IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

IN RE: XARELTO (RIVAROXABAN) ('310 PATENT LITIGATION)	:	MDL No. 1:21-md-03017-RGA-LDH
BAYER PHARMA AG, BAYER AG, and JANSSEN PHARMACEUTICALS, INC., *Plaintiffs*, v. AUROBINDO PHARMA LIMITED, and AUROBINDO PHARMA USA, INC. *Defendants*.	:	C.A. No. 1:23-cv-01372-RGA

DEFENDANTS AUROBINDO PHARMA LIMITED
AND AUROBINDO PHARMA USA, INC'S
ANSWER TO PLAINTIFFS' COMPLAINT FOR PATENT INFRINGEMENT

Defendants Aurobindo Pharma Ltd. ("APL") and Aurobindo Pharma USA, Inc. ("APUI") (collectively for identification purposes only, "Aurobindo"), by and through their undersigned counsel, respectfully submits their Answer to Plaintiffs' Complaint, stating as follows:

RESPONSES TO ALLEGATIONS PERTAINING TO THE 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 and amendment by Aurobindo Pharma 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").

RESPONSE: Aurobindo admits Plaintiffs purport to bring a civil action for alleged infringement of the '310 patent pursuant to the United States Patent Laws, Title 35, United States Code. Aurobindo admits Plaintiffs' claims relate to APL's ANDA No. 208544. Aurobindo admits APL

filed ANDA No. 208544 with the United States Food and Drug Administration ("FDA") in accordance with 21 U.S.C. § 355(j) and supplemented the same to seek approval to market APL's 2.5 mg strength ANDA product prior to the expiration of the '310 patent. Aurobindo denies the remaining allegations in this paragraph. Allegations not expressly admitted are denied.

RESPONSES TO ALLEGATIONS PERTAINING TO 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.

RESPONSE: Aurobindo is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph, and therefore denies the same.

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.

RESPONSE: Aurobindo is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph, and therefore denies the same.

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

RESPONSE: Aurobindo is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph, and therefore denies the same.

Defendants

5. On information and belief, Defendant Aurobindo Pharma Limited is a company organized and existing under the laws of the Republic of India, with a place of business at Plot No. 2, Maitrivihar, Amerpeet, Hyderabad-50038, Telangana, India.

RESPONSE: Admitted.

6. On information and belief, defendant Aurobindo Pharma USA, Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 279 Princeton-Hightstown Road, East Windsor, New Jersey 08520.

RESPONSE: Aurobindo admits that APUI is a corporation organized under the laws of Delaware with a place of business located at 279 Princeton Hightstown Road, East Windsor, New Jersey 08520. Aurobindo denies all remaining allegations in this paragraph. Allegations not expressly admitted are denied.

7. On information and belief, Aurobindo Pharma USA, Inc. is a wholly-owned subsidiary of Aurobindo Pharma Limited, and is controlled and dominated by Aurobindo Pharma Limited.

RESPONSE: Aurobindo admits Aurobindo Pharma USA, Inc., is a wholly-owned subsidiary of Aurobindo Pharma Limited. Aurobindo denies all allegations in this paragraph. Allegations not expressly admitted are denied.

8. On information and belief, Aurobindo Pharma Limited and Aurobindo Pharma USA, Inc. are in the business of, among other things, manufacturing, marketing, distributing, offering for sale, and selling generic versions of branded pharmaceutical drug products for the U.S. market. As a part of this business, on information and belief, Aurobindo Pharma Limited, acting in concert with Aurobindo Pharma USA, 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, Aurobindo Pharma Limited, acting in concert with Aurobindo Pharma USA, 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.

RESPONSE: Aurobindo admits Aurobindo Pharma Limited and Aurobindo Pharma USA, Inc., engage in the manufacturing, marketing, distributing, offering for sale and selling of FDA-approved drug products in the United States. Aurobindo admits that Aurobindo Pharma Limited submits ANDAs to FDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of drug products in and into the United States, with Aurobindo Pharma USA, Inc., acting as Aurobindo Pharma Limited's agent for ANDA filing purposes.

Aurobindo admits that some drug applications filed by Aurobindo Pharma Limited include Paragraph IV Certifications. Aurobindo denies all remaining allegations in this paragraph. Allegations not expressly admitted are denied.

9. On information and belief, and consistent with their practice with respect to other generic products, Aurobindo Pharma Limited and Aurobindo Pharma USA, Inc. acted in concert to prepare and submit ANDA No. 208544 for Aurobindo Pharma Limited's 2.5 mg rivaroxaban tablets ("Aurobindo's ANDA Product"), which was done at the direction of, under the control of, and for the direct benefit of Aurobindo Pharma Limited.

RESPONSE: Aurobindo admits Aurobindo Pharma Limited prepared and submitted ANDA No. 208544 and supplemented the same to seek approval of a 2.5 mg strength rivaroxaban tablet product. Aurobindo denies all remaining allegations in this paragraph. Allegations not expressly admitted are denied.

10. On information and belief, Aurobindo Pharma Limited and Aurobindo Pharma USA, 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/or distribution of generic pharmaceutical products throughout the United States, including into Delaware, and including with respect to Aurobindo's ANDA Product at issue.

RESPONSE: Denied.

11. On information and belief, following any FDA approval of ANDA No. 208544, Aurobindo Pharma Limited and Aurobindo Pharma USA, Inc. will act in concert to market, distribute, offer for sale, and sell Aurobindo's ANDA Product throughout the United States and within Delaware. These two entities—Aurobindo Pharma Limited and Aurobindo Pharma USA, Inc.—are hereafter collectively referred to as "Aurobindo."

RESPONSE: Denied.

12. On information and belief, following any FDA approval of ANDA No. 208544, Aurobindo will market, distribute, offer for sale, and sell Aurobindo's ANDA Product throughout the United States and within Delaware.

RESPONSE: Denied.

13. On information and belief, following any FDA approval of ANDA No. 208544, Aurobindo knows and intends that Aurobindo's ANDA Product will be marketed, used, distributed, offered for sale, and sold in the United States and within Delaware.

RESPONSE: Denied.

RESPONSES TO ALLEGATIONS PERTAINING TO JURISDICTION

14. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

RESPONSE: Aurobindo incorporates by reference its responses to the preceding paragraphs of this Complaint as if fully set forth herein.

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

RESPONSE: Aurobindo admits the Court has subject matter jurisdiction over this action. Aurobindo denies the remaining allegations in this paragraph. Allegations not expressly admitted are denied.

16. This Court has personal jurisdiction over each of Aurobindo Pharma Limited and Aurobindo Pharma USA, Inc.

RESPONSE: Solely for the purpose of this litigation, Aurobindo does not challenge personal jurisdiction. Aurobindo denies all remaining allegations in this paragraph. Allegations not expressly admitted are denied.

17. Aurobindo Pharma Limited is subject to personal jurisdiction in Delaware, because, among other things, Aurobindo Pharma Limited, itself and through its wholly owned subsidiary Aurobindo Pharma USA, Inc., has purposefully availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court here. On information and belief, Aurobindo Pharma Limited, itself and through its wholly-owned subsidiary Aurobindo Pharma USA, Inc., develops, manufactures, imports, markets, offers to sell, and/or sells generic drugs throughout the United States, including the State of Delaware, and therefore transacts business within the State of Delaware, and/or has engaged in systematic and continuous business contacts within the State of Delaware. In addition, on information and belief, Aurobindo Pharma Limited derives substantial revenue from generic pharmaceutical products that are used and/or consumed within Delaware, and that are manufactured by Aurobindo Pharma Limited and/or for which Aurobindo Pharma Limited is the named applicant on approved ANDAs. On information and belief, various products for which Aurobindo Pharma Limited is the named applicant on approved ANDAs are available at retail pharmacies in Delaware.

RESPONSE: Solely for the purpose of this litigation, Aurobindo does not challenge personal jurisdiction. Aurobindo denies all remaining allegations in this paragraph. Allegations not expressly admitted are denied.

18. In addition, Aurobindo Pharma Limited is subject to personal jurisdiction in Delaware because, on information and belief, it controls and dominates Aurobindo Pharma USA, Inc. and therefore the activities of Aurobindo Pharma USA, Inc. in this jurisdiction are attributed to Aurobindo Pharma Limited.

RESPONSE: Solely for the purpose of this litigation, Aurobindo does not challenge personal jurisdiction. Aurobindo denies all remaining allegations in this paragraph. Allegations not expressly admitted are denied.

19. This Court has personal jurisdiction over Aurobindo Pharma USA, Inc. because, among other things, Aurobindo Pharma USA, Inc. is a corporation formed under the laws of the State of Delaware, has registered to do business in the State of Delaware, and has appointed a registered agent in Delaware (Corporation Service Company, 251 Little Falls Drive, Wilmington, DE 19808) to accept service of process. Aurobindo Pharma USA, Inc. has thus consented to jurisdiction in Delaware. In addition, on information and belief, Aurobindo Pharma USA, Inc. develops, manufactures, imports, markets, offers to sell, and/or sells generic drugs throughout the United States, including in the State of Delaware and therefore transacts business within the State of Delaware related to Plaintiffs' claims, and/or has engaged in systematic and continuous business contacts within the State of Delaware.

RESPONSE: Solely for the purpose of this litigation, Aurobindo does not challenge personal jurisdiction. Aurobindo admits Aurobindo Pharma USA, Inc., is a Delaware corporation registered to do business in Delaware with a registered agent in Delaware. Aurobindo denies all remaining allegations in this paragraph. Allegations not expressly admitted are denied.

20. In addition, this Court has personal jurisdiction over Aurobindo Pharma Limited and Aurobindo Pharma USA, Inc. because, among other things, on information and belief: (1) Aurobindo Pharma Limited, acting in concert with Aurobindo Pharma USA, Inc., 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 Aurobindo's ANDA Product in the United States, including in Delaware; and (2) Aurobindo Pharma Limited and Aurobindo Pharma USA, Inc., acting in concert and/or as agents of one another, will market, distribute, offer for sale, and/or sell Aurobindo's ANDA Product in the United States, including in Delaware, upon approval of ANDA No. 208544, and will derive substantial revenue from the use or consumption of Aurobindo's ANDA Product in the State of Delaware. On information and belief, if ANDA No. 208544 is approved, the generic

Aurobindo 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.

RESPONSE: Solely for the purpose of this litigation, Aurobindo does not challenge personal jurisdiction. Aurobindo denies all remaining allegations in this paragraph. Allegations not expressly admitted are denied.

21. Further, this Court has personal jurisdiction over Aurobindo because Aurobindo Pharma Limited and Aurobindo Pharma USA, Inc. regularly engage in patent litigation concerning FDA-approved branded drug products in this district, have previously consented to jurisdiction in this district in prior cases arising out of the filing of their ANDAs, and have purposefully 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. Aurobindo Pharma Limited et al., C.A. No. 15-902-RGA, ECF No. 59 (D. Del. Dec. 21, 2015); Azurity Pharms., Inc. v. Aurobindo Pharma Ltd. et al., C.A. No. 21-1707-MSG, ECF No. 12 (D. Del. Jan. 7, 2022); Acadia Pharms. Inc. v. Aurobindo Pharma Ltd. et al., C.A. No. 20-985-RGA, ECF No. 10 (D. Del. Sept. 1, 2020); Pfizer Inc. et al. v. Aurobindo Pharma Ltd. et al., C.A. No. 19-748- CFC, ECF No. 11 (D. Del. July 8, 2019); Millennium Pharm. v. Aurobindo Pharma USA, Inc., C.A. No. 19-471-CFC, ECF No. 9 (D. Del. Apr. 9, 2019); Genentech, Inc. et al. v. Aurobindo Pharma Ltd. et al., C.A. No. 19-103-RGA, ECF No. 10 (D. Del. Feb. 20, 2019).

RESPONSE: Solely for the purpose of this litigation, Aurobindo does not challenge personal jurisdiction. Aurobindo denies all remaining allegations in this paragraph. Allegations not expressly admitted are denied.

22. Alternatively, if Aurobindo Pharma Limited's connections with Delaware, including its connections with Aurobindo Pharma USA, Inc., are found to be insufficient to confer personal jurisdiction, then, on information and belief, Aurobindo Pharma Limited is not subject to jurisdiction in any state's courts of general jurisdiction, and exercising jurisdiction over Aurobindo Pharma Limited in Delaware is consistent with the United States Constitution and laws. See Fed. R. Civ. P. 4(k)(2). Relatedly, Aurobindo Pharma Limited sent the Aurobindo Notice Letter (defined below), and provided an agent for service "[p]ursuant to 21 C.F.R. § 314.95(c)(9)," which applies "[i]if the applicant does not reside or have a place of business in the United States."

RESPONSE: Solely for the purpose of this litigation, Aurobindo does not challenge personal jurisdiction. Aurobindo denies all remaining allegations in this paragraph. Allegations not expressly admitted are denied.

RESPONSES TO ALLEGATIONS PERTAINING TO VENUE

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

RESPONSE: Solely for the purpose of this litigation, Aurobindo does not challenge venue in this judicial district. Aurobindo denies all allegations in this paragraph. Allegations not expressly admitted are denied.

24. Venue is proper in this district for Aurobindo Pharma USA, Inc. pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, Aurobindo Pharma USA, Inc. is incorporated in Delaware and subject to personal jurisdiction in this judicial district.

RESPONSE: Solely for the purpose of this litigation, Aurobindo does not challenge venue in this judicial district. Aurobindo denies all allegations in this paragraph. Allegations not expressly admitted are denied.

RESPONSES TO ALLEGATIONS PERTAINING TO THE FACTUAL BACKGROUND

25. 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, (i) to reduce the risk of major cardiovascular events (cardiovascular (CV) death, myocardial infarction (MI), and stroke) in adult patients with coronary artery disease (CAD); and (ii) to reduce the risk of major thrombotic vascular events (MI, ischemic stroke, acute limb ischemia, and major amputation of a vascular etiology) in adult patients with peripheral artery disease (PAD), including patients who have recently undergone a lower extremity revascularization procedure due to symptomatic PAD.

RESPONSE: Aurobindo is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph and, therefore, denies the same.

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

RESPONSE: Upon information and belief, admitted.

27. 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.

RESPONSE: Aurobindo admits Exhibit A appears to be a copy of the '310 patent, which is the best evidence of its contents. Aurobindo admits Exhibit A describes the '310 patent, which is titled "Reducing the Risk of Cardiovascular Events," as having issued November 10, 2020. Aurobindo denies all remaining allegations in his paragraph. Allegations not expressly admitted are denied.

28. 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."

RESPONSE: Aurobindo avers that the incorporation of each patent claim renders the allegations vague and ambiguous. Aurobindo admits the '310 patent claims certain methods involving rivaroxaban. Aurobindo admits this paragraph accurately quotes claim 1 of the '310 patent. Aurobindo denies all remaining allegations in this paragraph of the complaint. Allegations not expressly admitted are denied.

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

RESPONSE: Aurobindo is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph and, therefore, denies the same.

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

RESPONSE: Aurobindo is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph and, therefore, denies the same.

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

RESPONSE: Aurobindo is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph and, therefore, denies the same.

32. 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®.

RESPONSE: Upon information and belief, Aurobindo admits the '310 patent is listed in the Orange Book in connection with the 2.5 mg strength of the Xarelto branded drug product. Aurobindo denies all remaining allegations in this paragraph. Allegations not expressly admitted are denied.

RESPONSES TO COUNT I:
ALLEGED INFRINGEMENT OF THE '310 PATENT

33. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

RESPONSE: Aurobindo incorporates by reference its responses to the preceding paragraphs of this Complaint as if fully set forth herein.

34. By letter dated October 16, 2023 ("Aurobindo's Notice Letter"), Aurobindo notified, *inter alia*, Bayer and Janssen that Aurobindo had submitted to the FDA an amendment to ANDA No. 208544 for Aurobindo's ANDA Product. This product is a generic version of the 2.5 mg strength of XARELTO®.

RESPONSE: Aurobindo admits APL sent a Notice Letter dated October 16, 2023, notifying Bayer and Janssen of the filing of its ANDA supplement for its 2.5 mg strength rivaroxaban tablet. Aurobindo denies all further allegations in this paragraph. Allegations not admitted are denied.

35. In Aurobindo's Notice Letter, Aurobindo indicated that, in connection with its ANDA No. 208544, Aurobindo had filed, *inter alia*, a Paragraph IV Certification with respect to the '310 patent.

RESPONSE: Aurobindo admits APL's Notice Letter notified Bayer and Janssen that the ANDA supplement directed to APL's 2.5 mg rivaroxaban tablet product included a Paragraph IV

Certification with respect to the '310 patent. Aurobindo denies all further allegations in this paragraph. Allegations not expressly admitted are denied.

36. In Aurobindo's Notice Letter, Aurobindo stated that Aurobindo's ANDA Product contains rivaroxaban.

RESPONSE: Admitted.

37. On information and belief, the proposed labeling for Aurobindo'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 Aurobindo's ANDA Product further directs the administration of Aurobindo'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 Aurobindo's ANDA Product will be administered twice daily and aspirin is administered in an amount of 75-100 mg daily.

RESPONSE: Denied.

38. The purpose of ANDA No. 208544 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 Aurobindo's ANDA Product with its proposed labeling prior to the expiration of the '310 patent.

RESPONSE: Denied.

39. Aurobindo intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Aurobindo's ANDA Product with its proposed labeling immediately and imminently upon approval of ANDA No. 208544, *i.e.*, prior to the expiration of the '310 patent.

RESPONSE: Denied.

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

RESPONSE: Denied.

41. Aurobindo has knowledge of the claims of the '310 patent. Notwithstanding this knowledge, Aurobindo has continued to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Aurobindo's ANDA Product with its proposed labeling immediately and imminently upon approval of ANDA No. 208544. On

information and belief, by such activities, Aurobindo specifically intends to infringe the '310 patent.

RESPONSE: Aurobindo admits that it has knowledge of the claims of the '310 patent. Aurobindo denies all remaining allegations in this paragraph. Allegations not expressly admitted are denied.

42. On information and belief, Aurobindo 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.

RESPONSE: Denied.

43. On information and belief, Aurobindo knows that Aurobindo's ANDA Product with its proposed labeling is especially made or adapted for use in infringing the '310 patent, and that Aurobindo's ANDA Product with its proposed labeling is not suitable for substantial noninfringing use. Aurobindo's ANDA Product is a material part of the claimed invention. On information and belief, Aurobindo plans and intends to, and will, contribute to infringement of the '310 patent immediately and imminently upon approval of ANDA No. 208544.

RESPONSE: Denied.

44. Aurobindo's submission of ANDA No. 208544 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Aurobindo's ANDA Product was an act of infringement of the '310 patent under 35 U.S.C. § 271(e)(2).

RESPONSE: Denied.

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

RESPONSE: Denied.

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

RESPONSE: Denied.

47. The foregoing actions by Aurobindo 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.

RESPONSE: Denied.

48. Unless Aurobindo 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.

RESPONSE: Denied.

49. This action is being commenced before the expiration of forty-five days from the date Bayer and Janssen received Aurobindo's Notice Letter.

RESPONSE: Aurobindo is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph and, therefore, denies the same.

RESPONSES TO COUNT II:
DECLARATORY JUDGMENT OF ALLEGED INFRINGEMENT OF THE '310 PATENT

50. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

RESPONSE: Aurobindo incorporates by reference its responses to the preceding paragraphs of this Complaint as if fully set forth herein.

51. 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 Aurobindo on the other regarding Aurobindo's liability for infringement and active inducement of infringement of the '310 patent.

RESPONSE: Denied.

52. An actual case or controversy exists between Plaintiffs and Aurobindo with respect to Aurobindo's liability for infringement of the '310 patent.

RESPONSE: Admitted.

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

RESPONSE: Denied.

GENERAL DENIAL AND RESPONSES TO PLAINTIFFS' REQUEST FOR RELIEF

All allegations in Plaintiffs' Complaint not expressly admitted by Aurobindo are hereby denied. Having answered Plaintiffs' complaint, Aurobindo denies Plaintiffs are entitled to any of the relief requested in the Complaint or any relief whatsoever.

SEPARATE DEFENSES

Without prejudice to the denials set forth in its Answer to the Complaint, and without admitting any allegations of the Complaint not expressly admitted, Aurobindo asserts the following separate defenses to the Complaint without assuming the burden of proof on any such defense that would otherwise rest on Plaintiffs.

FIRST SEPARATE DEFENSE

The manufacture, use, or sale, offer for sale, or importation of the products that are the subject of Aurobindo's ANDA No. 208544 has not infringed, does not infringe, and would not, if marketed, manufactured, used, sold, offered for sale, or imported into the United States, infringe any valid or enforceable claim of the patents-in-suit.

SECOND SEPARATE DEFENSE

Each of the claims of the patent-in-suit is invalid for failure to satisfy one or more of the conditions for patentability set forth in Title 35 of the United States Code or for satisfying other bases (including judicially-created bases) for invalidation or unenforceability, for example, for at least the reasons set forth in APL's Notice Letter.

THIRD SEPARATE DEFENSE

Each of the claims of the patents in-suit is invalid as anticipated or obvious, pursuant to 35 U.S.C. §§ 102, 103, for example, for at least the reasons set forth in Aurobindo's Notice Letter.

FOURTH SEPARATE DEFENSE

Each of the claims of each of the patents-in-suit is invalid pursuant to 35 U.S.C. § 112, for example, indefiniteness, lack of enablement and/or written description.

FIFTH SEPARATE DEFENSE

By virtue of the prosecution proceedings before the United States Patent and Trademark Office of the patent applications leading to the patent-in-suit, Plaintiffs are estopped from maintaining that any valid or enforceable claim of the patent-in-suit is infringed by the product that is the subject of Aurobindo's ANDA No. 208544.

SIXTH SEPARATE DEFENSE

Plaintiffs have failed to state a claim upon which relief can be granted.

SEVENTH SEPARATE DEFENSE

Plaintiffs' filing of this action constitutes a material breach of one or more agreements between Aurobindo and Plaintiffs entered into prior to the filing of this action.

EIGHTH SEPARATE DEFENSE

Any and all additional defenses and counterclaims that discovery may reveal.

WHEREFORE, Aurobindo hereby demands judgment in its favor based on a finding of non-infringement and/or invalidity and/or unenforceability of the patents-in-suit, an award of all costs and fees incurred in defense of this Action and for such other relief as the Court may deem just and proper.

Dated: February 23, 2024

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