IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PFIZER, INC., *et al.*,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	C.A. No. 1:19-cv-00748-CFC
	)	
AUROBINDO PHARMA, LTD., *et al.*,	)	
	)	
Defendants.	)	
	)	

ANSWER TO COMPLAINT, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS

Defendants Aurobindo Pharma, Ltd., Aurobindo Pharma USA, Inc., and Eugia Pharma Specialities Ltd. (collectively "Aurobindo"), by and through their counsel, answer the Complaint of Plaintiffs Pfizer, Inc., Warner-Lambert Company, LLC, PF Prism C.V., Pfizer Manufacturing Holdings LLC, and Pfizer PFE Ireland Pharmaceuticals Holding 1 B.V. (collectively "Pfizer" or "Plaintiffs") as follows:

1. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, and for a declaratory judgment of patent infringement under 28 U.S.C. §§ 2201 and 2202 and the patent laws of the United States, Title 35, United States Code, that arises out of Aurobindo's submission of an Abbreviated New Drug Application ("ANDA") to the U.S. Food and Drug Administration ("FDA") seeking approval to commercially manufacture, use, offer for sale, sell, and/or import generic versions of IBRANCE® (Palbociclib) capsules, 75 mg, 100 mg, and 125 mg, prior to the expiration of U.S Patent No. 6,936,612 ("the '612 patent"); U.S. Patent No. 7,208,489 ("the '489 patent"); and U.S. Patent No. 7,456,168 ("the '168 patent"). These three patents are referred to collectively herein as "the patents-in-suit."

Answer:

Aurobindo admits that Plaintiffs' Complaint purports that this is an action for patent infringement under the patents laws of the United States, Title 35, United States Code, and for a declaratory judgment of patent infringement under 28 U.S.C. §§ 2201 and 2202 and the patent laws of the United States, Title 35, United States Code, that arises out of Aurobindo's submission of Abbreviated New Drug Application ("ANDA") No. 213086 to the U.S. Food and Drug Administration ("FDA") seeking approval to manufacture, use, offer for sale, sell and/or import generic versions of IBRANCE® (Palbociclib) capsules, 75 mg, 100 mg, and 125 mg, prior to the expiration of U.S. Patent No. 6,936,612 ("the '612 patent"); U.S. Patent No. 7,208,489 ("the '489 patent"); and U.S. Patent No. 7,456,168 ("the '168 patent") (together, "the Orange Book Patents"). Aurobindo denies that Plaintiffs are entitled to any relief and denies all remaining allegations of Paragraph 1.

2. Aurobindo Pharma USA, Inc., U.S. agent for Eugia Pharma Specialties [sic] Ltd., notified Pfizer by letter dated March 26, 2019 ("Aurobindo's Notice Letter") that it had submitted to the FDA ANDA No. 213086. ("Aurobindo's ANDA"), seeking approval from the FDA to engage in the commercial manufacture, use and/or sale of generic Palbociclib capsules, 75mg, 100 mg, and 125 mg ("Aurobindo's ANDA Product") prior to the expiration of the patents-in-suit.

Answer:

Aurobindo admits that Aurobindo Pharma USA, Inc., U.S. agent for Eugia Pharma Specialities Ltd., notified Pfizer by letter dated March 26, 2019 ("Aurobindo's Notice Letter") that it had submitted ANDA No. 213086 to the FDA, seeking approval from the FDA to engage in the commercial manufacture, use, and/or sale of generic Palbociclib capsules, 75 mg, 100 mg, and 125 mg prior to the expiration of the patents-in-suit.

PARTIES

3. Plaintiff Pfizer Inc. is a corporation organized and existing under the laws of the State of Delaware and having a place of business at 235 East 42nd Street, New York, New York 10017. Pfizer Inc. is the holder of New Drug Application ("NDA") No. 207103 for the manufacture and sale of palbociclib tablets, 75 mg, 100 mg and 125 mg, which has been approved by the FDA.

Answer:

On information and belief, Aurobindo admits the allegation.

4. Plaintiff Warner-Lambert Company LLC is a limited liability company organized and existing under the laws of the State of Delaware, and having a place of business at 235 East 42nd Street, New York, New York 10017.

Answer:

On information and belief, Aurobindo admits the allegation.

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, that for all purposes is represented by and acting through its general partner Pfizer Manufacturing Holdings LLC, a limited liability company organized under the laws of the State of Delaware, and having its address at 235 East 42nd Street, New York, New York 10017.

Answer:

On information and belief, Aurobindo admits the allegation.

6. Plaintiff Pfizer PFE Ireland Pharmaceuticals Holding 1 B.V. is a private limited liability company (besloten 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.

Answer:

On information and belief, Aurobindo admits the allegation.

7. Upon information and belief, defendant Aurobindo Pharma, Ltd. is a company organized and existing under the laws of the Republic of India with its principal place of business at Maitri Vihar, Plot #2, Ameerpet, Hyderabad 500038, Telangana, India. Upon information and belief, Aurobindo Pharma, Ltd. is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical drugs through various operating subsidiaries, including Aurobindo Pharma USA, Inc.

Answer:

Aurobindo admits that Aurobindo Pharma, Ltd. is a company organized and existing under the laws of the Republic of India with its principal place of business at Maitri Vihar, Plot #2, Ameerpet, Hyderabad 500 038, Telangana, India. Aurobindo denies the remaining allegations of Paragraph 7.

8. Upon information and belief, defendant Aurobindo Pharma USA, Inc. is a corporation organized and existing under the laws of the State of Delaware with its principal place of business at 279 Princeton Hightstown Road, East Windsor, New Jersey 08520. Upon information and belief, Aurobindo Pharma USA, Inc. is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical products for the U.S. market.

Answer:

Aurobindo admits that Aurobindo Pharma USA, Inc. is a corporation organized and existing under the laws of the State of Delaware with its principal place of business a 279 Princeton

Hightstown Road, East Windsor, New Jersey 08520. Aurobindo denies the remaining allegations of Paragraph 8.

9. Upon information and belief, defendant Eugia Pharma Specialties [sic] Ltd. is a company organized and existing under the laws of the Republic of India with its principal place of business at Maitri Vihar, Plot #2, Ameerpet, Hyderabad 500038, Telangana, India. Upon information and belief, Eugia Pharma Specialties [sic] Ltd. is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical products for the U.S. market.

Answer:

Aurobindo admits that Eugia Pharma Specialities, Ltd. is a company organized and existing under the laws of the Republic of India with its principal place of business at Maitri Vihar, Plot #2, Ameerpet, Hyderabad 500 038, Telangana, India. Aurobindo denies the remaining allegations of Paragraph 9.

10. Upon information and belief, Aurobindo Pharma USA, Inc. is a wholly-owned subsidiary of Aurobindo Pharma, Ltd., and the United States agent for Eugia Pharma Specialties [sic] Ltd.

Answer:

Aurobindo admits that Aurobindo Pharma USA, Inc. is a wholly-owned subsidiary of Aurobindo Pharma, Ltd., and the United States Agent for Eugia Pharma Specialities Ltd.

11. Upon information and belief, Eugia Pharma Specialties [sic] Ltd. is a subsidiary of Aurobindo Pharma, Ltd.

Answer:

Aurobindo admits that Eugia Pharma Specialities is a subsidiary of Aurobindo Pharma, Ltd.

12. Aurobindo Pharma, Ltd., Eugia Pharma Specialties [sic] Ltd., and Aurobindo Pharma USA, Inc. are collectively referred to herein as "Aurobindo."

Answer:

Paragraph 12 contains a statement to which no response is required.

13. Upon information and belief, Aurobindo Pharma, Ltd., Eugia Pharma Specialties [sic] Ltd., and Aurobindo Pharma USA, Inc. acted in concert to prepare and submit Aurobindo's ANDA to the FDA.

Answer:

Denied.

14. Upon information and belief, Aurobindo Pharma, Ltd., Eugia Pharma Specialties [sic] Ltd., and Aurobindo Pharma USA, Inc. know and intend that upon approval of Aurobindo's ANDA, Aurobindo Pharma, Ltd. and Eugia Pharma Specialties [sic] Ltd. will manufacture Aurobindo's ANDA Product and Aurobindo Pharma USA, Inc. will directly or indirectly market, sell, and distribute Aurobindo's ANDA Product throughout the United States, including in Delaware. Upon information and belief, Aurobindo Pharma, Ltd., Eugia Pharma Specialties [sic] Ltd., and Aurobindo Pharma USA, Inc. are agents of each other and/or operate in concert as integrated parts of the same business group, including with respect to Aurobindo's ANDA Product, and enter into agreements with each other that are nearer than arm's length. Upon information and belief, Aurobindo Pharma Ltd. and Eugia Pharma Specialties [sic] Ltd. participated in, assisted, and cooperated with Aurobindo Pharma USA, Inc. in the acts complained of herein.

Answer:

Paragraph 14 contains allegations related to future conduct about which no final decisions have been made, and so denies those allegations. Aurobindo denies the remaining allegations of Paragraph 14.

15. Upon information and belief, following any FDA approval of Aurobindo's ANDA, Aurobindo Pharma, Ltd., Eugia Pharma Specialties [sic] Ltd., and Aurobindo Pharma USA, Inc. will act in concert to distribute and sell Aurobindo's ANDA Product throughout the United States, including within Delaware.

Answer:

Paragraph 15 contains allegations related to future conduct about which no final decisions have been made, and so denies those allegations. Aurobindo denies the remaining allegations of Paragraph 15.

JURISDICTION AND VENUE

16. Jurisdiction is proper in this Court pursuant to 28 U.S.C. §§ 1331, 1338(a), and 2201 and 2202.

Answer:

Paragraph 16 contains conclusions of law to which a response is not required. To the extent a response is required, Aurobindo admits that this court has subject matter jurisdiction.

17. Aurobindo Pharma, Ltd. is subject to personal jurisdiction in Delaware because, among other things, Aurobindo Pharma, Ltd., itself and through its wholly-owned subsidiaries Aurobindo Pharma USA, Inc. and Eugia Pharma Specialties [sic] Ltd., has purposefully availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court here. Upon information and belief, Aurobindo Pharma, Ltd., itself and

through its wholly-owned subsidiaries Aurobindo Pharma USA, Inc. and Eugia Pharma Specialties [sic] Ltd., 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, and/or has engaged in systematic and continuous business contacts within the State of Delaware. In addition, Aurobindo Pharma, Ltd. is subject to personal jurisdiction in Delaware because, upon information and belief, it controls Aurobindo Pharma USA, Inc. and Eugia Pharma Specialties [sic] Ltd., and therefore the activities of Aurobindo Pharma USA, Inc. and Eugia Pharma Specialties [sic] Ltd. in this jurisdiction are attributed to Aurobindo Pharma, Ltd.

Answer:

Paragraph 17 contains conclusions of law to which a response is not required. To the extent a response is required, Aurobindo does not contest personal jurisdiction solely for the limited purposes of this particular action. Aurobindo denies the remaining allegations of Paragraph 17.

18. Aurobindo Pharma USA, Inc. is subject to personal jurisdiction in Delaware because, among other things, it has purposely availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court here. Aurobindo Pharma USA, Inc. is a corporation organized and existing under the laws of the State of Delaware, is qualified to do business in Delaware, and has appointed a registered agent for service of process in Delaware. It therefore has consented to general jurisdiction in Delaware. In addition, upon 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 Pfizer's claims, and/or has engaged in systematic and continuous business contacts within the State of Delaware.

Answer:

Paragraph 18 contains conclusions of law to which a response is not required. To the extent a response is required, Aurobindo does not contest personal jurisdiction solely for the limited purposes of this particular action. Aurobindo denies the remaining allegations of Paragraph 18.

19. Eugia Pharma Specialties [sic] Ltd. is subject to personal jurisdiction in Delaware because, among other things, Eugia Pharma Specialities Ltd., itself and through its agent Aurobindo Pharma USA, 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. Upon information and belief, Eugia Pharma Specialties [sic] Ltd., itself and through its agent 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 Pfizer's claims, and/or has engaged in systematic and continuous business contacts within the State of Delaware.

Answer:

Paragraph 19 contains conclusions of law to which a response is not required. To the extent a response is required, Aurobindo does not contest personal jurisdiction solely for the limited purposes of this particular action. Aurobindo denies the remaining allegations of Paragraph 19.

20. Aurobindo has previously used the process contemplated by the Hatch-Waxman Act to challenge branded pharmaceutical companies' patents by filing a certification of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), serving a notice letter on those companies, and engaging in patent litigation arising from the process contemplated by the Hatch-Waxman Act.

Answer:

Aurobindo admits that it has complied with regulatory requirements by filing a certification of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), has served notice letters as required by the FDCA, and has defended itself from allegations of patent infringement. Aurobindo denies the remaining allegations of Paragraph 20.

21. Upon information and belief, Aurobindo, with knowledge of the Hatch-Waxman Act process, directed Aurobindo's Notice Letter to, inter alia, Pfizer, Inc., an entity incorporated in Delaware, and alleged in Aurobindo's Notice Letter that Pfizer's patents are invalid. Upon information and belief, Aurobindo knowingly and deliberately challenged Pfizer's patent rights, and knew when it did so that it was triggering the forty-five day period for Pfizer to bring an action for patent infringement under the Hatch-Waxman Act.

Answer:

Aurobindo admits that its Notice Letter to Pfizer, Inc. includes a detailed statement describing why Aurobindo's ANDA Products will not infringe any valid and enforceable patent listed in the Orange Book for NDA No. 207103, as required by the FDCA. Aurobindo admits that, according to the FDCA, Pfizer could file suit within forty-five days of receipt of the Notice Letter to gain the benefit of a 30-month stay by the FDA for approval of Aurobindo's ANDA No. 213086. Aurobindo denies the remaining allegations of Paragraph 21.

22. Because Pfizer is incorporated in Delaware, Pfizer suffers injury and consequences from Aurobindo's filing of Aurobindo's ANDA, challenging Pfizer's patent rights, in Delaware. Upon information and belief, Aurobindo knew that it was deliberately challenging the patent rights of a Delaware entity and seeking to invalidate intellectual property held in Delaware. Aurobindo

has been a litigant in connection with other infringement actions under the Hatch-Waxman Act, and reasonably should have anticipated that by sending Aurobindo's Notice Letter to Pfizer, a Delaware corporation, that it would be sued in Delaware for patent infringement.

Answer:

Paragraph 22 contains conclusions of law to which a response is not required. To the extent a response is required, Aurobindo does not contest personal jurisdiction solely for the limited purposes of this particular action. Aurobindo denies that Plaintiffs have suffered injury and that they are entitled to any relief and denies all remaining allegations of Paragraph 22.

23. Upon information and belief, if Aurobindo's ANDA is approved, Aurobindo will directly or indirectly manufacture, market, sell, and/or distribute Aurobindo's ANDA Product within the United States, including in Delaware, consistently with Aurobindo's practices for the marketing and distribution of other generic pharmaceutical products. Upon information and belief, Aurobindo regularly does business in Delaware, and its practices with other generic pharmaceutical products have involved placing those products into the stream of commerce for distribution throughout the United States, including in Delaware. Upon information and belief, Aurobindo's generic pharmaceutical products are used and/or consumed within and throughout the United States, including in Delaware. Upon information and belief, Aurobindo's ANDA Product will be prescribed by physicians practicing in Delaware, dispensed by pharmacies located within Delaware, and used by patients in Delaware. Each of these activities would have a substantial effect within Delaware and would constitute infringement of Pfizer's patents in the event that Aurobindo's ANDA Product is approved before the patents expire.

Answer:

Paragraph 23 contains allegations related to future conduct about which no final decisions have been made, and so denies those allegations. Paragraph 23 also contains allegations related to future conduct of third parties, and so denies those allegations. Aurobindo denies that Plaintiffs have suffered injury and that they are entitled to any relief and denies all remaining allegations of Paragraph 23.

24. Upon information and belief, Aurobindo derives substantial revenue from generic pharmaceutical products that are used and/or consumed within Delaware, and which are manufactured by Aurobindo and/or for which Aurobindo Pharma, Ltd. or Aurobindo Pharma USA, Inc. is the named applicant on approved ANDAs. Upon information and belief, various products for which Aurobindo Pharma, Ltd. or Aurobindo Pharma USA, Inc. is the named applicant on approved ANDAs are available at retail pharmacies in Delaware.

Answer:

Aurobindo lacks sufficient information at this time to admit the allegations of Paragraph 24, and so denies them. Aurobindo denies all allegations of infringement, and all remaining allegations of Paragraph 24 are denied.

25. Venue is proper in this district as to Aurobindo Pharma USA, Inc. pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, inter alia, Aurobindo Pharma USA, 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 25 contains conclusions of law to which a response is not required. To the extent a response is required, Aurobindo does not contest venue solely for the limited purposes of this particular action.

26. Venue is proper in this district as to Aurobindo Pharma, Ltd. pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, inter alia Aurobindo Pharma, Ltd. is a corporation organized and existing under the laws of the Republic of India and is subject to personal jurisdiction in this judicial district.

Answer:

Paragraph 26 contains conclusions of law to which a response is not required. To the extent a response is required, Aurobindo does not contest venue solely for the limited purposes of this particular action.

27. Venue is proper in this district as to Eugia Pharma Specialties [sic] Ltd. pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, inter alia Eugia Pharma Specialties [sic] Ltd. is a corporation organized and existing under the laws of the Republic of India and is subject to personal jurisdiction in this judicial district.

Answer:

Paragraph 27 contains conclusions of law to which a response is not required. To the extent a response is required, Aurobindo does not contest venue solely for the limited purposes of this particular action.

COUNT I – INFRINGEMENT OF THE '612 PATENT

28. Pfizer incorporates each of the preceding paragraphs 1–27 as if fully set forth herein.

Answer:

Aurobindo incorporates by reference its responses to paragraphs 1-27 as if fully set forth herein.

29. The inventors named on the '612 patent are Mark Barvian, Richard J. Booth, John Quin, III, Joseph T. Repine, Derek J. Sheehan, Peter L. Toogood, Scott N. Vanderwel, and Hairong Zhou.

Answer:

Aurobindo admits that the '612 patent on its face lists Mark Barvian, Richard J. Booth, John Quin, III, Joseph T. Repine, Derek J. Sheehan, Peter L. Toogood, Scott N. Vanderwel, and Hairong Zhou as inventors.

30. The '612 patent, entitled "2-(Pyridin-2-ylamino)-pyrido[2,3-d]pyrimidin-7-ones" (attached as Exhibit A), was duly and legally issued on August 30, 2005.

Answer:

Aurobindo admits that the '612 patent is entitled "2-(Pyridin-2-ylamino)-pyrido[2,3-d]pyrimidin-7-ones" and states on its face that it was issued on August 30, 2005. Aurobindo also admits that what is represented appears to be a copy of the '612 patent is attached as Exhibit A. Aurobindo denies that that the '612 patent was legally issued.

31. Pfizer is the owner and assignee of the '612 patent.

Answer:

On information and belief, Aurobindo admits that Pfizer is the owner and assignee of the '612 patent.

32. Claim 1 of the '612 patent recites "[a] compound which is 6-Acetyl-8-cyclopentyl-5-methyl-2-(5-piperazin-1-yl-pyridin-2-ylamino)-8H-pyrido[2,3-d]pyrimidin-7-one."

Answer:

Aurobindo admits that claim 1 of the '612 patent attached to the Complaint as Exhibit A recites "[a] compound which is 6-Acetyl-8-cyclopental-5-methyl-2-(5-piperazin-1-yl-pyridin-2-ylamino)-8H-pyrido[2,3-d]pyrimidin-7-one."

33. Claim 2 of the '612 patent recites "A pharmaceutical composition comprising a therapeutically effective amount of the compound according to claim 1 and a pharmaceutical carrier therefor."

Answer:

Aurobindo admits that claim 2 of the '612 patent attached to the Complaint as Exhibit A recites "[a] pharmaceutical composition comprising a therapeutically effective amount of the compound according to claim 1 and a pharmaceutical carrier therefor."

34. IBRANCE® is covered by claims 1 and 2 of the '612 patent, and the '612 patent has been listed in connection with IBRANCE® in the FDA's Orange Book.

Answer:

Aurobindo admits that the '612 patent is listed in connection with IBRANCE® in the FDA's Orange Book. Aurobindo lacks sufficient information at this time to admit the remaining allegations of Paragraph 34, and so denies them.

35. In Aurobindo's Notice Letter, Aurobindo notified Pfizer of the submission of Aurobindo's ANDA to the FDA. The purpose of this submission was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Aurobindo's ANDA Product prior to the expiration of the '612 patent.

Answer:

Aurobindo admits that Aurobindo sent a notice letter to Pfizer, as required by the FDCA, informing Pfizer that Aurobindo had submitted to the FDA ANDA No. 213086, seeking approval from the FDA to engage in the commercial manufacture, use and/or sale of Aurobindo's ANDA Product. Aurobindo denies the remaining allegations of paragraph 35.

36. In Aurobindo's Notice Letter, Aurobindo also notified Pfizer that, as part of its ANDA, Aurobindo had filed certifications of the type described in Section 505(j)(2)(B)(iv) of the FDCA, 21 U.S.C. § 355 (j)(2)(B)(iv), with respect to the '612 patent. On information and belief, Aurobindo submitted its ANDA to the FDA containing certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '612 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Aurobindo's ANDA Product.

Answer:

Aurobindo admits that it notified Pfizer that, as part of its ANDA No. 213086, Aurobindo had filed certifications of the type described in Section 505(j)(2)(B)(iv) of the FDCA ("Paragraph IV Certification"), with respect to the Orange Book patents. Aurobindo admits that it submitted ANDA No. 213086 to the FDA containing a Paragraph IV certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that Aurobindo's ANDA Product will not infringe any valid or enforceable claim of the Orange Book-listed patents for NDA No. 207103. Aurobindo denies the remaining allegations of Paragraph 36.

37. Aurobindo's ANDA Product and the use of Aurobindo's ANDA Product are covered by claims 1 and 2 of the '612 patent.

Answer:

Denied.

38. In Aurobindo's Notice Letter, Aurobindo did not contest the infringement of claim 1 or 2 of the '612 patent on any basis other than the alleged invalidity of those claims.

Answer:

Aurobindo admits that, as required by the FDCA, it provided a detailed statement explaining why Aurobindo's ANDA Product will not infringe any valid and enforceable claim of the Orange Book-listed patents for NDA No. 207103. Aurobindo denies all remaining allegations of Paragraph 38.

39. Aurobindo's submission of Aurobindo's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Aurobindo's ANDA Product before the expiration of the '612 patent was an act of infringement of the '612 patent under 35 U.S.C. § 271(e)(2)(A).

Answer:

Denied.

40. On information and belief, Aurobindo will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Aurobindo's ANDA Product immediately and imminently upon approval of its ANDA.

Answer:

The allegations of Paragraph 40 relate to future conduct to which no final decision has been made, and so Aurobindo denies these allegations.

41. The manufacture, use, sale, offer for sale, or importation of Aurobindo's ANDA Product would infringe claims 1 and 2 of the '612 patent.

Answer:

Denied.

42. On information and belief, the manufacture, use, sale, offer for sale, or importation of Aurobindo's ANDA Product in accordance with, and as directed by, its proposed product labeling would infringe claims 1 and 2 of the '612 patent.

Answer:

Denied.

43. On information and belief, Aurobindo plans and intends to, and will, actively induce infringement of the '612 patent when Aurobindo's ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval. Aurobindo's activities will be done with knowledge of the '612 patent and specific intent to infringe that patent.

Answer:

The allegations of Paragraph 43 relate to future conduct to which no final decision has been made, and so Aurobindo denies these allegations. Aurobindo denies all allegations of infringement.

44. On information and belief, Aurobindo knows that Aurobindo's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '612 patent, that Aurobindo's ANDA Product is not a staple article or commodity of commerce, and that Aurobindo's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. On information and belief, Aurobindo plans and intends to, and will, contribute to infringement of the '612 patent immediately and imminently upon approval of Aurobindo's ANDA.

Answer:

The allegations of Paragraph 44 relate to future conduct to which no final decision has been made, and so Aurobindo denies these allegations. Aurobindo denies all allegations of infringement.

45. Notwithstanding Aurobindo's knowledge of the claims of the '612 patent, Aurobindo has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Aurobindo's ANDA Product with its product labeling following FDA approval of Aurobindo's ANDA prior to the expiration of the '612 patent.

Answer:

Denied.

46. The foregoing actions by Aurobindo constitute and/or will constitute infringement of the '612 patent; active inducement of infringement of the '612 patent; and contribution to the infringement by others of the '612 patent.

Answer:

Denied.

47. On information and belief, Aurobindo has acted with full knowledge of the '612 patent and without a reasonable basis for believing that it would not be liable for infringement of the '612 patent; active inducement of infringement of the '612 patent; and/or contribution to the infringement by others of the '612 patent.

Answer:

Denied.

48. Pfizer will be substantially and irreparably damaged by infringement of the '612 patent.

Answer:

Denied.

49. Unless Aurobindo is enjoined from infringing the ’612 patent, actively inducing infringement of the ’612 patent, and contributing to the infringement by others of the ’612 patent, Pfizer will suffer irreparable injury. Pfizer has no adequate remedy at law.

Answer:

Denied.

COUNT II – DECLARATORY JUDGMENT OF INFRINGEMENT OF THE ’612 PATENT

50. Pfizer incorporates each of the preceding paragraphs 1–49 as if fully set forth herein.

Answer:

Aurobindo incorporates by reference its responses to paragraphs 1-49 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 Pfizer on the one hand and Aurobindo on the other regarding Aurobindo’s infringement, active inducement of infringement, and contribution to the infringement by others of the ’612 patent, and/or the validity of the ’612 patent.

Answer:

Aurobindo admits there is an actual controversy between Pfizer and Aurobindo relating to the ’612 patent. Aurobindo denies the remaining allegations of Paragraph 51.

52. Claim 1 of the ’612 patent recites “[a] compound which is 6-Acetyl-8-cyclopentyl-5-methyl-2-(5-piperazin-1-yl-pyridin-2-ylamino)-8H-pyrido[2,3-d]pyrimidin-7-one.”

Answer:

Aurobindo admits that claim 1 of the '612 patent attached to the Complaint as Exhibit A recites "[a] compound which is 6-Acetyl-8-cyclopental-5-methyl-2-(5-piperazin-1-yl-pyridin-2-ylamino)-8H-pyrido[2,3-d]pyrimidin-7-one."

53. Claim 2 of the '612 patent recites "A pharmaceutical composition comprising a therapeutically effective amount of the compound according to claim 1 and a pharmaceutical carrier therefor."

Answer:

Aurobindo admits that claim 2 of the '612 patent attached to the Complaint as Exhibit A recites "[a] pharmaceutical composition comprising a therapeutically effective amount of the compound according to claim 1 and a pharmaceutical carrier therefor."

54. In Aurobindo's Notice Letter, Aurobindo notified Pfizer of the submission of Aurobindo's ANDA to the FDA. The purpose of this submission was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Aurobindo's ANDA Product prior to the expiration of the '612 patent.

Answer:

Aurobindo admits that it notified Pfizer of the submission of ANDA No. 213086 to the FDA. Aurobindo also admits that it submitted ANDA No. 213086 to the FDA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Aurobindo's ANDA Product prior to the expiration of the '612 patent.

55. In Aurobindo's Notice Letter, Aurobindo also notified Pfizer that, as part of its ANDA, Aurobindo had filed certifications of the type described in Section 505(j)(2)(B)(iv) of the FDCA, 21 U.S.C. § 355 (j)(2)(B)(iv), with respect to the '612 patent. On information and belief,

Aurobindo submitted its ANDA to the FDA containing certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '612 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Aurobindo's ANDA Product.

Answer:

Aurobindo admits that it notified Pfizer that, as part of its ANDA No. 213086, Aurobindo had filed certifications of the type described in Section 505(j)(2)(B)(iv) of the FDCA ("Paragraph IV Certification"), with respect to the '612 patent. Aurobindo admits that it submitted ANDA No. 213086 to the FDA containing a Paragraph IV certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that Aurobindo's ANDA Product will not infringe any valid or enforceable claim of the Orange Book-listed patents for NDA No. 207103. Aurobindo denies the remaining allegations of Paragraph 55.

56. Aurobindo's ANDA Product and the use of Aurobindo's ANDA Product are covered by claims 1 and 2 of the '612 patent.

Answer:

Denied.

57. In Aurobindo's Notice Letter, Aurobindo did not contest the infringement of claim 1 or 2 of the '612 patent on any basis other than the alleged invalidity of those claims.

Answer:

Aurobindo admits that it cannot infringe invalid claims. Aurobindo denies the remaining allegations of Paragraph 57.

58. On information and belief, Aurobindo will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Aurobindo's ANDA Product immediately and imminently upon approval of its ANDA.

Answer:

The allegations of Paragraph 58 relate to future conduct to which no final decision has been made, and so Aurobindo denies these allegations.

59. The manufacture, use, sale, offer for sale, or importation of Aurobindo's ANDA Product would infringe claims 1 and 2 of the '612 patent.

Answer:

Denied.

60. On information and belief, the manufacture, use, sale, offer for sale, or importation of Aurobindo's ANDA Product in accordance with, and as directed by, its proposed product labeling would infringe claims 1 and 2 of the '612 patent.

Answer:

Denied.

61. On information and belief, Aurobindo plans and intends to, and will, actively induce infringement of the '612 patent when Aurobindo's ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval. Aurobindo's activities will be done with knowledge of the '612 patent and specific intent to infringe that patent.

Answer:

Denied.

62. On information and belief, Aurobindo knows that Aurobindo's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '612 patent, that

Aurobindo's ANDA Product is not a staple article or commodity of commerce, and that Aurobindo's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. On information and belief, Aurobindo plans and intends to, and will, contribute to infringement of the '612 patent immediately and imminently upon approval of Aurobindo's ANDA.

Answer:

Denied.

63. Notwithstanding Aurobindo's knowledge of the claims of the '612 patent, Aurobindo has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Aurobindo's ANDA Product with its product labeling following FDA approval of Aurobindo's ANDA prior to the expiration of the '612 patent.

Answer:

Aurobindo admits that it submitted ANDA No. 213086 to the FDA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Aurobindo's ANDA Product prior to the expiration of the '612 patent. Aurobindo denies the remaining allegations in Paragraph 63.

64. The foregoing actions by Aurobindo constitute and/or will constitute infringement of the '612 patent; active inducement of infringement of the '612 patent; and contribution to the infringement by others of the '612 patent.

Answer:

Denied.

65. On information and belief, Aurobindo has acted with full knowledge of the '612 patent and without a reasonable basis for believing that it would not be liable for infringement of

the ’612 patent; active inducement of infringement of the ’612 patent; and/or contribution to the infringement by others of the ’612 patent.

Answer:

Denied.

66. Pfizer will be substantially and irreparably damaged by infringement of the ’612 patent.

Answer:

Denied.

67. The Court should declare that the commercial manufacture, use, sale, offer for sale or importation of Aurobindo’s ANDA Product with its proposed labeling, or any other Aurobindo drug product that is covered by or whose use is covered by the ’612 patent, will infringe, induce the infringement of, and contribute to the infringement by others of the ’612 patent, and that the claims of the ’612 patent are not invalid.

Answer:

Denied.

COUNT III – INFRINGEMENT OF THE ’489 PATENT

68. Pfizer incorporates each of the preceding paragraphs 1–67 as if fully set forth herein.

Answer:

Aurobindo incorporates by reference its responses to paragraphs 1-67 as if fully set forth herein.

69. The inventors named on the ’489 patent are Mark Barvian, Richard J. Booth, John Quin, III, Joseph T. Repine, Derek J. Sheehan, Peter L. Toogood, Scott N. Vanderwel, and Hairong Zhou.

Answer:

Aurobindo admits that the ’489 patent on its face lists Mark Barvian, Richard J. Booth, John Quin, III, Joseph T. Repine, Derek J. Sheehan, Peter L. Toogood, Scott N. Vanderwel, and Hairong Zhou as inventors.

70. The ’489 patent, entitled “2-(pyridin-2-ylamino)-pyrido [2,3-d]pyrimidin-7-ones” (attached as Exhibit B), was duly and legally issued on April 24, 2007.

Answer:

Aurobindo admits that the ’489 patent attached to the Complaint as Exhibit B is entitled “2-(pyridine-2-ylamino)-pyrido [2,3-d]pyrimidin-7-ones” and states on its face that it was issued on April 24, 2007. Aurobindo also admits that what is represented to be a copy of the ’489 patent is attached to the Complaint as Exhibit B. Aurobindo denies that that the ’489 patent was legally issued.

71. Pfizer is the owner and assignee of the ’489 patent.

Answer:

On information and belief, Aurobindo admits that Pfizer is the owner and assignee of the ’489 patent.

72. The ’489 patent claims, inter alia, a compound of the formula recited in claim 1 of the ’489 patent.

Answer:

Aurobindo admits that the '489 patent claims a compound of the formula recited in claim 1 of the '489 patent.

73. IBRANCE® is covered by one or more claims of the '489 patent, including claim 1–7 and 9 of the '489 patent, and the '489 patent has been listed in connection with IBRANCE® in the FDA's Orange Book.

Answer:

Aurobindo admits that the '489 patent is listed in connection with IBRANCE® in the FDA's Orange Book. Aurobindo lacks sufficient information at this time to admit the remaining allegations of Paragraph 73, and so denies them.

74. In Aurobindo's Notice Letter, Aurobindo notified Pfizer of the submission of Aurobindo's ANDA to the FDA. The purpose of this submission was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Aurobindo's ANDA Product prior to the expiration of the '489 patent.

Answer:

Aurobindo admits that it notified Pfizer of the submission of ANDA No. 213086 to the FDA. Aurobindo also admits that it submitted ANDA No. 213086 to the FDA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Aurobindo's ANDA Product prior to the expiration of the '489 patent.

75. In Aurobindo's Notice Letter, Aurobindo also notified Pfizer that, as part of its ANDA, Aurobindo had filed certifications of the type described in Section 505(j)(2)(B)(iv) of the FDCA, 21 U.S.C. § 355 (j)(2)(B)(iv), with respect to the '489 patent. On information and belief, Aurobindo submitted its ANDA to the FDA containing certifications pursuant to 21 U.S.C. §

355(j)(2)(A)(vii)(IV) asserting that the '489 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Aurobindo's ANDA Product.

Answer:

Aurobindo admits that it notified Pfizer that, as part of its ANDA No. 213086, Aurobindo had filed certifications of the type described in Section 505(j)(2)(B)(iv) of the FDCA ("Paragraph IV Certification"), with respect to the '489 patent. Aurobindo admits that it submitted ANDA No. 213086 to the FDA containing a Paragraph IV certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that Aurobindo's ANDA Product will not infringe any valid or enforceable claim of the Orange Book-listed patents for NDA No. 207103. Aurobindo denies the remaining allegations of Paragraph 75.

76. Aurobindo's ANDA Product and the use of Aurobindo's ANDA Product are covered by at least claims 1–7 and 9 of the '489 patent.

Answer:

Denied.

77. In Aurobindo's Notice Letter, Aurobindo did not contest the infringement of claim 1–7 and 9 of the '489 patent on any basis other than the alleged invalidity of those claims.

Answer:

Aurobindo admits that it cannot infringe invalid claims. Aurobindo denies the remaining allegations of Paragraph 77.

78. Aurobindo's submission of Aurobindo's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of

Aurobindo's ANDA Product before the expiration of the '489 patent was an act of infringement of the '489 patent under 35 U.S.C. § 271(e)(2)(A).

Answer:

Denied.

79. On information and belief, Aurobindo will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Aurobindo's ANDA Product immediately and imminently upon approval of its ANDA.

Answer:

The allegations of Paragraph 79 relate to future conduct to which no final decision has been made, and so Aurobindo denies these allegations.

80. The manufacture, use, sale, offer for sale, or importation of Aurobindo's ANDA Product would infringe one or more claims of the '489 patent, including, inter alia, claims 1–7 and 9 of the '489 patent.

Answer:

Denied.

81. On information and belief, the manufacture, use, sale, offer for sale, or importation of Aurobindo's ANDA Product in accordance with, and as directed by, its proposed product labeling would infringe one or more claims of the '489 patent, including, inter alia, claims 1–7 and 9 of the '489 patent.

Answer:

Denied.

82. On information and belief, Aurobindo plans and intends to, and will, actively induce infringement of the '489 patent when Aurobindo's ANDA is approved, and plans and

intends to, and will, do so immediately and imminently upon approval. Aurobindo's activities will be done with knowledge of the '489 patent and specific intent to infringe that patent.

Answer:

Denied.

83. On information and belief, Aurobindo knows that Aurobindo's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '489 patent, that Aurobindo's ANDA Product is not a staple article or commodity of commerce, and that Aurobindo's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. On information and belief, Aurobindo plans and intends to, and will, contribute to infringement of the '489 patent immediately and imminently upon approval of Aurobindo's ANDA.

Answer:

Denied.

84. Notwithstanding Aurobindo's knowledge of the claims of the '489 patent, Aurobindo has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Aurobindo's ANDA Product with its product labeling following FDA approval of Aurobindo's ANDA prior to the expiration of the '489 patent.

Answer:

Aurobindo admits that it submitted ANDA No. 213086 to the FDA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Aurobindo's ANDA Product prior to the expiration of the '489 patent. Aurobindo denies the remaining allegations in Paragraph 84.

85. The foregoing actions by Aurobindo constitute and/or will constitute infringement of the ’489 patent; active inducement of infringement of the ’489 patent; and contribution to the infringement by others of the ’489 patent.

Answer:

Denied.

86. On information and belief, Aurobindo has acted with full knowledge of the ’489 patent and without a reasonable basis for believing that it would not be liable for infringement of the ’489 patent; active inducement of infringement of the ’489 patent; and/or contribution to the infringement by others of the ’489 patent.

Answer:

Denied.

87. Pfizer will be substantially and irreparably damaged by infringement of the ’489 patent.

Answer:

Denied.

88. Unless Aurobindo is enjoined from infringing the ’489 patent, actively inducing infringement of the ’489 patent, and contributing to the infringement by others of the ’489 patent, Pfizer will suffer irreparable injury. Pfizer has no adequate remedy at law.

Answer:

Denied.

COUNT IV – DECLARATORY JUDGMENT OF INFRINGEMENT OF THE ’489 PATENT

89. Pfizer incorporates each of the preceding paragraphs 1–88 as if fully set forth herein.

Answer:

Aurobindo incorporates by reference its responses to Paragraphs 1-88 as if fully set forth herein.

90. 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 Pfizer on the one hand and Aurobindo on the other regarding Aurobindo's infringement, active inducement of infringement, and contribution to the infringement by others of the '489 patent, and/or the validity of the '489 patent.

Answer:

Paragraph 90 contains conclusions of law to which a response is not required.

91. The '489 patent claims, inter alia, a compound of the formula recited in claim 1 of the '489 patent.

Answer:

Aurobindo admits that the '489 patent claims a compound of the formula recited in claim 1 of the '489 patent.

92. In Aurobindo's Notice Letter, Aurobindo notified Pfizer of the submission of Aurobindo's ANDA to the FDA. The purpose of this submission was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Aurobindo's ANDA Product prior to the expiration of the '489 patent.

Answer:

Aurobindo admits that it notified Pfizer of the submission of ANDA No. 213086 to the FDA. Aurobindo also admits that it submitted ANDA No. 213086 to the FDA to obtain approval

to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Aurobindo's ANDA Product prior to the expiration of the '489 patent.

93. In Aurobindo's Notice Letter, Aurobindo also notified Pfizer that, as part of its ANDA, Aurobindo had filed certifications of the type described in Section 505(j)(2)(B)(iv) of the FDCA, 21 U.S.C. § 355 (j)(2)(B)(iv), with respect to the '489 patent. On information and belief, Aurobindo submitted its ANDA to the FDA containing certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '489 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Aurobindo's ANDA Product.

Answer:

Aurobindo admits that it notified Pfizer that, as part of its ANDA No. 213086, Aurobindo had filed certifications of the type described in Section 505(j)(2)(B)(iv) of the FDCA ("Paragraph IV Certification"), with respect to the '489 patent. Aurobindo admits that it submitted ANDA No. 213086 to the FDA containing a Paragraph IV certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that Aurobindo's ANDA Product will not infringe any valid or enforceable claim of the Orange Book-listed patents for NDA No. 207103. Aurobindo denies the remaining allegations of Paragraph 93.

94. Aurobindo's ANDA Product and the use of Aurobindo's ANDA Product are covered by at least claims 1–7 and 9 of the '489 patent.

Answer:

Denied.

95. In Aurobindo's Notice Letter, Aurobindo did not contest the infringement of claim 1–7 and 9 of the '489 patent on any basis other than the alleged invalidity of those claims.

Answer:

Aurobindo admits that it cannot infringe invalid claims. Aurobindo denies the remaining allegations of Paragraph 95.

96. Aurobindo's submission of Aurobindo's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Aurobindo's ANDA Product before the expiration of the '489 patent was an act of infringement of the '489 patent under 35 U.S.C. § 271(e)(2)(A).

Answer:

Denied.

97. On information and belief, Aurobindo will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Aurobindo's ANDA Product immediately and imminently upon approval of its ANDA.

Answer:

The allegations of Paragraph 97 relate to future conduct to which no final decision has been made, and so Aurobindo denies these allegations.

98. The manufacture, use, sale, offer for sale, or importation of Aurobindo's ANDA Product would infringe one or more claims of the '489 patent, including, inter alia, claims 1–7 and 9 of the '489 patent.

Answer:

Denied.

99. On information and belief, the manufacture, use, sale, offer for sale, or importation of Aurobindo's ANDA Product in accordance with, and as directed by, its proposed product

labeling would infringe one or more claims of the '489 patent, including, inter alia, claims 1–7 and 9 of the '489 patent.

Answer:

Denied.

100. On information and belief, Aurobindo plans and intends to, and will, actively induce infringement of the '489 patent when Aurobindo's ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval. Aurobindo's activities will be done with knowledge of the '489 patent and specific intent to infringe that patent.

Answer:

Denied.

101. On information and belief, Aurobindo knows that Aurobindo's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '489 patent, that Aurobindo's ANDA Product is not a staple article or commodity of commerce, and that Aurobindo's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. On information and belief, Aurobindo plans and intends to, and will, contribute to infringement of the '489 patent immediately and imminently upon approval of Aurobindo's ANDA.

Answer:

Denied.

102. Notwithstanding Aurobindo's knowledge of the claims of the '489 patent, Aurobindo has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Aurobindo's ANDA Product with its product labeling following FDA approval of Aurobindo's ANDA prior to the expiration of the '489 patent.

Answer:

Aurobindo admits that it submitted ANDA No. 213086 to the FDA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Aurobindo's ANDA Product prior to the expiration of the '489 patent. Aurobindo denies the remaining allegations in Paragraph 102.

103. The foregoing actions by Aurobindo constitute and/or will constitute infringement of the '489 patent; active inducement of infringement of the '489 patent; and contribution to the infringement by others of the '489 patent.

Answer:

Denied.

104. On information and belief, Aurobindo has acted with full knowledge of the '489 patent and without a reasonable basis for believing that it would not be liable for infringement of the '489 patent; active inducement of infringement of the '489 patent; and/or contribution to the infringement by others of the '489 patent.

Answer:

Denied.

105. Pfizer will be substantially and irreparably damaged by infringement of the '489 patent.

Answer:

Denied.

106. The Court should declare that the commercial manufacture, use, sale, offer for sale or importation of Aurobindo's ANDA Product with its proposed labeling, or any other Aurobindo drug product that is covered by or whose use is covered by the '489 patent, will infringe, induce

the infringement of, and contribute to the infringement by others of the '489 patent, and that the claims of the '489 patent are not invalid.

Answer:

Denied.

COUNT V – INFRINGEMENT OF THE '168 PATENT

107. Pfizer incorporates each of the preceding paragraphs 1–106 as if fully set forth herein.

Answer:

Aurobindo incorporates its responses to Paragraphs 1-106 as if fully set forth herein.

108. The inventors named on the '168 patent are Mark Barvian, Richard J. Booth, John Quin, III, Joseph T. Repine, Derek J. Sheehan, Peter L. Toogood, Scott N. Vanderwel, and Hairong Zhou.

Answer:

Aurobindo admits that the '168 patent on its face lists Mark Barvian, Richard J. Booth, John Quin, III, Joseph T. Repine, Derek J. Sheehan, Peter L. Toogood, Scott N. Vanderwel, and Hairong Zhou as inventors.

109. The '168 patent, entitled "2-(pyridin-2-ylamino)-pyrido [2,3-d]pyrimidin-7-ones" (attached as Exhibit C), was duly and legally issued on November 25, 2008.

Answer:

Aurobindo admits that the '168 patent is entitled "2-(pyridine-2-ylamino)-pyrido [2,3-d]pyrimidin-7-ones" and states on its face that it was issued on November 25, 2008. Aurobindo also admits that what is represented to be a copy of the '168 patent is attached as Exhibit C. Aurobindo denies that that the '168 patent was legally issued.

110. Pfizer is the owner and assignee of the '168 patent.

Answer:

On information and belief, Aurobindo admits that Pfizer is the owner and assignee of the '168 patent.

111. The '168 patent claims, inter alia, "[a] method of treating breast cancer in a mammal comprising administering to said mammal an amount of a compound of" the formula recited in claim 1 of the '168 patent.

Answer:

Aurobindo admits that the '168 patent attached to the Complaint as Exhibit C claims "[a] method of treating breast cancer in a mammal comprising administering to said mammal an amount of a compounds of" the formula recited in claim 1 of the '168 patent.

112. IBRANCE®, as well as methods of using IBRANCE®, are covered by one or more claims of the '168 patent, including claim 1 of the '168 patent, and the '168 patent has been listed in connection with IBRANCE® in the FDA's Orange Book.

Answer:

Aurobindo admits that the '168 patent is listed in connection with IBRANCE® in the FDA's Orange Book. Aurobindo lacks sufficient information at this time to admit the remaining allegations of Paragraph 112, and so denies them.

113. In Aurobindo's Notice Letter, Aurobindo notified Pfizer of the submission of Aurobindo's ANDA to the FDA. The purpose of this submission was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Aurobindo's ANDA Product prior to the expiration of the '168 patent.

Answer:

Aurobindo admits that it notified Pfizer of the submission of ANDA No. 213086 to the FDA. Aurobindo also admits that it submitted ANDA No. 213086 to the FDA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Aurobindo's ANDA Product prior to the expiration of the '168 patent.

114. In Aurobindo's Notice Letter, Aurobindo also notified Pfizer that, as part of its ANDA, Aurobindo had filed certifications of the type described in Section 505(j)(2)(B)(iv) of the FDCA, 21 U.S.C. § 355 (j)(2)(B)(iv), with respect to the '168 patent. On information and belief, Aurobindo submitted its ANDA to the FDA containing certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '168 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Aurobindo's ANDA Product.

Answer:

Aurobindo admits that it notified Pfizer that, as part of its ANDA No. 213086, Aurobindo had filed certifications of the type described in Section 505(j)(2)(B)(iv) of the FDCA ("Paragraph IV Certification"), with respect to the '168 patent. Aurobindo admits that it submitted ANDA No. 213086 to the FDA containing a Paragraph IV certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that Aurobindo's ANDA Product will not infringe any valid or enforceable claim of the Orange Book-listed patents for NDA No. 207103. Aurobindo denies the remaining allegations of Paragraph 114.

115. The use of Aurobindo's ANDA Product is covered by claims 1–4 of the '168 patent.

Answer:

Denied.

116. Aurobindo's submission of Aurobindo's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Aurobindo's ANDA Product before the expiration of the '168 patent was an act of infringement of the '168 patent under 35 U.S.C. § 271(e)(2)(A).

Answer:

Denied.

117. On information and belief, Aurobindo will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Aurobindo's ANDA Product immediately and imminently upon approval of its ANDA.

Answer:

The allegations of Paragraph 117 relate to future conduct to which no final decision has been made, and so Aurobindo denies these allegations.

118. The manufacture, use, sale, offer for sale, or importation of Aurobindo's ANDA Product would directly and/or indirectly infringe claims 1–4 of the '168 patent.

Answer:

Denied.

119. On information and belief, the manufacture, use, sale, offer for sale, or importation of Aurobindo's ANDA Product in accordance with, and as directed by, its proposed product labeling would directly and/or indirectly infringe claims 1–4 of the '168 patent.

Answer:

Denied.

120. On information and belief, Aurobindo plans and intends to, and will, actively induce infringement of the '168 patent when Aurobindo's ANDA is approved, and plans and

intends to, and will, do so immediately and imminently upon approval. Aurobindo's activities will be done with knowledge of the '168 patent and specific intent to infringe that patent.

Answer:

Denied.

121. On information and belief, Aurobindo knows that Aurobindo's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '168 patent, that Aurobindo's ANDA Product is not a staple article or commodity of commerce, and that Aurobindo's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. On information and belief, Aurobindo plans and intends to, and will, contribute to infringement of the '168 patent immediately and imminently upon approval of Aurobindo's ANDA.

Answer:

Denied.

122. Notwithstanding Aurobindo's knowledge of the claims of the '168 patent, Aurobindo has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Aurobindo's ANDA Product with its product labeling following FDA approval of Aurobindo's ANDA prior to the expiration of the '168 patent.

Answer:

Aurobindo also admits that it submitted ANDA No. 213086 to the FDA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Aurobindo's ANDA Product prior to the expiration of the '168 patent. Aurobindo denies the remaining allegations of Paragraph 122.

123. The foregoing actions by Aurobindo constitute and/or will constitute infringement of the ’168 patent; active inducement of infringement of the ’168 patent; and contribution to the infringement by others of the ’168 patent.

Answer:

Denied.

124. On information and belief, Aurobindo has acted with full knowledge of the ’168 patent and without a reasonable basis for believing that it would not be liable for infringement of the ’168 patent; active inducement of infringement of the ’168 patent; and/or contribution to the infringement by others of the ’168 patent.

Answer:

Denied.

125. Pfizer will be substantially and irreparably damaged by infringement of the ’168 patent.

Answer:

Denied.

126. Unless Aurobindo is enjoined from infringing the ’168 patent, actively inducing infringement of the ’168 patent, and contributing to the infringement by others of the ’168 patent, Pfizer will suffer irreparable injury. Pfizer has no adequate remedy at law.

Answer:

Denied.

COUNT VI – DECLARATORY JUDGMENT OF INFRINGEMENT OF THE ’168 PATENT

127. Pfizer incorporates each of the preceding paragraphs 1–126 as if fully set forth herein.

Answer:

Aurobindo incorporates by reference its responses to Paragraphs 1-126 as if fully set forth herein.

128. 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 Pfizer on the one hand and Aurobindo on the other regarding Aurobindo's infringement, active inducement of infringement, and contribution to the infringement by others of the '168 patent, and/or validity of the '612 patent.

Answer:

Paragraph 128 contains legal conclusions to which a response is not required.

129. The '168 patent claims, inter alia, "[a] method of treating breast cancer in a mammal comprising administering to said mammal an amount of a compound of" the formula recited in claim 1 of the '168 patent.

Answer:

Aurobindo admits that the '168 patent attached to the Complaint as Exhibit C claims "[a] method of treating breast cancer in a mammal comprising administering to said mammal and amount of a compound of" the formula recited in claim 1 of the '168 patent.

130. In Aurobindo's Notice Letter, Aurobindo notified Pfizer of the submission of Aurobindo's ANDA to the FDA. The purpose of this submission was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Aurobindo's ANDA Product prior to the expiration of the '168 patent.

Answer:

Aurobindo admits that it notified Pfizer of the submission of ANDA No. 213086 to the FDA. Aurobindo also admits that it submitted ANDA No. 213086 to the FDA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Aurobindo's ANDA Product prior to the expiration of the '168 patent.

131. In Aurobindo's Notice Letter, Aurobindo also notified Pfizer that, as part of its ANDA, Aurobindo had filed certifications of the type described in Section 505(j)(2)(B)(iv) of the FDCA, 21 U.S.C. § 355 (j)(2)(B)(iv), with respect to the '168 patent. On information and belief, Aurobindo submitted its ANDA to the FDA containing certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '168 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Aurobindo's ANDA Product.

Answer:

Aurobindo admits that it notified Pfizer that, as part of its ANDA No. 213086, Aurobindo had filed certifications of the type described in Section 505(j)(2)(B)(iv) of the FDCA ("Paragraph IV Certification"), with respect to the '168 patent. Aurobindo admits that it submitted ANDA No. 213086 to the FDA containing a Paragraph IV certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that Aurobindo's ANDA Product will not infringe any valid or enforceable claim of the Orange Book-listed patents for NDA No. 207103. Aurobindo denies the remaining allegations of Paragraph 131.

132. The use of Aurobindo's ANDA Product is covered by claims 1–4 of the '168 patent.

Answer:

Denied.

133. Aurobindo's submission of Aurobindo's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Aurobindo's ANDA Product before the expiration of the '168 patent was an act of infringement of the '168 patent under 35 U.S.C. § 271(e)(2)(A).

Answer:

Denied.

134. On information and belief, Aurobindo will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Aurobindo's ANDA Product immediately and imminently upon approval of its ANDA.

Answer:

The allegations of Paragraph 134 relate to future conduct to which no final decision has been made, and so Aurobindo denies these allegations.

135. The manufacture, use, sale, offer for sale, or importation of Aurobindo's ANDA Product would directly and/or indirectly infringe claims 1–4 of the '168 patent.

Answer:

Denied.

136. On information and belief, the manufacture, use, sale, offer for sale, or importation of Aurobindo's ANDA Product in accordance with, and as directed by, its proposed product labeling would directly and/or indirectly infringe claims 1–4 of the '168 patent.

Answer:

Denied.

137. On information and belief, Aurobindo plans and intends to, and will, actively induce infringement of the '168 patent when Aurobindo's ANDA is approved, and plans and

intends to, and will, do so immediately and imminently upon approval. Aurobindo's activities will be done with knowledge of the '168 patent and specific intent to infringe that patent.

Answer:

Denied.

138. On information and belief, Aurobindo knows that Aurobindo's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '168 patent, that Aurobindo's ANDA Product is not a staple article or commodity of commerce, and that Aurobindo's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. On information and belief, Aurobindo plans and intends to, and will, contribute to infringement of the '168 patent immediately and imminently upon approval of Aurobindo's ANDA.

Answer:

Denied.

139. Notwithstanding Aurobindo's knowledge of the claims of the '168 patent, Aurobindo has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Aurobindo's ANDA Product with its product labeling following FDA approval of Aurobindo's ANDA prior to the expiration of the '168 patent.

Answer:

Aurobindo also admits that it submitted ANDA No. 213086 to the FDA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Aurobindo's ANDA Product prior to the expiration of the '168 patent. Aurobindo denies the remaining allegations of Paragraph 139.

140. The foregoing actions by Aurobindo constitute and/or will constitute infringement of the '168 patent; active inducement of infringement of the '168 patent; and contribution to the infringement by others of the '168 patent.

Answer:

Denied.

141. On information and belief, Aurobindo has acted with full knowledge of the '168 patent and without a reasonable basis for believing that it would not be liable for infringement of the '168 patent; active inducement of infringement of the '168 patent; and/or contribution to the infringement by others of the '168 patent.

Answer:

Denied.

142. Pfizer will be substantially and irreparably damaged by infringement of the '168 patent.

Answer:

Denied.

143. The Court should declare that the commercial manufacture, use, sale, offer for sale or importation of Aurobindo's ANDA Product with its proposed labeling, or any other Aurobindo drug product that is covered by or whose use is covered by the '168 patent, will infringe, induce the infringement of, and contribute to the infringement by others of the '168 patent, and that the claims of the '168 patent are not invalid.

Answer:

Denied.

PRAYER FOR RELIEF

Aurobindo denies that Plaintiffs are entitled to any relief. Aurobindo respectfully requests that the Court dismiss Plaintiffs' Complaint with prejudice, enter judgment in favor of Aurobindo, award Aurobindo its reasonable attorneys' fees and costs incurred in defending this suit, and award Aurobindo such other relief as the Court deems just and proper.

AFFIRMATIVE DEFENSES

Further answering the Complaint, and as additional defenses thereto, Aurobindo asserts the following separate defenses without prejudice to the denials in this Answer and without admitting any allegations of the Complaint not otherwise admitted.

First Affirmative Defense

The claims of the '612 patent are invalid for failure to comply with one or more conditions for patentability set forth in one or more provisions of 35 U.S.C. § 101 *et seq.*, including 35 U.S.C. §§ 101, 102, 103, 112 and/or 116, double patenting, or under other judicially-created bases for invalidation or unenforceability.

Second Affirmative Defense

The claims of the '489 patent are invalid for failure to comply with one or more conditions for patentability set forth in one or more provisions of 35 U.S.C. § 101 *et seq.*, including 35 U.S.C. §§ 101, 102, 103, 112 and/or 116, double patenting, or under other judicially-created bases for invalidation or unenforceability.

Third Affirmative Defense

The claims of the '168 patent are invalid for failure to comply with one or more conditions for patentability set forth in one or more provisions of 35 U.S.C. § 101 *et seq.*, including 35 U.S.C.

§§ 101, 102, 103, 112 and/or 116, double patenting, or under other judicially-created bases for invalidation or unenforceability.

Fourth Affirmative Defense

Plaintiffs' Complaint fails to state a claim upon which relief can be granted, and fails to state a claim for willful infringement and/or exceptional case. The Complaint fails to provide the requisite detail to assert infringement and does not provide a good faith basis for the claim that is being made.

Fifth Affirmative Defense

Plaintiffs are not entitled to relief because they have not appropriately pled, shown, nor proven adequate standing for the relief sought.

Sixth Affirmative Defense

Plaintiffs' cause of action is barred, in whole or in part, by the doctrine of prosecution history estoppel and other doctrines that limit the application of the claims to the accused products. Plaintiffs are estopped from arguing and have waived arguments that its claims cover Aurobindo's ANDA Product by virtue of amendment, positions, and arguments made to the USPTO when obtaining the Orange Book Patents.

Seventh Affirmative Defense

Plaintiffs are not entitled to injunctive relief because they have not and cannot prove the required elements to obtain such relief, including that: (1) they have suffered irreparable injury; (2) there is no adequate remedy at law; (3) a remedy in equity is warranted; and (4) the public interest warrants an injunction.

Eighth Affirmative Defense

The manufacture, use, or sale of Aurobindo's ANDA Product described in ANDA No. 213086 has not infringed and would not, if marketed, infringe, contribute to the infringement of, or induce the infringement of any valid and/or enforceable claim of the '612 patent, either literally or under the doctrine of equivalents.

Ninth Affirmative Defense

The manufacture, use, or sale of Aurobindo's ANDA Product described in ANDA No. 213086 has not infringed and would not, if marketed, infringe, contribute to the infringement of, or induce the infringement of any valid and/or enforceable claim of the '489 patent, either literally or under the doctrine of equivalents.

Tenth Affirmative Defense

The manufacture, use, or sale of Aurobindo's ANDA Product described in ANDA No. 213086 has not infringed and would not, if marketed, infringe, contribute to the infringement of, or induce the infringement of any valid and/or enforceable claim of the '168 patent, either literally or under the doctrine of equivalents.

Reservation of Affirmative Defenses

Aurobindo reserves the right to assert additional defenses that may be developed through discovery, or otherwise, in this action.

AUROBINDO'S COUNTERCLAIMS

Defendants/Counterclaim-Plaintiffs Aurobindo Pharma, LTD., Aurobindo Pharma USA, Inc., and Eugia Pharma Specialities LTD (collectively "Aurobindo"), by and through their counsel, brings the following Counterclaims against Plaintiffs/Counter-Defendants Pfizer, Inc., Warner-Lambert Company, LLC, PF Prism C.V., Pfizer Manufacturing Holdings LLC, and Pfizer PFE Ireland Pharmaceuticals Holding 1 B.V. (collectively "Pfizer" or "Counter-Defendants") for a declaratory judgment that U.S. Patent Nos. 6,936,612 ("the '612 patent"); 7,208,489 ("the '489 patent"); and 7,456,168 ("the '168 patent") (collectively the "Asserted Patents") are invalid and/or not infringed by Aurobindo's palbociclib product that is the subject of Abbreviated New Drug Application ("ANDA") No. 213086 ("Aurobindo's ANDA Product").

THE PARTIES

1. Counterclaim-Plaintiff Aurobindo Pharma, Ltd. is a company organized and existing under the laws of the Republic of India with its principal place of business at Maitri Vihar, Plot #2, Ameerpet, Hyderabad 500 038, Telangana, India.

2. Counterclaim-Plaintiff Aurobindo Pharma USA, Inc. is a corporation organized and existing under the laws of the State of Delaware with its principal place of business a 279 Princeton Hightstown Road, East Windsor, New Jersey 08520. Aurobindo Pharma USA, Inc. is a wholly-owned subsidiary and the U.S. Agent of Aurobindo Pharma, Ltd.

3. Counterclaim-Plaintiff Eugia Pharma Specialities, Ltd. is a company organized and existing under the laws of the Republic of India with its principal place of business at Maitri Vihar, Plot #2, Ameerpet, Hyderabad 500 038, Telangana, India. Eugia Pharma Specialities, Ltd. is a wholly-owned subsidiary of Aurobindo Pharma, Ltd.

4. On information and belief, and based on Paragraph 3 of the Counterclaim-Defendants' Complaint, Counterclaim-Defendant Pfizer, Inc. is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 235 East 42nd Street, New York, New York 10017.

5. On information and belief, and based on Paragraph 4 of Counterclaim-Defendants' Complaint, Counterclaim-Defendant Warner-Lambert Company LLC is a limited liability company organized and existing under the laws of the State of Delaware, having a place of business at 235 East 42nd Street, New York, New York 10017. On information and belief, Warner-Lambert Company LLC is a wholly-owned subsidiary of Pfizer, Inc.

6. On information and belief, and based on Paragraph 5 of the Counterclaim-Defendants' Complaint, Counterclaim-Defendant 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, that for all purposes is represented and acting through its general partner Pfizer Manufacturing Holdings LLC, a limited liability company organized under the laws of the State of Delaware, and having its address at 235 East 42nd Street, New York, New York 10017. On information and belief, PF PRISM C.V. and Pfizer Manufacturing Holdings LLC are wholly-owned subsidiaries of Pfizer, Inc.

7. On information and belief, and based on Paragraph 6 of the Counterclaim-Defendants' Complaint, Counterclaim-Defendant Pfizer PFE Ireland Pharmaceuticals Holding 1 B.V. is a private limited liability company (*besloten vennooschap*) organized under the laws of the Netherlands, having its registered seat in Rotterdam, the Netherlands, having its business address at Rivium Westlaam 142, 2909 LD, Capelle aan den IJssel, the Netherlands. On information and

belief, Pfizer PFE Ireland Pharmaceuticals Holding 1 B.V. is a wholly-owned subsidiary of Pfizer, Inc.

BACKGROUND

8. Aurobindo filed ANDA No. 213086 with the FDA seeking approval to market palbociclib, referencing the approved New Drug Application ("NDA") for IBRANCE®, NDA No. 207103.

9. On information and belief, Pfizer is the current holder of NDA No. 207103.

10. The United States Food and Drug Administration's "Approved Drug Products with Therapeutic Equivalence Evaluation," also known as the "Orange Book," lists the Asserted Patents as covering IBRANCE® as manufactured under NDA No. 207103.

11. As part of its ANDA, Aurobindo submitted to the FDA a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4) ("Paragraph IV Certification") that the Asserted Patents are invalid, unenforceable, or will not be infringed by the manufacture, use, or sale of Aurobindo's Proposed ANDA Product.

12. On or about March 26, 2019, Aurobindo sent by FedEx a letter concerning its Paragraph IV certification (the "Notice Letter") to Pfizer, Inc. and Warner-Lambert Company LLC.

13. The Notice Letter included a detailed statement of the factual and legal bases for Aurobindo's opinion that the Asserted patents are invalid, unenforceable, and/or not infringed by Aurobindo's Proposed ANDA Product.

14. Counterclaim-Defendants have actual knowledge of the contents of the Notice Letter.

JURISDICTION AND VENUE

15. This Court has subject matter jurisdiction over the counterclaims for declaratory judgement pursuant to 28 U.S.C. §§ 2201, 2202, 1331, 1338(a), based on an actual controversy between Aurobindo and Counter-Defendants arising under the patent laws of the United States, 35 U.S.C. §§ 100 *et seq*.

16. This Court has personal jurisdiction over Counterclaim-Defendants because Counterclaim-Defendants have voluntarily subjected themselves to the Court's jurisdiction by filing the Complaint, and for other reasons.

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

FIRST COUNTERCLAIM
(Declaration of Non-infringement of the '612 Patent)

18. Aurobindo incorporates by reference the allegations set forth in Paragraphs 1-17 of the Counterclaims as if fully set forth herein.

19. The commercial manufacture, use, offer of sale, sale, or importation of Aurobindo's Proposed ANDA Product has not infringed, does not infringe, and would not directly infringe or indirectly infringe any valid claim of the '612 patent, either literally or under the doctrine of equivalents, for at least the reasons Aurobindo presented in the Notice Letter, which is incorporated here by reference.

20. Further, Aurobindo will not infringe, contribute to the infringement of, or induce the infringement of any valid and/or enforceable claim of the '612 patent, and will not be liable for such infringement, for at least the reasons Aurobindo presented in the Notice Letter, which is incorporated here by reference.

21. Counterclaim-Defendants bear the burden of proving infringement and will not be able to meet that burden.

22. Aurobindo is entitled to a declaration that it does not infringe, directly or indirectly, any valid claim of the '612 patent.

SECOND COUNTERCLAIM
(Declaration of Invalidity of the '612 Patent)

23. Aurobindo incorporates by reference the allegations set forth in Paragraphs 1-22 of the Counterclaims as if fully set forth herein.

24. All claims of the '612 patent are invalid for failure to satisfy one or more of the requirements of 35 U.S.C. §§ 101, 102, 103, 112, 116, the defenses recognized in 35 U.S.C. § 282(b), double patenting, and/or other judicially-created bases for invalidation, at least for the reasons stated in the Notice Letter.

25. For example, as described in the Notice Letter, claims 1 and 2 of the '612 patent are invalid as obvious under § 103 in light of at least the following prior art: International Publication No. WO2001/70741; International Publication No. WO1998/33798; Mark Barvian *et al.*, *Pyrido[2,3-d]pyrimidin-7-one Inhibitors of Cyclin-Dependent Kinases*, 43 J. MED. CHEM. 4606 (2000); Sylvester R. Klutchko *et al.*, *2-Substituted Aminopyrido[2,3-d]pyrimidin-7(8H)-ones. Structure-Activity Relationships Against Selected Tyrosine Kinases and in Vitro and in Vivo Anticancer Activity*, 41 J. MED. CHEM. 3276 (1998); International Publication No. WO1996/15128; Peter L. Toogood, *Cyclin-Dependent Kinase Inhibitors for Treating Cancer*, 21 MED. RES. REV. 487 (2001); International Publication No. WO1996/22990; U.S. Patent No. 5,801,183; and/or International Publication No. WO1996/34867.

26. Aurobindo is entitled to a declaration that the claims of the '612 patent are invalid.

THIRD COUNTERCLAIM
(Declaration of Non-infringement of the '489 Patent)

27. Aurobindo incorporates by reference the allegations set forth in Paragraphs 1-26 of the Counterclaims as if fully set forth herein.

28. The commercial manufacture, use, offer of sale, sale, or importation of Aurobindo's Proposed ANDA Product has not infringed, does not infringe, and would not directly infringe or indirectly infringe any valid claim of the '489 patent, either literally or under the doctrine of equivalents, for at least the reasons Aurobindo presented in the Notice Letter, which is incorporated here by reference.

29. Further, Aurobindo will not infringe, contribute to the infringement of, or induce the infringement of any valid and/or enforceable claim of the '489 patent, and will not be liable for such infringement, for at least the reasons Aurobindo presented in the Notice Letter, which is incorporated here by reference.

30. Counterclaim-Defendants bare the burden of proving infringement and will not be able to meet that burden.

31. Aurobindo is entitled to a declaration that it does not infringe, directly or indirectly, any valid claim of the '489 patent.

FOURTH COUNTERCLAIM
(Declaration of Invalidity of the '489 Patent)

32. Aurobindo incorporates by reference the allegations set forth in Paragraphs 1-31 of the Counterclaims as if fully set forth herein.

33. All claims of the '489 patent are invalid for failure to satisfy one or more of the requirements of 35 U.S.C. §§ 101, 102, 103, 112, 116, the defenses recognized in 35 U.S.C. §

282(b), double patenting, and/or other judicially-created bases for invalidation, at least for the reasons stated in the Notice Letter, which is incorporated here by reference.

34. For example, as described in the Notice Letter, at least claims 1-4, 6-7, and 9 of the '489 patent are anticipated in view of International Publication No. WO1998/33798.

35. Moreover, as described in the Notice Letter, claims 1-9 of the '489 patent are invalid as obvious under § 103 in light of at least the following prior art: International Publication No. WO2001/70741; International Publication No. WO1998/33798; Mark Barvian *et al.*, *Pyrido[2,3-d]pyrimidin-7-one Inhibitors of Cyclin-Dependent Kinases*, 43 J. MED. CHEM. 4606 (2000); Sylvester R. Klutchko *et al.*, *2-Substituted Aminopyrido[2,3-d]pyrimidin-7(8H)-ones. Structure-Activity Relationships Against Selected Tyrosine Kinases and in Vitro and in Vivo Anticancer Activity*, 41 J. MED. CHEM. 3276 (1998); International Publication No. WO1996/15128; Peter L. Toogood, *Cyclin-Dependent Kinase Inhibitors for Treating Cancer*, 21 MED. RES. REV. 487 (2001); International Publication No. WO1996/22990; U.S. Patent No. 5,801,183; and/or International Publication No. WO1996/34867.

36. Aurobindo is entitled to a declaration that the claims of the '489 patent are invalid.

FIFTH COUNTERCLAIM
(Declaration of Non-infringement of the '168 Patent)

37. Aurobindo incorporates by reference the allegations set forth in Paragraphs 1-36 of the Counterclaims as if fully set forth herein.

38. The commercial manufacture, use, offer of sale, sale, or importation of Aurobindo's Proposed ANDA Product has not infringed, does not infringe, and would not directly infringe or indirectly infringe any valid claim of the '168 patent, either literally or under the doctrine of equivalents, for at least the reasons Aurobindo presented in the Notice Letter, which is incorporated here by reference.

39. Further, Aurobindo will not infringe, contribute to the infringement of, or induce the infringement of any valid and/or enforceable claim of the '168 patent, and will not be liable for such infringement, for at least the reasons Aurobindo presented in the Notice Letter, which is incorporated here by reference.

40. Counterclaim-Defendants bear the burden of proving infringement and will not be able to meet that burden. In addition, the Notice letter identifies elements that are already known to be absent from Aurobindo's ANDA Product. For example, claims 1-4 of the '168 patent are directed to certain methods of treatment, which Aurobindo does not and will not practice.

41. Aurobindo is entitled to a declaration that it does not infringe, directly or indirectly, any valid claim of the '168 patent.

SIXTH COUNTERCLAIM
(Declaration of Invalidity of the '168 Patent)

42. Aurobindo incorporates by reference the allegations set forth in Paragraphs 1-41 of the Counterclaims as if fully set forth herein.

43. All claims of the '168 patent are invalid for failure to satisfy one or more of the requirements of 35 U.S.C. §§ 101, 102, 103, 112, 116, the defenses recognized in 35 U.S.C. § 282(b), double patenting, and/or other judicially-created bases for invalidation, at least for the reasons stated in the Notice Letter.

44. For example, as described in the Notice Letter, claims of the '168 patent are anticipated in view of International Publication No. WO1998/33798.

45. Moreover, as described in the Notice Letter, claims 1-4 of the '168 patent are invalid as obvious under § 103 in light of at least the following prior art: International Publication No. WO2001/70741; International Publication No. WO1998/33798; Mark Barvian *et al.*, *Pyrido[2,3-d]pyrimidin-7-one Inhibitors of Cyclin-Dependent Kinases*, 43 J. MED. CHEM. 4606

(2000); Sylvester R. Klutchko *et al.*, *2-Substituted Aminopyrido[2,3-d]pyrimidin-7(8H)-ones. Structure-Activity Relationships Against Selected Tyrosine Kinases and in Vitro and in Vivo Anticancer Activity*, 41 J. MED. CHEM. 3276 (1998); International Publication No. WO1996/15128; Peter L. Toogood, *Cyclin-Dependent Kinase Inhibitors for Treating Cancer*, 21 MED. RES. REV. 487 (2001); International Publication No. WO1996/22990; U.S. Patent No. 5,801,183; and/or International Publication No. WO1996/34867; David W. Fry *et al.*, *Cell Cycle and Biochmeical Effects of PD 0183812*, 276 J. BIO. CHEM. 16617 (2001); and/or Mark M. Moasser *et al.*, *Inhibition of Src Kinases by a Selective Tyrosine Kinase Inhibitor Causes Mitotic Arrest*, 59 CANCER RES. 6145 (1999).

46. Aurobindo is entitled to a declaration that the claims of the '168 patent are invalid.

PRAYER FOR RELIEF

WHEREFORE, Aurobindo respectfully requests the Court Enter a Judgment and Order in its favor and against Counterclaim-Defendants to include:

A. A declaration that the claims of the Asserted Patents are invalid;

B. A declaration that Aurobindo's submission of ANDA No. 213086 seeking FDA approval to market palbociclib capsules before the expiry of the Asserted Patents has not infringed, and will not infringe, any valid claim of the Asserted Patents;

C. A declaration that Aurobindo's commercial use, offer for sale, sale, or importation of the palbociclib product that is the subject of ANDA No. 213086 will not infringe, induce infringement, or contribute to any infringement of any valid claim of the Asserted patents;

D. A declaration that Counterclaim-Defendants are entitled to no damages, interest, costs, or other relief from or against Aurobindo;

E. A declaration that this is an exceptional case under 35 U.S.C. § 285 and awarding Aurobindo's attorneys' fees, costs, and expenses;

F. A declaration that Counterclaim-Defendants are not entitled to injunctive relief;

G. A declaration preliminarily and permanently enjoining Counterclaim-Defendants, their officers, agents, servants, employees, attorneys, and any person who acts in concert or participation with Counterclaim-Defendants, from taking any action to unlawfully prevent the FDA approval of ANDA No. 213086 and the product described therein;

H. A declaration preliminarily and permanently enjoining Counterclaim-Defendants, their officers, agents, servants, employees, attorneys, and any person who acts in concert or participation with Counterclaim-Defendants, from asserting or otherwise seeking to enforce the Asserted Patents against Aurobindo or anyone in privity with Aurobindo; and

I. Such other and further relief as the Court may deem proper.

Dated: July 8, 2019

Respectfully Submitted,

/s/ Kenneth L. Dorsney

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