IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PFIZER INC., C.P. PHARMACEUTICALS INTERNATIONAL C.V., PF PRISM C.V., PBG PUERTO RICO LLC and PF PRISM IMB B.V.,	)	
Plaintiffs,	)	
v.	)	C.A. No. 21-022 (LPS)
AUROBINDO PHARMA LTD. AND AUROBINDO PHARMA USA, INC.,	)	
Defendants.	)	

AUROBINDO PHARMA LTD. AND AUROBINDO PHARMA USA, INC.'S ANSWER TO COMPLAINT

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

RESPONSE TO ALLEGATIONS CONCERNING THE NATURE OF THE ACTION

1. This is an action by Pfizer against Aurobindo for infringement of United States Patent No. 6,965,027 ("the '027 patent") and United States Reissue Patent No. RE41,783 ("the RE'783 patent").

RESPONSE: Aurobindo admits Plaintiffs purport to bring a civil action to assert infringement of the patents identified in this paragraph under the Patent Laws of the United States, 35 U.S.C. §§ 100 *et seq.* Aurobindo denies all further allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

2. This action arises out of Aurobindo Pharma Ltd.'s filing of Abbreviated New Drug Application ("ANDA") No. 215356 seeking approval by the United States Food and

Drug Administration ("FDA") to sell generic copies of Pfizer's 5 mg and 10 mg Xeljanz® (tofacitinib) tablets prior to the expiration of the '027 and RE'783 patents. Aurobindo's ANDA products are referred to hereinafter individually as "Aurobindo 5 mg Generic Tablets" and "Aurobindo 10 mg Generic Tablets" and collectively as "Aurobindo 5 mg and 10 mg Generic Tablets."

RESPONSE: Aurobindo admits APL filed ANDA No. 215356, which seeks regulatory approval for tofacitinib tablets prior to the expiration of the '027 and RE'783 patents. Aurobindo denies all further allegations in this paragraph. Allegations not expressly admitted are denied.

RESPONSE TO ALLEGATIONS PERTAINING TO THE PARTIES

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

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 C.P. Pharmaceuticals International C.V. is a limited partnership (*commanditaire vennootschap*) organized under the laws of the Netherlands, having a place of business at Rivium Westlaan 142, 2909 LD, Capelle aan den IJssel, the Netherlands. Pfizer Inc. is the ultimate parent company of C.P. Pharmaceuticals International C.V.

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.

5. Plaintiff PF PRISM C.V. is a limited partnership (*commanditaire vennootschap*) organized under the laws of the Netherlands, having its registered seat in Rotterdam, the Netherlands, having its business address at Rivium Westlaan 142, 2909 LD, Capelle aan den IJssel, the Netherlands, and registered at the Trade Register held by the Chamber of Commerce in Rotterdam, the Netherlands, under number 51840456. Pfizer Inc. is the ultimate parent company of PF PRISM C.V.

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.

6. Plaintiff PBG Puerto Rico LLC is a limited liability company organized and existing under the laws of Puerto Rico and having its principal place of business at

Professional Offices Park V, 996 San Roberto Street, 4th Floor, San Juan, Puerto Rico 00926. Pfizer Inc. is the ultimate parent company of PBG Puerto Rico LLC.

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.

7. Plaintiff PF PRISM IMB B.V. is a private limited liability company (*besloten vennootschap*) under the law of the Netherlands, having its registered seat in Rotterdam, the Netherlands, and having its business address at Rivium Westlaan 142, 2909 LD, Capelle aan den IJssel, the Netherlands. Pfizer Inc. is the ultimate parent company of PF PRISM IMB B.V.

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.

8. On information and belief, defendant Aurobindo Pharma Ltd. is a company organized and existing under the laws of India, having its principal place of business at Plot No. 2, Maitrivihar, Ameerpet, Hyderabad-500038, Telangana, India.

RESPONSE: Aurobindo admits that APL is a company organized under the laws of India with a place of business located at Plot No. 2, Maitrivihar, Ameerpet, Hyderabad – 500038, Telangana, India. Aurobindo denies all remaining allegations in this paragraph. Allegations not expressly admitted are denied.

9. On information and belief, defendant Aurobindo Pharma USA, Inc. is a company organized and existing under the laws of Delaware, having its principal place of business at 279 Princeton Hightstown Road, East Windsor, NJ 08520. On information and belief, Aurobindo Pharma Ltd. is the ultimate parent company of Aurobindo Pharma USA, Inc. On information and belief, Aurobindo Pharma USA, Inc. is the U.S. agent for Aurobindo Pharma Ltd.

RESPONSE: Aurobindo admits APUI is a corporation organized under the laws of Delaware with a place of business located at 279 Princeton Hightstown Road, East Windsor, NJ 08520. Aurobindo admits APUI is a wholly owned subsidiary of APL that acts at times as APL's agent in the United States. Aurobindo denies all remaining allegations in this paragraph. Allegations not expressly admitted are denied.

RESPONSE TO ALLEGATIONS PERTAINING TO JURISDICTION AND VENUE

10. This action arises under the patent laws of the United States, Title 35, United States Code. The Court has subject matter jurisdiction over this action pursuant to the provisions of 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

RESPONSE: Aurobindo admits the Court has subject matter jurisdiction over claims arising under the Patent Laws of the United States, Title 35 of the United States Code. Aurobindo denies all remaining allegations in this paragraph. Allegations not expressly admitted are denied.

11. This Court has personal jurisdiction over Defendants.

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.

12. This Court has personal jurisdiction over Defendants by virtue of the fact, *inter alia*, that Aurobindo Pharma USA, Inc. is a Delaware corporation and Aurobindo Pharma Ltd. is the ultimate parent company of 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.

13. Aurobindo Pharma USA, Inc. is a wholly-owned subsidiary of Aurobindo Pharma Ltd. (https://www.aurobindo.com/wp-content/uploads/2020/08/Aurobindo-Pharma-Limited-Annual-Report-2019-20.pdf, at 95, last accessed on Jan. 5, 2021). On information and belief, Aurobindo Pharma Ltd., directly or through its subsidiary Aurobindo Pharma USA, Inc., manufactures, markets, imports, and sells generic drugs for distribution in Delaware and throughout the United States.

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

14. On information and belief, Defendants are agents of each other and/or work in concert with each other on the development, obtaining of regulatory approval, manufacture, marketing, sale, and/or distribution of generic drugs, including the proposed Aurobindo 5 mg and 10 mg Generic Tablets.

RESPONSE: Denied.

15. On information and belief, if ANDA No. 215356 is approved, Aurobindo 5 mg and 10 mg Generic Tablets will, among other things, be marketed and distributed in Delaware, prescribed by physicians practicing in Delaware, dispensed by pharmacies located in Delaware, and/or used by patients in Delaware.

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.

16. Aurobindo's infringing activities with respect to its filing of ANDA No. 215356 and its intent to commercialize and sell Aurobindo 5 mg and 10 mg Generic Tablets have led and/or will lead to foreseeable harm and injury to Plaintiffs, including Pfizer Inc., which is incorporated in Delaware.

RESPONSE: Denied.

17. On information and belief, Defendants maintain substantial, systematic, and continuous contacts with Delaware. Aurobindo Pharma USA, Inc.'s website states that the company has earned its "reputation by building an extremely robust company, ensuring AuroControl through vertical integration [and] multiple manufacturing units in . . . the U.S. " (https://www.aurobindousa.com/company/investors/, last accessed on Jan. 5, 2021). Aurobindo Pharma Ltd.'s 2019-2020 annual report states that the company has so far "[f]iled 586 ANDAs with USFDA and received approval for 425 ANDAs, including 28 tentative approvals," and refers to Aurobindo's "core geographies such as USA." (https://www.aurobindo.com/wpcontent/uploads/2020/08/Aurobindo-Pharma-Limited-Annual-Report-2019-20.pdf, at 6, 11, last accessed on Jan. 5, 2021). As of March 31, 2020, Aurobindo claims to be "the second largest generics company in the US in terms of prescriptions (Rx) dispensed as per IQVIA data." (*Id.* at 67).

RESPONSE: Denied.

18. In the alternative, this Court has jurisdiction over Aurobindo Pharma Ltd. under Federal Rule of Civil Procedure 4(k)(2). Aurobindo Pharma Ltd. has contacts with the United States by, *inter alia*, having filed ANDA No. 215356 with the FDA.

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. Venue is proper in this judicial district pursuant to the provisions of 28 U.S.C. §§ 1391 and 1400(b).

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

RESPONSE TO ALLEGATIONS PERTAINING TO THE FACTUAL BACKGROUND
RESPONSE TO ALLEGATIONS PERTAINING TO XELJANZ

20. The active ingredient in Pfizer's Xeljanz product is tofacitinib citrate. Xeljanz contains tofacitinib citrate in an amount equivalent to 5 mg and 10 mg of tofacitinib base in tablets formulated for twice-daily administration.

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

21. The FDA-approved Prescribing Information for Xeljanz states that tofacitinib citrate has the following chemical name: (3R,4R)-4-methyl-3-(methyl-7H-pyrrolo [2,3-d] pyrimidin-4-ylamino)-ß-oxo-1-piperidinepropanenitrile, 2-hydroxy-1,2,3-propanetricarboxylate (1:1).

RESPONSE: Upon information and belief, Aurobindo admits the paragraph accurately restates the chemical name for tofacitinib citrate included in the prescribing information for Xeljanz. Aurobindo is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in this paragraph and, on that basis, denies them. Allegations not expressly admitted are denied.

22. Tofacitinib citrate is an inhibitor of Janus kinases ("JAKs") and is indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response or intolerance to methotrexate, for the treatment of adult patients with active psoriatic arthritis who have had an inadequate response or intolerance to methotrexate or other disease-modifying antirheumatic drugs (DMARDs), for the treatment of adult patients with moderately to severely active ulcerative colitis who have had an inadequate response or who are intolerant to TNF blockers, and for the treatment of active polyarticular course of juvenile idiopathic arthritis (pcJIA) in patients 2 years of age and older.

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

RESPONSE TO ALLEGATIONS PERTAINING TO THE ORANGE BOOK LISTING FOR XELJANZ

23. PF PRISM C.V. holds approved New Drug Application ("NDA") No. 203214 for EQ 5 and EQ 10 mg base tofacitinib citrate tablets, which Pfizer sells under the registered name Xeljanz.

RESPONSE: Upon information and belief, admitted.

24. Pursuant to 21 U.S.C. § 355(b)(1) and the regulations the FDA has promulgated pursuant thereto, the '027 and RE'783 patents are listed in the FDA publication titled "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book") for the Xeljanz NDA.

RESPONSE: Upon information and belief, Aurobindo admits the '027 and RE'783 patents are listed in the FDA's Orange Book in connection with the Xeljanz NDA. Aurobindo is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in this paragraph and, on that basis, denies them. Allegations not expressly admitted are denied.

25. The Orange Book lists the expiration date for the '027 patent as March 25, 2023, and the expiration date for the RE'783 patent as December 8, 2025.

RESPONSE: Upon information and belief, admitted.

RESPONSE TO ALLEGATIONS PERTAINING TO THE '027 PATENT

26. On November 15, 2005, the USPTO issued the '027 patent, titled "Crystalline 3-{4-methyl-3-[methyl-(7H-pyrrolo[2,3-d]pyrimidin-4-yl)-amino]-piperidin-1-yl}-3-oxopropionitrile citrate." The '027 patent is duly and legally assigned to Pfizer Inc. A copy of the '027 patent is attached hereto as Exhibit A.

RESPONSE: Upon information and belief, Exhibit A to the Complaint appears to be a copy of the '027 patent, which is the best source of information regarding its contents. Aurobindo is without knowledge or information sufficient to form a belief as to the truth of the

allegations in this paragraph and, on that basis, denies them. Allegations not expressly admitted are denied.

27. C.P. Pharmaceuticals International C.V. is the exclusive licensee of the '027 patent.

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

28. C.P. Pharmaceuticals International C.V. conveyed rights under the '027 patent to Pfizer Pharmaceuticals LLC, PF PRISM C.V., and Pfizer PFE Ireland Pharmaceuticals Holding 1 B.V.

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

29. Pfizer Pharmaceuticals LLC has conveyed its rights to the '027 patent to PBG Puerto Rico LLC.

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

30. Pfizer PFE Ireland Pharmaceuticals Holding 1 B.V. has conveyed its rights to the '027 patent to PF PRISM IMB B.V.

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

RESPONSE TO ALLEGATIONS PERTAINING TO THE RE '783 PATENT

31. On September 28, 2010, the USPTO issued the RE'783 patent, titled "Pyrrolo[2,3-d]pyrimidine Compounds." The RE'783 patent is a reissue of U.S. Patent No. 6,627,754, which issued on September 30, 2003. The RE'783 patent is duly and legally assigned to Pfizer Inc. A copy of the RE'783 patent is attached hereto as Exhibit B.

RESPONSE: Upon information and belief, Exhibit B to the Complaint appears to be a copy of the RE'783 patent, which is the best source of information regarding its contents.

Aurobindo is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph and, on that basis, denies them. Allegations not expressly admitted are denied.

32. On December 14, 2016, the United States Patent and Trademark Office ("USPTO") issued a Notice of Final Determination extending the expiration date of the RE'783 patent to December 8, 2025.

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

33. C.P. Pharmaceuticals International C.V. is the exclusive licensee of the RE'783 patent.

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

34. C.P. Pharmaceuticals International C.V. conveyed rights under the RE'783 patent to Pfizer Pharmaceuticals LLC, PF PRISM C.V., and Pfizer PFE Ireland Pharmaceuticals Holding 1 B.V.

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

35. Pfizer Pharmaceuticals LLC has conveyed its rights to the RE'783 patent to PBG Puerto Rico LLC.

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

36. Pfizer PFE Ireland Pharmaceuticals Holding 1 B.V. has conveyed its rights to the RE'783 patent to PF PRISM IMB B.V.

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

RESPONSE TO ALLEGATIONS PERTAINING TO AUROBINDO'S ANDA

37. By letter dated November 25, 2020 (the "Aurobindo Notice Letter"), and received by Pfizer on November 30, 2020, Aurobindo notified Pfizer that it had filed ANDA No. 215356 with the FDA, seeking approval under the Federal Food, Drug and Cosmetic Act to market and sell Aurobindo 5 mg and 10 mg Generic Tablets -- generic copies of Xeljanz (tofacitinib citrate EQ 5 mg and EQ 10 mg tablets) -- prior to the expiration of the '027 and RE'783 patents. The Aurobindo Notice Letter describes the Aurobindo 5 mg and 10 mg Generic Tablets as "tofacitinib citrate tablets in 5 mg and 10 mg strengths."

RESPONSE: Aurobindo admits APL notified Pfizer of the filing of its ANDA No. 215356 seeking approval of tofacitinib citrate tablets in 5 mg and 10 mg strengths by letter dated November 25, 2020. Aurobindo denies all further allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

38. The Aurobindo Notice Letter states that ANDA No. 215356 seeks "to obtain approval to engage in the commercial manufacture, use or sale of" Aurobindo 5 mg and 10 mg Generic Tablets prior to the expiration of the '027 and RE'783 patents.

RESPONSE: Aurobindo admits APL's Notice Letter described ANDA No. 215356 as seeking to obtain approval of tofacitinib citrate tablets in 5 mg and 10 mg strengths. Aurobindo denies all remaining allegations in this paragraph. Allegations not expressly admitted are denied.

39. The Aurobindo Notice Letter asserts that ANDA No. 215356 contains a "Paragraph IV" certification under 21 U.S.C. § 355(j)(2)(B)(iv)(II) alleging that the '027 and RE'783 patents "are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use or sale of" Aurobindo 5 mg and 10 mg Generic Tablets.

RESPONSE: Aurobindo admits APL's Notice Letter concluded that the '027 and RE'783 patents are invalid, unenforceable and/or will not be infringed by APL's ANDA. Aurobindo denies all further allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

40. Attached to the Aurobindo Notice Letter was Aurobindo's Detailed Factual and Legal Basis for Aurobindo's Paragraph IV Certification regarding U.S. Patent Nos. 6,965,027 and RE41,783 ("Aurobindo's Detailed Statement") asserting the purported factual

and legal bases for Aurobindo's contention that the '027 and RE'783 patents are invalid and/or will not be infringed by the commercial manufacture, use, or sale of Aurobindo 5 mg and 10 mg Generic Tablets.

RESPONSE: Aurobindo admits APL's Notice Letter included a Detailed Factual and Legal Basis for Aurobindo's Paragraph IV certification regarding the '027 and RE'783 patents and setting out a detailed analysis concluding that the '027 and RE'783 patents are invalid, unenforceable and/or will not be infringed by APL's ANDA. Aurobindo denies all further allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

41. Aurobindo's Detailed Statement alleges that all claims of the '027 and RE'783 patents are invalid. Aurobindo's Detailed Statement does not contain a noninfringement argument with respect to either the '027 patent or the RE'783 patent.

RESPONSE: Aurobindo admits APL's Notice Letter provides a basis for invalidating the '027 and RE'783 and avers that APL reserved all rights to assert any other defenses without limitation. Aurobindo denies the remaining allegations in this paragraph. Allegations not expressly admitted are denied.

42. On information and belief, Aurobindo Pharma Ltd. and Aurobindo Pharma USA, Inc. collaborated and acted in concert in the decision to prepare and file and in the preparation and filing of ANDA No. 215356.

RESPONSE: Denied.

43. On information and belief, upon approval of ANDA No. 215356, Aurobindo will sell and distribute Aurobindo 5 mg and 10 mg Generic Tablets throughout the United States.

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

RESPONSE TO COUNT I
(Alleged Infringement of the '027 Patent by Aurobindo 5 mg Generic Tablets)

44. The allegations of paragraphs 1-43 above are repeated and re-alleged as if set forth fully herein.

RESPONSE: Aurobindo restates and incorporates each response to paragraphs 1-43 as though fully set forth herein.

45. Pursuant to 35 U.S.C. § 271(e)(2)(A), Aurobindo's filing of ANDA No. 215356 seeking approval to market Aurobindo 5 mg Generic Tablets is an act of infringement of at least claim 1 of the '027 patent entitling Pfizer to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the effective date of approval for ANDA No. 215356 be a date which is not earlier than the expiration date of the '027 patent.

RESPONSE: Denied.

46. Aurobindo had knowledge of the '027 patent when it submitted ANDA No. 215356 to the FDA

RESPONSE: Aurobindo admits APL had knowledge of the '027 patent when submitting ANDA No. 215356 to the FDA. Aurobindo denies all further allegations in this paragraph. Allegations not expressly admitted are denied.

47. On information and belief, upon FDA approval, Aurobindo intends to engage in the manufacture, use, offer for sale, sale, and/or importation of Aurobindo 5 mg Generic Tablets and will thereby infringe at least claim 1 of the '027 patent.

RESPONSE: Denied.

48. The foregoing actions by Aurobindo constitute and/or would constitute infringement of at least claim 1 of the '027 patent.

RESPONSE: Denied.

49. Pfizer will be substantially and irreparably harmed if Aurobindo is not enjoined from infringing the '027 patent. Pfizer has no adequate remedy at law.

RESPONSE: Denied.

RESPONSE TO COUNT II

(Alleged Infringement of the'027 Patent by Aurobindo 10 mg Generic Tablets)

50. The allegations of paragraphs 1-49 above are repeated and re-alleged as if set forth fully herein.

RESPONSE: Aurobindo restates and incorporates each response to paragraphs1-49 as though fully set forth herein.

51. Pursuant to 35 U.S.C. § 271(e)(2)(A), Aurobindo's filing of ANDA No. 215356 seeking approval to market Aurobindo 10 mg Generic Tablets is an act of infringement of at least claim 1 of the '027 patent entitling Pfizer to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the effective date of approval for ANDA No. 215356 be a date which is not earlier than the expiration date of the '027 patent.

RESPONSE: Denied.

52. Aurobindo had knowledge of the '027 patent when it submitted ANDA No. 215356 to the FDA.

RESPONSE: Aurobindo admits APL had knowledge of the '027 patent when submitting ANDA No. 215356 to the FDA. Aurobindo denies all further allegations in this paragraph. Allegations not expressly admitted are denied.

53. On information and belief, upon FDA approval, Aurobindo intends to engage in the manufacture, use, offer for sale, sale, and/or importation of Aurobindo 10 mg Generic Tablets and will thereby infringe at least claim 1 of the '027 patent.

RESPONSE: Denied.

54. The foregoing actions by Aurobindo constitute and/or would constitute infringement of at least claim 1 of the '027 patent.

RESPONSE: Denied.

55. Pfizer will be substantially and irreparably harmed if Aurobindo is not enjoined from infringing the '027 patent. Pfizer has no adequate remedy at law.

RESPONSE: Denied.

RESPONSE TO COUNT III
(Alleged Infringement of the RE '783 Patent by Aurobindo 5 mg Generic Tablets)

56. The allegations of paragraphs 1-55 above are repeated and re-alleged as if set forth fully herein.

RESPONSE: Aurobindo restates and incorporates each response to paragraphs 1-55 as though fully set forth herein.

57. Pursuant to 35 U.S.C. § 271(e)(2)(A), Aurobindo's filing of ANDA No. 215356 seeking approval to market Aurobindo 5 mg Generic Tablets is an act of infringement of at least claim 4 of the RE'783 patent entitling Pfizer to the relief provided by 35 U.S.C. § 271(e)(4), including, inter alia, an order of this Court that the effective date of approval for ANDA No. 215356 be a date which is not earlier than the expiration date of the RE'783 patent.

RESPONSE: Denied.

58. Aurobindo had knowledge of the RE'783 patent when it submitted ANDA No. 215356 to the FDA.

RESPONSE: Aurobindo admits APL had knowledge of the RE'783 patent when submitting ANDA No. 215356 to the FDA. Aurobindo denies all further allegations in this paragraph. Allegations not expressly admitted are denied.

59. On information and belief, upon FDA approval, Aurobindo intends to engage in the manufacture, use, offer for sale, sale, and/or importation of Aurobindo 5 mg Generic Tablets and will thereby infringe at least claim 4 of the RE'783 patent.

RESPONSE: Denied.

60. The foregoing actions by Aurobindo constitute and/or would constitute infringement of at least claim 4 of the RE'783 patent.

RESPONSE: Denied.

61. Pfizer will be substantially and irreparably harmed if Aurobindo is not enjoined from infringing the RE'783 patent. Pfizer has no adequate remedy at law.

RESPONSE: Denied.

RESPONSE TO COUNT IV
(Alleged Infringement of the RE '783 Patent by Aurobindo 10 mg Generic Tablets)

62. The allegations of paragraphs 1-61 above are repeated and re-alleged as if set forth fully herein.

RESPONSE: Aurobindo restates and incorporates each response to paragraphs 1-61 as though fully set forth herein.

63. Pursuant to 35 U.S.C. § 271(e)(2)(A), Aurobindo's filing of ANDA No. 215356 seeking approval to market Aurobindo 10 mg Generic Tablets is an act of infringement of at least claim 4 of the RE'783 patent entitling Pfizer to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the effective date of approval for ANDA No. 215356 be a date which is not earlier than the expiration date of the RE'783 patent.

RESPONSE: Denied.

64. Aurobindo had knowledge of the RE'783 patent when it submitted ANDA No. 215356 to the FDA.

RESPONSE: Aurobindo admits APL had knowledge of the RE'783 patent when submitting ANDA No. 215356 to the FDA. Aurobindo denies all further allegations in this paragraph. Allegations not expressly admitted are denied.

65. On information and belief, upon FDA approval, Aurobindo intends to engage in the manufacture, use, offer for sale, sale, and/or importation of Aurobindo 10 mg Generic Tablets and will thereby infringe at least claim 4 of the RE'783 patent.

RESPONSE: Denied.

66. The foregoing actions by Aurobindo constitute and/or would constitute infringement of at least claim 4 of the RE'783 patent.

RESPONSE: Denied.

67. Pfizer will be substantially and irreparably harmed if Aurobindo is not enjoined from infringing the RE'783 patent. Pfizer has no adequate remedy at law.

RESPONSE: Denied.

RESPONSE TO COUNT V
(Aurobindo Pharma USA, Inc.'s Inducing of Infringement by Aurobindo Pharma Ltd.)

68. The allegations of paragraphs 1-67 above are repeated and re-alleged as if set forth fully herein.

RESPONSE: Aurobindo restates and incorporates each response to paragraphs 1-67 as though fully set forth herein.

69. On information and belief, Aurobindo Pharma USA, Inc. actively and knowingly caused to be submitted, assisted with, participated in, contributed to, and/or directed the submission by Aurobindo Pharma Ltd. of ANDA No. 215356 to the FDA, knowing of the '027 and RE'783 patents.

RESPONSE: Denied.

70. The filing of ANDA No. 215356 by Aurobindo Pharma Ltd. constituted direct infringement under 35 U.S.C. § 271(e). On information and belief, under 35 U.S.C. §§ 271(b) and 271(e)(2)(A), Aurobindo Pharma USA, Inc. induced the infringement of the '027 and RE'783 patents by actively and knowingly causing to be submitted, and/or assisting with, participating in, contributing to, and/or directing the submission of ANDA No. 215356 to the FDA knowing that the submission of ANDA No. 215356 would constitute direct infringement of the '027 and RE'783 patents.

RESPONSE: Denied.

GENERAL DENIAL AND RESPONSE TO PLAINTIFFS' REQUEST FOR RELIEF

All allegation 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 APL's ANDA No. 215356 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 each of the patents-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 dated November 25, 2020.

THIRD SEPARATE DEFENSE

Each of the claims of each 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 APL's Notice Letter dated November 25, 2020.

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, for indefiniteness, lack of enablement and/or written description, for example, for at least the reasons set forth in APL's Notice Letter November 25, 2020.

FIFTH SEPARATE DEFENSE

By virtue of the prosecution proceedings before the United States Patent and Trademark Office of the patent applications leading to the patents-in-suit, Plaintiffs are estopped from maintaining that any valid or enforceable claim of the patents-in-suit is infringed by the product that is the subject of Aurobindo's ANDA No. 215356.

SIXTH SEPARATE DEFENSE

One or more of the plaintiffs lacks standing to assert this Action.

SEVENTH SEPARATE DEFENSE

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

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 2, 2021

Respectfully Submitted,

/s/ Kenneth L. Dorsney

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