IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BAYER PHARMA AG, BAYER AG and JANSSEN PHARMACEUTICALS, INC.,	)	
Plaintiffs,	)	
v.	)	C.A. No. 21-cv-00314-RGA
LUPIN LIMITED and LUPIN PHARMACEUTICALS, INC.,	)	
Defendants.	)	

LUPIN LIMITED'S AND LUPIN PHARMACEUTICALS, INC.'S ANSWER, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS

Defendants Lupin Limited and Lupin Pharmaceuticals, Inc. (collectively, "Defendants"), by and through their counsel, hereby answer and respond to each of the allegations in the Complaint by Plaintiffs Bayer Pharma AG, Bayer AG, and Janssen Pharmaceuticals, Inc. (collectively, "Plaintiffs") (D.I. 1), and assert their separate defenses, and Lupin Limited asserts its separate counterclaims, as follows.

GENERAL DENIAL

Pursuant to Fed. R. Civ. P. 8(b)(3), Defendants deny all allegations in Plaintiffs' Complaint except those expressly admitted below.

NATURE OF THE ACTION

1. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, that arises out of the submission by Lupin Limited of an Abbreviated New Drug Application ("ANDA") to the U.S. Food and Drug Administration ("FDA") seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of a generic version of Plaintiffs' 2.5 mg XARELTO® product prior to the expiration of U.S. Patent No. 10,828,310 ("the '310 patent").

ANSWER: Paragraph 1 states legal conclusions and allegations to which no answer is required. To the extent an answer is deemed required, Defendants admit that the Complaint

purports to state a claim for infringement of U.S. Patent No. 10,828,310 ("the '310 patent") under the patent laws of the United States, Title 35, United States Code. Defendants further admit that Lupin Limited submitted an Abbreviated New Drug Application ("ANDA") with the U.S. Food and Drug Administration ("FDA") seeking approval for rivaroxaban tablets 2.5 mg, prior to the expiration of the '310 patent. Defendants deny that the Complaint states a proper claim for infringement of the '310 patent and/or that such claim has any merit. Defendants deny any remaining allegations in Paragraph 1.

THE PARTIES

Plaintiffs

2. Plaintiff Bayer Pharma AG is a corporation organized and existing under the laws of the Federal Republic of Germany, with a place of business at Müllerstrasse 178, 13353 Berlin, Germany.

ANSWER: Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 2, and therefore deny them.

3. Plaintiff Bayer AG is a corporation organized and existing under the laws of the Federal Republic of Germany, with a place of business at Kaiser-Wilhelm-Allee 1, 51368 Leverkusen, Germany.

ANSWER: Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 3, and therefore deny them.

4. Plaintiff Janssen Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the Commonwealth of Pennsylvania, with a principal place of business at 1125 Trenton-Harbourton Road, Titusville, New Jersey.

ANSWER: Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 4, and therefore deny them.

Lupin

5. On information and belief, Defendant Lupin Limited is a corporation organized and existing under the laws of India, with a place of business at B/4 Laxmi Towers, Bandra Kurla complex, Bandra (E), Mumbai 400051, India.

ANSWER: Defendants admit that Lupin Limited is an entity organized and existing under the laws of India, with a place of business at 3rd Floor, Kalpataru Inspire, Off Wertern Express Highway, Santacruz (E), Mumbai 400 051, India.

6. On information and belief, Defendant Lupin Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of Delaware, with a place of business at Harborplace Tower, 111 S. Calvert Street, 21st Floor, Baltimore, MD 21202.

ANSWER: Defendants admit that Lupin Pharmaceuticals, Inc. is a Delaware corporation, but state that it has a place of business at 111 South Calvert Street, Harborplace Tower, 21st Floor, Baltimore, Maryland 21202. Defendants deny that Lupin Pharmaceuticals, Inc. is a proper party to this action.

7. On information and belief, Lupin Pharmaceuticals, Inc. is a wholly-owned subsidiary of Lupin Limited, and is controlled and dominated by Lupin Limited.

ANSWER: Paragraph 7 states legal conclusions and allegations to which no answer is required. To the extent an answer is deemed required, Defendants admit that Lupin Pharmaceuticals, Inc. is an indirect, wholly-owned subsidiary of Lupin Limited. Defendants deny any remaining allegations in Paragraph 7.

8. On information and belief, Lupin Limited is in the business of, among other things, manufacturing, marketing, distributing, offering for sale, and selling generic drug products. As a part of this business, on information and belief, Lupin Limited, acting in concert with Lupin Pharmaceuticals, Inc., files ANDAs with the FDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of generic versions of drug products that are covered by United States patents. On information and belief, as part of these ANDAs, Lupin Limited, acting in concert with Lupin Pharmaceuticals, Inc., files certifications of the type described in Section 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act ("Paragraph IV Certifications") to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of generic drug products prior to the expiration of United States patents that cover such products.

ANSWER: Defendants admit that Lupin Limited filed ANDA No. 208555 with the FDA seeking approval of its proposed rivaroxaban tablets, 2.5 mg. Defendants further admit that ANDA No. 208555 includes a Paragraph IV certification, as described in Section 505(j)(2)(A)(vii)(IV) of

the Federal Food, Drug, and Cosmetic Act. Defendants deny any remaining allegations in Paragraph 8.

9. On information and belief, Lupin Limited and Lupin Pharmaceuticals, Inc. acted in concert to prepare and submit ANDA No. 208555 for Lupin Limited's 2.5 mg rivaroxaban tablets ("Lupin's ANDA Product"), which was done at the direction of, under the control of, and for the direct benefit of Lupin Limited.

ANSWER: Defendants admit that Lupin Limited filed ANDA No. 208555 with the FDA seeking approval of its proposed rivaroxaban tablets, 2.5 mg. Defendants deny any remaining allegations in Paragraph 9.

10. On information and belief, Lupin Limited and Lupin Pharmaceuticals, Inc. are agents of each other, and/or operate in concert as integrated parts of the same business group, and enter into agreements with each other that are nearer than arm's length, including with respect to the development, regulatory approval, marketing, sale, offer for sale, and distribution of generic pharmaceutical products throughout the United States, including into Delaware, and including with respect to Lupin's ANDA Product at issue.

ANSWER: Paragraph 10 states legal conclusions and allegations to which no answer is required. To the extent an answer is deemed required, denied.

11. On information and belief, following any FDA approval of ANDA No. 208555, Lupin Limited and Lupin Pharmaceuticals, Inc. will act in concert to market, distribute, offer for sale, and sell Lupin's ANDA Product throughout the United States and within Delaware. These two entities are hereafter collectively referred to as "Lupin."

ANSWER: Paragraph 11 states legal conclusions and allegations to which no answer is required. To the extent an answer is deemed required, Defendants admit that Lupin Limited filed ANDA No. 208555 with the FDA seeking approval for its proposed rivaroxaban tablets, 2.5 mg. Defendants deny any remaining allegations in Paragraph 11.

12. On information and belief, following any FDA approval of ANDA No. 208555, Lupin knows and intends that its ANDA Product will be marketed, used, distributed, offered for sale, and sold in the United States and within Delaware.

ANSWER: Paragraph 12 states legal conclusions and allegations to which no answer is required. To the extent an answer is deemed required, Defendants admit that Lupin Limited filed

ANDA No. 208555 with the FDA seeking approval for its proposed rivaroxaban tablets, 2.5 mg. Defendants deny any remaining allegations in Paragraph 12.

JURISDICTION

13. Plaintiffs incorporate each of the preceding paragraphs 1-12 as if each is fully set forth herein.

ANSWER: Paragraph 13 contains no allegations of fact to which a response is required. To the extent an answer is required, Defendants repeat and incorporate by reference their responses to Paragraphs 1-12 as if fully stated herein.

14. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

ANSWER: Paragraph 14 states legal conclusions and allegations to which no answer is required. To the extent an answer is deemed required, Defendants admit that this Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a) solely for the claims directed against Lupin Limited under 35 U.S.C. § 271(e)(2). Defendants deny any remaining allegations in Paragraph 14.

15. This Court has personal jurisdiction over Lupin Pharmaceuticals, Inc. because, among other things, Lupin Pharmaceuticals, Inc. has purposely availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court here. Lupin Pharmaceuticals, Inc. is a corporation formed under the laws of the state of Delaware, and has appointed registered agents in Delaware (The Corporation Trust Company, Corporation Trust Center, 1209 Orange St., Wilmington, DE) to accept service of process. It therefore has consented to general jurisdiction in Delaware.

ANSWER: Paragraph 15 states legal conclusions and allegations to which no answer is required. To the extent an answer is deemed required, Defendants admit Lupin Pharmaceuticals, Inc. is a Delaware corporation and has a registered agent in Delaware. Defendants deny that Lupin Pharmaceuticals, Inc. is a proper party to this action. Defendants deny any remaining allegations in Paragraph 15.

16. Upon information and belief, Lupin Pharmaceuticals, Inc. is responsible for marketing, distributing, offering for sale, and/or selling generic copies of branded pharmaceutical products for the U.S. market, including in Delaware, and relies on contributions from Lupin Limited.

ANSWER: Paragraph 16 states legal conclusions and allegations to which no answer is required. To the extent an answer is deemed required, Defendants deny the allegations in Paragraph 16.

17. Upon information and belief, Lupin Pharmaceuticals, Inc., acting as the agent of Lupin Limited, markets, distributes, offers for sale, and/or sells in Delaware and elsewhere in the United States generic pharmaceutical products that are manufactured by Lupin Limited or for which Lupin is the named applicant on approved ANDAs.

ANSWER: Paragraph 17 states legal conclusions and allegations to which no answer is required. To the extent an answer is deemed required, Defendants deny the allegations in Paragraph 17.

18. In addition, this Court has personal jurisdiction over Lupin because, among other things, on information and belief: (1) Lupin has filed an ANDA for the purpose of seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Lupin's ANDA Product in the United States, including in Delaware; and (2) Lupin will market, distribute, offer for sale, and/or sell Lupin's ANDA Product in the United States, including in Delaware, upon approval of ANDA No. 208555, and will derive substantial revenue from the use or consumption of Lupin's ANDA Product in the State of Delaware. On information and belief, if ANDA No. 208555 is approved, the generic Lupin product charged with infringing the '310 patent would, among other things, be marketed, distributed, offered for sale, and/or sold in Delaware, prescribed by physicians practicing in Delaware, and dispensed by pharmacies located within Delaware, and/or used by patients in Delaware, all of which would have a substantial effect on Delaware.

ANSWER: Paragraph 18 states legal conclusions and allegations to which no answer is required. To the extent an answer is deemed required, Defendants do not contest personal jurisdiction in this Court for purposes of this action only. Defendants deny any remaining allegations of Paragraph 18.

19. Alternatively, if Lupin Limited's connections with Delaware, including its connections with Lupin Pharmaceuticals, Inc., are found to be insufficient to confer personal jurisdiction, then, upon information and belief, Lupin Limited is not subject to jurisdiction in any

state's courts of general jurisdiction, and exercising jurisdiction over Lupin Limited in Delaware is consistent with the United States Constitution and laws. *See* Fed. R. Civ. P. 4(k)(2).

ANSWER: Paragraph 19 states legal conclusions and allegations to which no answer is required. To the extent an answer is deemed required, Lupin Limited does not contest personal jurisdiction in this Court for purposes of this action only. Defendants deny any remaining allegations of Paragraph 19.

20. Lupin Limited and Lupin Pharmaceuticals, Inc. regularly engage in patent litigation concerning FDA-approved branded drug products in this district, do not contest personal jurisdiction in this district, and have availed themselves of the rights and benefits of this Court by asserting claims and/or counterclaims in this Court, *see, e.g.*, *Bayer Intellectual Property GmbH, et al., v. Lupin Ltd. and Lupin Pharmaceuticals, Inc.*, C.A. No. 17-1047-RGA (D.I. 9); *Genentech, Inc., et al. v. Lupin Ltd. and Lupin Pharmaceuticals, Inc.*, C.A. No. 19-109-RGA (D.I. 10).

ANSWER: Paragraph 20 states legal conclusions and allegations to which no answer is required. To the extent an answer is deemed required, Defendants do not contest personal jurisdiction in this Court for purposes of this action only. Defendants further specifically deny that Lupin Pharmaceuticals, Inc. is a proper party to this action. Defendants deny any remaining allegations of Paragraph 20.

VENUE

21. Venue is proper in this district for Lupin Limited pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia,* Lupin Limited is a corporation organized and existing under the laws of India and is subject to personal jurisdiction in this judicial district.

ANSWER: Paragraph 21 states legal conclusions and allegations to which no answer is required. To the extent an answer is deemed required, Lupin Limited does not contest venue in this Court for purposes of this action only. Defendants deny any remaining allegations of Paragraph 21.

22. Venue is proper in this district for Lupin Pharmaceuticals, Inc. pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, Lupin Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of Delaware and is subject to personal jurisdiction in this judicial district.

ANSWER: Paragraph 22 states legal conclusions and allegations to which no answer is required. To the extent an answer is deemed required, Defendants admit that Lupin Pharmaceuticals, Inc. is a Delaware corporation. Defendants deny that Lupin Pharmaceuticals, Inc. is a proper party to this action. Defendants deny any remaining allegations of Paragraph 22.

FACTUAL BACKGROUND

23. XARELTO® (active ingredient rivaroxaban) is a factor Xa inhibitor. The 2.5 mg tablet strength of XARELTO® is indicated for administration orally twice daily, in combination with aspirin (75-100 mg) once daily, to reduce the risk of major cardiovascular events (cardiovascular (CV) death, myocardial infarction (MI), and stroke) in patients with chronic coronary artery disease (CAD) or peripheral artery disease (PAD).

ANSWER: Upon information and belief, Defendants admit that the 2.5 mg rivaroxaban tablets are marketed under the trade name Xarelto®. Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 23, and therefore deny them.

24. Janssen is the holder of New Drug Application No. 022406 for XARELTO®, which has been approved by the FDA.

ANSWER: Upon information and belief, Defendants admit that Janssen Pharmaceuticals, Inc. is identified in FDA records as the holder of NDA No. 022406. Upon information and belief, Defendants admit that the products that are subject to NDA No. 022406 were approved by the FDA and are marketed under the trade name Xarelto®. Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 24, and therefore deny them.

25. The ’310 patent, entitled “Reducing the Risk of Cardiovascular Events,” was duly and legally issued on November 10, 2020. The ’310 patent is attached as Exhibit A.

ANSWER: Defendants admit that Plaintiffs purport to attach a copy of the ’310 patent to the Complaint as Exhibit A. Defendants further admit that the face of the ’310 patent indicates that it issued on November 10, 2020 and is titled “Reducing the Risk of Cardiovascular Events.”

Defendants deny any remaining allegations in Paragraph 25, including any suggestion or implication that the '310 patent was duly and legally issued or is valid or enforceable.

26. As set forth in greater detail in the '310 patent, the claims of the '310 patent, incorporated by reference herein, cover certain methods involving rivaroxaban. For example, independent claim 1 recites, "A method of reducing the risk of myocardial infarction, stroke or cardiovascular death in a human patient with coronary artery disease and/or peripheral artery disease, comprising administering to the human patient rivaroxaban and aspirin in amounts that are clinically proven effective in reducing the risk of myocardial infarction, stroke or cardiovascular death in a human patient with coronary artery disease and/or peripheral arterial disease, wherein rivaroxaban is administered in an amount of 2.5 mg twice daily and aspirin is administered in an amount of 75-100 mg daily."

ANSWER: Paragraph 26 states legal conclusions and allegations to which no answer is required. To the extent an answer is deemed required, Defendants deny the allegations in Paragraph 26, including any suggestion or implication that the claims of the '310 patent are valid or enforceable.

27. Bayer Pharma AG is the assignee of the '310 patent.

ANSWER: Defendants admit that the United States Patent and Trademark Office's ("USPTO") patent assignment records indicate that Bayer Pharma AG is the purported assignee of the '310 patent. Defendants are without knowledge or information sufficient to form a belief as to the remaining allegations of Paragraph 27, and therefore deny them.

28. Bayer AG is an exclusive licensee under the '310 patent.

ANSWER: Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 28, and therefore deny them.

29. Janssen is an exclusive sublicensee under the '310 patent.

ANSWER: Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 29, and therefore deny them.

30. Pursuant to 21 U.S.C. § 355, the '310 patent is listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book") in connection with the 2.5 mg strength of XARELTO®.

ANSWER: Paragraph 30 states legal conclusions and allegations to which no answer is required. To the extent an answer is deemed required, upon information and belief, Defendants admit that the '310 patent is listed in FDA's publication titled *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book") as purportedly associated with Xarelto®. Defendants lack sufficient knowledge and information to form a belief as to the truth of the remaining allegations contained in Paragraph 30, and therefore deny them.

COUNT I: ALLEGED INFRINGEMENT OF THE '310 PATENT

31. Plaintiffs incorporate each of the preceding paragraphs 1-30 as if fully set forth herein.

ANSWER: Paragraph 31 contains no allegations of fact to which a response is required. To the extent an answer is required, Defendants repeat and incorporate by reference their responses to Paragraphs 1-30 as if fully stated herein.

32. By letter dated January 15, 2021 ("Lupin's Notice Letter"), Lupin notified, *inter alia*, Plaintiffs that Lupin had submitted to the FDA ANDA No. 208555 for Lupin's ANDA Product. This product is a generic version of the 2.5 mg strength of XARELTO®.

ANSWER: Defendants admit that Lupin Limited sent a letter dated January 15, 2021 (the "Notice Letter") to Plaintiffs that notified Plaintiffs of Lupin Limited's submission of ANDA No. 208555 to the FDA seeking approval for its proposed rivaroxaban tablets, 2.5 mg, prior to the expiration of the '310 patent. Defendants state that Lupin Limited's Notice Letter speaks for itself, and Defendants deny the allegations of Paragraph 32 to the extent they deviate from or otherwise do not accurately reflect or describe the Notice Letter or Lupin Limited's proposed rivaroxaban tablets, 2.5 mg. Defendants deny any remaining allegations in Paragraph 32.

33. In Lupin's Notice Letter, Lupin indicated that, in connection with its ANDA No. 208555, Lupin had filed a Paragraph IV Certification with respect to the '310 patent.

ANSWER: Defendants admit that Lupin Limited's Notice Letter notified Plaintiffs that Lupin Limited, in connection with its ANDA No. 208555, had filed a paragraph IV certification

under Section 505(j)(2)(A)(vii) of the Federal Food, Drug, and Cosmetic Act, with respect to the '310 patent. Defendants state that Lupin Limited's Notice Letter speaks for itself, and Defendants deny the allegations of Paragraph 33 to the extent they deviate from or otherwise do not accurately reflect or describe the Notice Letter. Defendants deny any remaining allegations in Paragraph 33.

34. In Lupin's Notice Letter, Lupin stated that Lupin's ANDA Product contains rivaroxaban.

ANSWER: Defendants admit that Lupin Limited's Notice Letter states that Lupin Limited submitted ANDA No. 208555 to the FDA seeking approval for its proposed rivaroxaban tablets, 2.5 mg. Defendants state that Lupin Limited's Notice Letter speaks for itself, and Defendants deny the allegations of Paragraph 34 to the extent they deviate from or otherwise do not accurately reflect or describe the Notice Letter. Defendants deny any remaining allegations in Paragraph 34.

35. On information and belief, the proposed labeling for Lupin's ANDA Product directs a method of reducing the risk of major cardiovascular events (cardiovascular (CV) death, myocardial infarction (MI), and stroke) in patients with chronic coronary artery disease (CAD) or peripheral artery disease (PAD). On information and belief, the proposed labeling for Lupin's ANDA Product further directs the administration of Lupin's ANDA Product and aspirin in amounts that are clinically proven effective in reducing the risk of MI, stroke or CV death in a human patient with CAD and/or PAD, wherein Lupin's ANDA Product will be administered twice daily and aspirin is administered in an amount of 75-100 mg daily.

ANSWER: Denied.

36. The purpose of ANDA No. 208555 was, *inter alia*, to obtain approval under the Federal Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, offer for sale, and/or sale of Lupin's ANDA Product with its proposed labeling prior to the expiration of the '310 patent.

ANSWER: Lupin Limited admits that it submitted ANDA No. 208555 to the FDA in compliance with Section 505(j) of the Federal Food, Drug, and Cosmetic Act seeking FDA approval for its proposed rivaroxaban tablets, 2.5 mg, prior to the expiration of the '310 patent. Defendants deny any remaining allegations in Paragraph 36.

37. Lupin intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Lupin's ANDA Product with its proposed labeling immediately

and imminently upon approval of ANDA No. 208555, *i.e.*, prior to the expiration of the '310 patent.

ANSWER: Lupin Limited admits that it submitted ANDA No. 208555 to the FDA in compliance with Section 505(j) of the Federal Food, Drug, and Cosmetic Act seeking FDA approval for its proposed rivaroxaban tablets, 2.5 mg, prior to the expiration of the '310 patent. Defendants deny any remaining allegations in Paragraph 37.

38. On information and belief, the manufacture, use (including in accordance with and as directed by Lupin's proposed labeling for Lupin's ANDA Product), offer for sale, sale, marketing, distribution, and/or importation of Lupin's ANDA Product will infringe at least claim 1 of the '310 patent.

ANSWER: Denied.

39. In Lupin's Notice Letter, Lupin did not contest that the use of Lupin's ANDA Product in accordance with its proposed labeling would infringe the '310 patent, assuming the patent is valid.

ANSWER: Denied.

40. Lupin has knowledge of the claims of the '310 patent. Notwithstanding this knowledge, Lupin has continued to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Lupin's ANDA Product with its proposed labeling immediately and imminently upon approval of ANDA No. 208555. On information and belief, by such activities, Lupin specifically intends to infringe the '310 patent.

ANSWER: Paragraph 40 states legal conclusions and allegations to which no answer is required. To the extent an answer is deemed required, Defendants deny the allegations in Paragraph 40.

41. On information and belief, Lupin plans and intends to, and will, actively induce infringement of the '310 patent when its ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

ANSWER: Denied.

42. On information and belief, Lupin knows that Lupin's ANDA Product with its proposed labeling is especially made or adapted for use in infringing the '310 patent, and that Lupin's ANDA Product with its proposed labeling is not suitable for substantial noninfringing use. On information and belief, Lupin plans and intends to, and will, contribute to infringement of the '310 patent immediately and imminently upon approval of ANDA No. 208555.

ANSWER: Denied.

43. Lupin's submission of ANDA No. 208555 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Lupin's ANDA Product was an act of infringement of the '310 patent under 35 U.S.C. § 271(e)(2).

ANSWER: Lupin Limited admits that it submitted ANDA No. 208555 to the FDA seeking approval for its proposed rivaroxaban tablets, 2.5 mg, prior to expiration of the '310 patent. Defendants deny any remaining allegations in Paragraph 43.

44. On information and belief, Lupin has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import Lupin's ANDA Product with its proposed labeling prior to the expiration of the '310 patent.

ANSWER: Denied.

45. Lupin intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Lupin's ANDA Product with its proposed labeling prior to the expiration of the '310 patent.

ANSWER: Denied.

46. The foregoing actions by Lupin constitute and/or will constitute infringement of the '310 patent, active inducement of infringement of the '310 patent, and/or contribution to the infringement by others of the '310 patent.

ANSWER: Denied.

47. Unless Lupin is enjoined from infringing the '310 patent, actively inducing infringement of the '310 patent, and contributing to the infringement by others of the '310 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

ANSWER: Denied.

48. This action is being commenced before the expiration of forty-five days from the date Bayer and Janssen received the Lupin Notice Letter.

ANSWER: Paragraph 48 states legal conclusions and allegations to which no answer is required. To the extent an answer is deemed required, admitted.

COUNT II: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '310 PATENT

49. Plaintiffs incorporate each of the preceding paragraphs 1-48 as if fully set forth herein.

ANSWER: Paragraph 49 contains no allegations of fact to which a response is required. To the extent an answer is required, Defendants repeat and incorporate by reference their responses to Paragraphs 1-48 as if fully stated herein.

50. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Plaintiffs on the one hand and Lupin on the other regarding Lupin's liability for infringement and active inducement of infringement of the '310 patent.

ANSWER: Denied.

51. An actual case or controversy exists between Plaintiffs and Lupin with respect to infringement of the '310 patent.

ANSWER: Denied.

52. The Court should declare that the commercial manufacture, use, sale, offer for sale or importation of Lupin's ANDA Product will infringe and induce the infringement of the '310 patent.

ANSWER: Denied.

ALLEGED PRAYER FOR RELIEF

All remaining allegations not specifically admitted herein are denied. Defendants further deny that Plaintiffs are entitled to any judgment or relief against Defendants, and, therefore, specifically deny paragraphs (a) through (f) of Plaintiffs' Prayer for Relief.

DEFENDANTS' AFFIRMATIVE DEFENSES

Without prejudice to the responses and denials set forth in Defendants' Answer, without admitting any allegations of the Complaint not expressly admitted, and without assuming the burden of proof on any such defense that would otherwise rest with Plaintiffs, Defendants assert the following separate defenses to the Complaint:

First Affirmative Defense

The Complaint, in whole or in part, fails to state a claim upon which relief can be granted.

Second Affirmative Defense

The claims of the '310 patent are invalid and/or unenforceable for failure to comply with and/or satisfy one or more of the conditions and requirements of Title 35 of the United States Code, including, but not limited to, one or more of 35 U.S.C. §§ 101, 102, 103, 112, 116, 120 and/or double patenting and the defenses recognized in 35 U.S.C. § 282(b).

Third Affirmative Defense

Defendants do not, have not, and will not infringe, literally or under the doctrine of equivalents, willfully or otherwise, any valid, enforceable, and properly construed claim of the '310 patent, either directly, indirectly, contributorily, by inducement, or in any other manner. The manufacture, use, offer for sale, sale, and/or importation of the products that are subject to Lupin Limited's ANDA No. 208555 do not, have not, and will not infringe, literally or under the doctrine of equivalents, willfully or otherwise, any valid, enforceable, and properly construed claim of the '310 patent, either directly, indirectly, contributorily, by inducement, or in any other manner.

Fourth Affirmative Defense

Plaintiffs are barred by 35 U.S.C. § 288 from recovering any costs associated with this suit.

Fifth Affirmative Defense

Lupin Pharmaceuticals, Inc. is not a proper party to this action.

Reservation of Rights

Defendants expressly reserve the right to supplement and/or amend their Answer to Plaintiffs' Complaint, including, but not limited to, supplementation and/or amendment of their defenses and amplifications of denials, as additional facts and information become known through the course of this case and discovery.

COUNTERCLAIMS BY LUPIN LIMITED

Counterclaim-Plaintiff Lupin Limited, for its Counterclaims against Plaintiffs/Counterclaim Defendants Bayer Pharma AG, Bayer AG, and Janssen Pharmaceuticals, Inc. (collectively, "Bayer/Janssen"), alleges as follows:

1. This is a counterclaim action for declaratory judgment of noninfringement and/or invalidity of one or more claims of U.S. Patent No. 10,828,310 ("the '310 patent").

2. Lupin Limited is a corporation organized and existing under the laws of India, having a place of business at 3rd Floor, Kalpataru Inspire, Off Western Express Highway, Santacruz (E), Mumbai 400 051, India.

3. On information and belief, and based on the allegations in the Complaint, Bayer Pharma AG is a corporation organized and existing under the laws of the Federal Republic of Germany, with a place of business at Müllerstrasse 178, 13353 Berlin, Germany.

4. On information and belief, and based on the allegations in the Complaint, Bayer AG is a corporation organized and existing under the laws of the Federal Republic of Germany, with a place of business at Kaiser-Wilhelm-Allee 1, 51368 Leverkusen, Germany.

5. On information and belief, and based on the allegations in the Complaint, Janssen Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the Commonwealth of Pennsylvania, with a principal place of business at 1125 Trenton-Harbourton Road, Titusville, New Jersey.

JURISDICTION AND VENUE

6. Lupin Limited seeks a declaratory judgment pursuant to 28 U.S.C. §§ 2201 and 2202.

7. The Court has jurisdiction over these counterclaims pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, 2202, and/or 35 U.S.C. § 271(e))(2).

8. This is an action based on an actual controversy between Lupin Limited and Bayer/Janssen concerning the noninfringement and/or invalidity of the '310 patent arising under the Patent Laws of the United States, 35 U.S.C. §§ 100 *et seq*., and Lupin Limited's right to continue to seek approval by the Food and Drug Administration ("FDA") of Abbreviated New Drug Application ("ANDA") No. 208555, and upon FDA approval, to manufacture, use, sell, and offer to sell within, and/or import into, the United States the rivaroxaban tablets, 2.5 mg, that are the subject of Lupin Limited's ANDA No. 208555 ("Lupin Limited's rivaroxaban ANDA Products").

9. The Court has personal jurisdiction over Bayer/Janssen because, on information and belief, Bayer/Janssen transact business within the State of Delaware and/or have engaged in systematic and continuous business contacts within the State of Delaware. Further, Bayer/Janssen have subjected themselves to the jurisdiction of this Court by virtue of filing their Complaint.

10. Venue is legally proper in this District under 28 U.S.C. § 1391, § 1400(b), 21 U.S.C. § 355(j)(5)(C)(i)(II), and/or by Bayer/Janssen's choice of forum.

BACKGROUND

11. On information and belief, on or about November 10, 2020, the United States Patent and Trademark Office ("USPTO") issued the '310 patent, titled "Reducing the Risk of Cardiovascular Events." According to the information on the face of the patent, the '310 patent is assigned to Bayer Pharma AG. On information and belief, and based on the allegations in the Complaint, Bayer AG is an exclusive licensee under the '310 patent, and Janssen Pharmaceuticals, Inc. is the exclusive sublicensee under the '310 patent.

12. On information and belief, Janssen Pharmaceuticals, Inc. is the holder of New Drug Application ("NDA") No. 022406 for rivaroxaban tablets, 2.5 mg, with the proprietary name Xarelto®.

13. On information and belief, Bayer/Janssen caused the FDA to list the '310 patent in the FDA's publication, *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book") in connection with NDA No. 022406.

14. By maintaining the listing of the '310 patent in the Orange Book, Bayer/Janssen represent that a claim of infringement of the '310 patent "could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." *See* 21 U.S.C. § 355(b)(1)(G).

15. On information and belief, Bayer/Janssen have not caused the FDA to remove the '310 patent from the Orange Book in connection with NDA No. 022406.

16. By letter dated January 15, 2021, Lupin Limited timely notified Bayer/Janssen that it had submitted ANDA No. 208555 to the FDA with a Paragraph IV certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '310 patent ("Lupin Limited's Notice Letter"). Lupin Limited's Notice Letter met the statutory and regulatory requirements for such notice letters, and included a detailed statement of the factual and legal bases for Lupin Limited's opinion that the claims of the '310 patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, sale, offer for sale, and/or importation of Lupin Limited's rivaroxaban ANDA Products. Lupin Limited incorporates by reference its Notice Letter.

17. Lupin Limited's Notice Letter contained an Offer of Confidential Access that offered to provide Bayer/Janssen with confidential access to information from ANDA No. 208555

for the purpose of Bayer/Janssen making a determination of whether an infringement action could be brought with respect to the ’310 patent.

18. On March 1, 2021, Bayer/Janssen filed an infringement action against Lupin Limited alleging infringement of the ’310 patent.

19. In view of the foregoing, there has been, and is now, an actual, substantial, and continuing, justiciable controversy between Lupin Limited and Bayer/Janssen having sufficient immediacy and reality to warrant the issuance of a declaration of rights by the Court with respect to noninfringement and/or invalidity of the ’310 patent, and as to Lupin Limited’s right to obtain FDA approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of Lupin Limited’s rivaroxaban ANDA Products.

COUNT I
Declaratory Judgment of Noninfringement of the ’310 Patent

20. Lupin Limited repeats and incorporates by reference each of the foregoing paragraphs 1-19 of its Counterclaims.

21. Bayer/Janssen have accused Lupin Limited of infringing claims of the ’310 patent in connection with ANDA No. 208555.

22. Lupin Limited denies infringement of any valid, enforceable, properly construed claim of the ’310 patent and alleges that Lupin Limited has not, and does not, infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid, enforceable, properly construed claim of the ’310 patent, including for at least the reasons set forth in the detailed statement included with Lupin Limited’s Notice Letter.

23. The manufacture, use, sale, or offer for sale within, and/or importation into, the United States of Lupin Limited’s rivaroxaban ANDA Products will not constitute infringement

(either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), of any valid, enforceable, properly construed claim of the '310 patent.

24. Lupin Limited's rivaroxaban ANDA Products will not infringe any valid and/or enforceable claim of the '310 patent, at least because Lupin Limited's rivaroxaban ANDA Products do not satisfy the claims of the '310 patent, either literally or under the doctrine of equivalents.

25. Lupin Limited is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of Lupin Limited's rivaroxaban ANDA Products does not, and would not if marketed, infringe any valid and/or enforceable claim of the '310 patent.

COUNT II
Declaratory Judgment of Invalidity of the '310 Patent

26. Lupin Limited repeats and incorporates by reference each of the foregoing paragraphs 1-25 of its Counterclaims.

27. The claims of the '310 patent are invalid for the failure to satisfy one or more of the provisions of Title 35 of the United States Code, including 35 U.S.C. § 100 *et seq*., including, without limitation, the requirements of 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or the doctrine of obviousness-type double patenting and/or any other judicially created requirements for patentability and enforceability of patents and/or in view of the defenses recognized in 35 U.S.C. § 282.

28. For at least the reasons explained in Lupin Limited's January 15, 2021 Notice Letter, each of the claims of the '310 patent are invalid at least under 35 U.S.C. §§ 102 and/or 103 in view of the prior art cited therein.

29. Lupin Limited is entitled to a judicial declaration that the claims of the '310 patent are invalid.

DEMAND FOR JUDGMENT

WHEREFORE, Lupin Limited prays that the Court enter judgment in its favor and against Bayer/Janssen as follows:

A. That the Court order the Complaint dismissed with prejudice and judgment be entered in favor of Lupin Limited;

B. That a judgment be entered declaring the claims of the '310 patent invalid;

C. That a judgment be entered declaring that the filing of Lupin Limited's ANDA No. 208555 seeking FDA approval to market the rivaroxaban tablets, 2.5 mg, that are the subject of ANDA No. 208555 prior to the expiration of the '310 patent has not infringed and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid, enforceable, properly construed claim of the '310 patent;

D. That a judgment be entered declaring that the manufacture, import, use, sale, and/or offer to sell Lupin Limited's rivaroxaban ANDA Products has not infringed, does not infringe, and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily) any valid, enforceable claim of the '310 patent;

E. Granting Lupin Limited judgment in its favor on Bayer/Janssen's claims;

F. Granting Lupin Limited judgment in its favor on its own Counterclaims;

G. That a judgment be entered declaring that this action is an exceptional case within the meaning of 35 U.S.C. § 285;

H. Declaring that Lupin Limited is the prevailing party and awarding costs, attorneys' fees, and expenses to Lupin Limited; and

I. Awarding Lupin Limited such other and further relief to which it may be entitled.

Date: May 3, 2021

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