

3. Pfizer purports to be a corporation organized and existing under the laws of Delaware, having its principal place of business at 235 East 42nd Street, New York, New York 10017.

JURISDICTION

4. These Counterclaims arise under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*; the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202; and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003) ("MMA") (21 U.S.C. § 355(j) and 35 U.S.C. § 271(e)(5)).

5. This Court has original jurisdiction over the subject matter of these Counterclaims under 28 U.S.C. §§ 1331 and 1338(a); under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202; and under the MMA (21 U.S.C. § 355(j) and 35 U.S.C. § 271(e)(5)).

6. This Court has personal jurisdiction over Counterclaim-Defendants because Counterclaim-Defendants have availed themselves of the rights and privileges—and subjected

themselves to the jurisdiction—of this forum by suing Sandoz Inc. in this District, and/or because Counterclaim-Defendants conduct substantial business in, and have regular systemic contact with, this District.

BACKGROUND

A. Eliquis® (apixaban tablet; oral, 2.5 mg and 5 mg)

8. BMS purports to be the holder of approved New Drug Application ("NDA") No. 202155 for Eliquis® (apixaban tablet; oral, 2.5 mg and 5 mg).

B. Patents-in-Suit

9. On or about November 22, 2005, the United States Patent and Trademark Office ("PTO") issued U.S. Patent No. 6,967,208 (the "'208 patent").

10. On or about May 3, 2016, the PTO issued U.S. Patent No. 9,326,945 (the "'945 patent").

11. Counterclaim-Defendants purport and claim to have the right to enforce the '945 and '208 patents.

12. By listing the '945 and '208 patents in the electronic version of U.S. Food and Drug Administration's ("FDA") publication, *Approved Drug Products with Therapeutic Equivalence Evaluations* (a/k/a FDA's Orange Book), Counterclaim-Defendants maintain that an infringement suit could reasonably be asserted against any generic Abbreviated New Drug Application ("ANDA") applicant—including Sandoz Inc.—that attempts to seek approval for, and market, a generic version of Eliquis® before patent expiration.

C. Sandoz Inc.'s ANDA for Apixaban Tablets, 2.5 mg and 5 mg Suit

13. Sandoz Inc. has filed ANDA No. 209981 with FDA seeking approval for Apixaban Tablets, 2.5 mg and 5 mg ("Sandoz Inc.'s ANDA").

14. Sandoz Inc.'s ANDA includes certifications under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certifications") to the '945 and '208 patents, stating that, in Sandoz Inc.'s opinion and to the best of its knowledge, such patents are invalid, unenforceable and/or not infringed.

15. Counterclaim-Defendants sued Sandoz Inc. for alleged infringement of the '945 and '208 patents in this District. Sandoz Inc. denies all allegations of infringement.

COUNT I
Declaratory Judgment of Invalidity of the '208 Patent

16. Sandoz Inc. realleges and incorporates by reference the allegations of paragraphs 1-15 as if fully set forth herein.

17. There is an actual, substantial, and continuing case or controversy between Sandoz Inc. and Counterclaim-Defendants regarding, *inter alia*, the invalidity of the '208 patent.

18. The claims of the '208 patent are invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code, including, without limitation, 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or for double-patenting.

19. Sandoz Inc. reserves the right to provide additional bases for invalidity of the '208 patent in its contentions, responses to discovery requests, expert reports, and/or pleadings filed and/or served later in this action.

20. Sandoz Inc. is entitled to a judicial declaration that the claims of the '208 patent are invalid.

COUNT II
Declaratory Judgment of Non-Infringement of the '208 Patent

21. Sandoz Inc. realleges and incorporates by reference the allegations of paragraphs 1-20 as if fully set forth herein.

22. There is an actual, substantial, and continuing case or controversy between Sandoz Inc. and Counterclaim-Defendants regarding, *inter alia*, the non-infringement of the ’208 patent.

23. Sandoz Inc.’s manufacture, use, offer for sale, sale, importation, and/or marketing of the Apixaban Tablets, 2.5 mg and 5 mg products described in Sandoz Inc.’s ANDA has not infringed, does not infringe, and would not—if made, used, sold, offered for sale, imported or marketed—infringe, either directly or indirectly, any valid or enforceable claim of the ’208 patent, either literally or under the doctrine of equivalents.

24. Counterclaim-Defendants bear the burden of proving by preponderance of the evidence that every limitation set forth in the asserted claims is found in the accused product, either literally or by a substantial equivalent. To date, Counterclaim-Defendants have not set forth any evidence attempting to prove infringement of the ’208 patent.

25. Sandoz Inc. is entitled to a judicial declaration that the manufacture, use, offer for sale, sale, importation, and/or marketing of the Apixaban Tablets, 2.5 mg and 5 mg products described in Sandoz Inc.’s ANDA have not infringed, do not infringe, and would not—if made, used, sold, offered for sale, imported or marketed—infringe, either directly or indirectly, any valid or enforceable claim of the ’208 patent, either literally or under the doctrine of equivalents.

COUNT III
Declaratory Judgment of Invalidity of the ’945 Patent

26. Sandoz Inc. realleges and incorporates by reference the allegations of paragraphs 1-25 as if fully set forth herein.

27. There is an actual, substantial, and continuing case or controversy between Sandoz Inc. and Counterclaim-Defendants regarding, *inter alia*, the invalidity of the ’945 patent.

28. The claims of the ’945 patent are invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code, including, without limitation, 35 U.S.C. §§ 102, 103, and/or 112, and/or for double-patenting.

29. Sandoz Inc. reserves the right to provide additional bases for invalidity of the ’945 patent in its contentions, responses to discovery requests, expert reports, and/or pleadings filed and/or served later in this action.

30. Sandoz Inc. is entitled to a judicial declaration that the claims of the ’945 patent are invalid.

COUNT IV
Declaratory Judgment of Non-Infringement of the ’945 Patent

31. Sandoz Inc. realleges and incorporates by reference the allegations of paragraphs 1-30 as if fully set forth herein.

32. There is an actual, substantial, and continuing case or controversy between Sandoz Inc. and Counterclaim-Defendants regarding, *inter alia*, the non-infringement of the ’945 patent.

33. Sandoz Inc.’s manufacture, use, offer for sale, sale, importation, and/or marketing of the Apixaban Tablets, 2.5 mg and 5 mg products described in Sandoz Inc.’s ANDA have not infringed, do not infringe, and would not—if made, used, sold, offered for sale, imported or marketed—infringe, either directly or indirectly, any valid or enforceable claim of the ’945 patent, either literally or under the doctrine of equivalents.

34. Counterclaim-Defendants bear the burden of proving by preponderance of the evidence that every limitation set forth in the asserted claims is found in the accused product, either literally or by a substantial equivalent. To date, Counterclaim-Defendants have not set forth any evidence attempting to prove infringement of the ’945 patent.

35. Sandoz Inc. is entitled to a judicial declaration that the manufacture, use, offer for sale, sale, importation, and/or marketing of the Apixaban Tablets, 2.5 mg and 5 mg products described in Sandoz Inc.'s ANDA have not infringed, do not infringe, and would not—if made, used, sold, offered for sale, imported or marketed—infringe, either directly or indirectly, any valid or enforceable claim of the '945 patent, either literally or under the doctrine of equivalents.

PRAYER FOR RELIEF

WHEREFORE, Sandoz Inc. respectfully prays for judgment in its favor and against Counterclaim-Defendants:

(a) Declaring that the manufacture, use, sale, offer for sale, importation, and/or marketing of the Apixaban Tablets, 2.5 mg and 5 mg products described in Sandoz Inc.'s ANDA has not infringed, does not infringe, and would not—if made, used, sold, offered for sale, imported or marketed—infringe, either directly or indirectly, any valid and/or enforceable claim of the '208 patent, either literally or under the doctrine of equivalents;

(b) Declaring that the claims of the '208 patent are invalid;

(c) Declaring that the manufacture, use, sale, offer for sale, importation, and/or marketing of the Apixaban Tablets, 2.5 mg and 5 mg products described in Sandoz Inc.'s ANDA has not infringed, does not infringe, and would not—if made, used, sold, offered for sale, imported or marketed—infringe, either directly or indirectly, any valid and/or enforceable claim of the '945 patent, either literally or under the doctrine of equivalents;

(d) Declaring that the claims of the '945 patent are invalid;

(e) Ordering that the Complaint (D.I. 1) be dismissed with prejudice and judgment

entered in favor of Sandoz Inc.;

(f) Declaring this case exceptional and awarding Sandoz Inc. its reasonable attorney fees and costs under 35 U.S.C. § 285; and

(g) Awarding Sandoz Inc. such other and further relief as the Court may deem just and proper.

DEMAND FOR JURY TRIAL

Sandoz Inc. hereby demands a jury trial on all issues so triable.

Dated: June 12, 2017

Respectfully submitted,

HEYMAN ENERIO
GATTUSO & HIRZEL LLP

/s/ Dominick T. Gattuso

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