

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

PFIZER INC., WARNER-LAMBERT)
COMPANY LLC, PF PRISM C.V., PFIZER)
MANUFACTURING HOLDINGS LLC,)
PFIZER PFE IRELAND)
PHARMACEUTICALS HOLDING 1 B.V.,)
and PF PRISM IMB B.V.)
)
Plaintiffs,)
)
v.) C.A. No. 20-1528-CFC
)
AUROBINDO PHARMA, LTD.,)
AUROBINDO PHARMA USA, INC. and)
EUGIA PHARMA SPECIALTIES LTD.,)
)
Defendants.)

**AUROBINDO PHARMA, LTD., AUROBINDO PHARMA USA, INC., AND EUGIA
PHARMA SPECIALTIES LTD.’S 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, and PF PRISM IMB 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. 10,723,730 (“the ’730 patent”).

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. 10,723,730 (“the ’730 patent”). 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 Ltd., notified Pfizer by letter dated October 14, 2020 (“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, 75 mg, 100 mg, and 125 mg (“Aurobindo’s ANDA Product”) prior to the expiration of the ’730 patent.

Answer:

Aurobindo admits that Aurobindo Pharma USA, Inc., U.S. agent for Eugia Pharma Specialities Ltd., notified Pfizer by letter dated October 14, 2020 (“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 ’730 patent.

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 capsules, 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 IMB B.V. is a private limited company (*besloten venootschap*) organized 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.

Answer:

On information and belief, Aurobindo admits the allegation.

6. 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 products 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 6.

7. 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 7.

8. 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 8.

9. 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.

10. 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.

11. Aurobindo Pharma, Ltd., Eugia Pharma Specialties [sic] Ltd., and Aurobindo Pharma USA, Inc. are collectively referred to herein as “Aurobindo.”

Answer:

Paragraph 11 contains a statement to which no response is required.

12. 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.

13. 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 13 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 13.

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

JURISDICTION

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

Answer:

Paragraph 15 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.

16. 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 16 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 16.

17. 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 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. Eugia Pharma Specialties [sic] Ltd. is subject to personal jurisdiction in Delaware because, among other things, Eugia Pharma Specialties [sic] 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, 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. Aurobindo has previously used the process contemplated by the Drug Price Competition and Patent Term Restoration Act of 1984, 21 U.S.C. § 355(j) (the “Hatch-Waxman Act”), to challenge branded pharmaceutical companies’ patents by filing a certification of the type described in Section 505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act (“FDCA”), 21 U.S.C. § 355(j)(2)(B)(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 in Section 505(j)(2)(B)(iv) of the FDCA, 21 U.S.C. § 355(j)(2)(B)(iv), and has defended itself from allegations of patent infringement. Aurobindo denies the remaining allegations of Paragraph 19.

20. 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 '730 patent is 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. included a detailed statement describing why the '730 patent is invalid and why Aurobindo's ANDA Products will not infringe any valid and enforceable claim of the '730 patent, 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. Aurobindo denies the remaining allegations of Paragraph 20.

21. Because Pfizer Inc. 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 21 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 21.

22. 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, consistent 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 patent in the event that Aurobindo's ANDA Product is approved before the patents expire.

Answer:

Paragraph 22 contains allegations related to future conduct about which no final decisions have been made, and so denies those allegations. Paragraph 22 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 22.

23. 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 23, and so denies them. Aurobindo denies all allegations of infringement, and all remaining allegations of Paragraph 23 are denied.

24. 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 24 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. Aurobindo denies the remaining allegations of Paragraph 24.

25. 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 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. Aurobindo denies the remaining allegations of Paragraph 25.

26. 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 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. Aurobindo denies the remaining allegations of Paragraph 26.

FACTUAL BACKGROUND

27. IBRANCE®, which contains palbociclib, is approved for the treatment of HR-positive, HER2-negative advanced or metastatic breast cancer.

Answer:

Upon information and belief, Aurobindo admits that IBRANCE® contains palbociclib. Aurobindo admits that IBRANCE® is approved by the FDA for the treatment of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer in combination with an aromatase inhibitor as initial endocrine based therapy in post-menopausal women, or fulvestrant in women with disease progression following endocrine therapy.

28. Upon information and belief, Aurobindo's ANDA Product is a generic version of IBRANCE®.

Answer:

Aurobindo admits that Aurobindo's ANDA Product is a capsule containing palbociclib. Aurobindo denies the remaining allegations of Paragraph 28.

29. Aurobindo's Notice Letter purported to include an "Offer of Confidential Access" to Pfizer to Aurobindo's ANDA. The offer, however, was subject to various unreasonably restrictive conditions.

Answer:

Aurobindo admits that Aurobindo's Notice Letter contained an "Offer of Confidential Access" to Pfizer to Aurobindo's ANDA, but denies that the Offer of Confidential Access contained unreasonably restrictive conditions. Aurobindo also states that it has produced its ANDA in its entirety to Pfizer.

30. On October 19, 2020, counsel for Plaintiffs sent a letter to counsel for Aurobindo attempting to negotiate access to Aurobindo's internal documents, data and/or samples relevant to infringement based on reasonable confidentiality terms. As of the filing of this Complaint, counsel for Plaintiffs had not received a response.

Answer:

Aurobindo admits that counsel for Aurobindo received a letter from counsel for Plaintiffs around October 19, 2020, but denies they contained reasonable confidentiality terms or reasonable requests for samples and/or data. Aurobindo also states that it has produced its ANDA in its entirety to Pfizer.

31. Plaintiffs are filing this Complaint within forty-five days of receipt of Aurobindo's Notice Letter.

Answer:

Aurobindo admits that Plaintiffs filed this action within forty-five days of receipt of Aurobindo's Notice Letter.

COUNT I – INFRINGEMENT OF THE '730 PATENT

32. Pfizer incorporates each of the preceding paragraphs 1–31 as if fully set forth herein.

Answer:

Aurobindo incorporates by reference its responses to paragraphs 1–31 as if fully set forth herein.

33. The inventors of the '730 patent are Brian Patrick Chekal and Nathan D. Ide.

Answer:

Aurobindo admits that the '730 patent on its face lists Brian Patrick Chekal and Nathan D. Ide as inventors.

34. The '730 patent, entitled "Solid Forms of a Selective Cdk4/6 Inhibitor" (attached as Exhibit A), was duly and legally issued on July 28, 2020.

Answer:

Aurobindo admits that the '730 patent is entitled "Solid Forms of a Selective CDK4/6 Inhibitor" and states on its face that it was issued on July 28, 2020. Aurobindo also admits that what is represented appears to be a copy of the '730 patent is attached as Exhibit A. Aurobindo denies that that the '730 patent was legally issued.

35. Pfizer is the owner and assignee of the '730 patent.

Answer:

On information and belief, Aurobindo admits that Pfizer is the owner and assignee of the '730 patent.

36. IBRANCE® is covered by one or more claims of the '730 patent, which has been listed in connection with IBRANCE® in the FDA's publication *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as "the Orange Book").

Answer:

Aurobindo admits that the '730 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 36, and so denies them.

37. 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 '730 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 37.

38. In Aurobindo's Notice Letter, Aurobindo also notified Pfizer that, as part of its ANDA, Aurobindo had filed a certification 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 '730 patent. Upon 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 '730 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 filed certifications of the type described in Section 505(j)(2)(B)(iv) of the FDCA ("Paragraph IV Certification"), with respect to the '730 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 '730 patent. Aurobindo denies the remaining allegations of Paragraph 38.

39. Upon information and belief, Aurobindo's ANDA Product and the use of Aurobindo's ANDA Product are covered by one or more claims of the '730 patent, either literally or under the doctrine of equivalents.

Answer:

Denied.

40. As an example, claim 1 of the '730 patent recites:

A crystalline free base of 6-acetyl-8-cyclopentyl-5-methyl-2-(5-piperazin-1-yl-pyridin-2-ylamino)-8H-pyrido[2,3-d]pyrimidin-7-one, having a powder X-ray diffraction pattern comprising peaks at diffraction angles (2θ) of 8.0 ± 0.2 , 10.1 ± 0.2 and 11.5 ± 0.2 and a primary particle size distribution characterized by a D90 value of from about 30 μm to about 65 μm .

Answer:

Aurobindo admits that claim 1 of the '730 patent attached to the Complaint as Exhibit A recites:

A crystalline free base of 6-acetyl-8-cyclopentyl-5-methyl-2-(5-piperazin-1-yl-pyridin-2-ylamino)-8H-pyrido[2,3-d]pyrimidin-7-one, having a powder X-ray diffraction pattern comprising peaks at diffraction angles (2θ) of 8.0 ± 0.2 , 10.1 ± 0.2 and 11.5 ± 0.2 and a primary particle size distribution characterized by a D₉₀ value of from about 30 μm to about 65 μm .

41. Upon information and belief, Aurobindo's ANDA Product infringes claim 1 of the '730 patent, literally or under the doctrine of equivalents.

Answer:

Denied.

42. As an example, Claim 7 of the '730 patent recites:

A crystalline free base of 6-acetyl-8-cyclopentyl-5-methyl-2-(5-piperazin-1-yl-pyridin-2-ylamino)-8H-pyrido[2,3-d]pyrimidin-7-one, having a powder X-ray diffraction pattern comprising peaks at diffraction angles (2θ) of 8.0 ± 0.2 , 10.1 ± 0.2 and 11.5 ± 0.2 and a volume mean diameter characterized by a D[4,3] value of from about 15 μm to about 40 μm .

Answer:

Aurobindo admits that claim 7 of the '730 patent attached to the Complaint as Exhibit A recites:

A crystalline free base of 6-acetyl-8-cyclopentyl-5-methyl-2-(5-piperazin-1-yl-pyridin-2-ylamino)-8H-pyrido[2,3-d]pyrimidin-7-one, having a powder X-ray diffraction pattern comprising peaks at diffraction angles (2θ) of 8.0 ± 0.2 , 10.1 ± 0.2 and 11.5 ± 0.2 and a volume mean diameter characterized by a D[4,3] value of from about 15 μm to about 40 μm .

43. Upon information and belief, Aurobindo's ANDA Product infringes claim 7 of the '730 patent, literally or under the doctrine of equivalents.

Answer:

Denied.

44. As an example, Claim 15 of the '730 patent recites:

A crystalline free base of 6-acetyl-8-cyclopentyl-5-methyl-2-(5-piperazin-1-yl-pyridin-2-ylamino)-8H-pyrido[2,3-d]pyrimidin-7-one, having a powder X-ray diffraction pattern comprising peaks at diffraction angles (2θ) of 8.0 ± 0.2 , 10.1 ± 0.2 and 11.5 ± 0.2 and a volume mean diameter characterized by a D[4,3] value of from about $15\text{ }\mu\text{m}$ to about $30\text{ }\mu\text{m}$.

Answer:

Aurobindo admits that claim 15 of the '730 patent attached to the Complaint as Exhibit A recites:

A crystalline free base of 6-acetyl-8-cyclopentyl-5-methyl-2-(5-piperazin-1-yl-pyridin-2-ylamino)-8H-pyrido[2,3-d]pyrimidin-7-one, having a powder X-ray diffraction pattern comprising peaks at diffraction angles (2θ) of 8.0 ± 0.2 , 10.1 ± 0.2 and 11.5 ± 0.2 and a volume mean diameter characterized by a D[4,3] value of from about $15\text{ }\mu\text{m}$ to about $30\text{ }\mu\text{m}$.

45. Upon information and belief, Aurobindo's ANDA Product infringes claim 15 of the '730 patent, literally or under the doctrine of equivalents.

Answer:

Denied.

46. 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 '730 patent was an act of infringement of the '730 patent under 35 U.S.C. § 271(e)(2)(A).

Answer:

Denied.

47. Upon 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 47 relate to future conduct to which no final decision has been made, and so Aurobindo denies these allegations.

48. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of Aurobindo's ANDA Product would infringe one or more claims of the '730 patent, either literally or under the doctrine of equivalents.

Answer:

Denied.

49. Upon 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 '730 patent.

Answer:

Denied.

50. Upon information and belief, Aurobindo plans and intends to, and will, actively induce infringement of the '730 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 '730 patent and specific intent to infringe that patent.

Answer:

The allegations of Paragraph 50 relate to future conduct to which no final decision has been made, and so Aurobindo denies these allegations. Aurobindo denies all allegations of infringement.

51. Upon information and belief, Aurobindo knows that Aurobindo's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '730 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. Upon information and belief, Aurobindo plans and intends to, and will, contribute to infringement of the '730 patent immediately and imminently upon approval of Aurobindo's ANDA.

Answer:

The allegations of Paragraph 51 relate to future conduct to which no final decision has been made, and so Aurobindo denies these allegations. Aurobindo denies all allegations of infringement.

52. Notwithstanding Aurobindo's knowledge of the claims of the '730 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 '730 patent.

Answer:

Denied.

53. The foregoing actions by Aurobindo constitute and/or will constitute infringement of the '730 patent; active inducement of infringement of the '730 patent; and contribution to the infringement by others of the '730 patent.

Answer:

Denied.

54. Upon information and belief, Aurobindo has acted with full knowledge of the '730 patent and without a reasonable basis for believing that it would not be liable for infringement of the '730 patent; active inducement of infringement of the '730 patent; and/or contribution to the infringement by others of the '730 patent.

Answer:

Denied.

55. Pfizer will be substantially and irreparably harmed by infringement of the '730 patent.

Answer:

Denied.

56. Unless Aurobindo is enjoined from infringing the '730 patent, actively inducing infringement of the '730 patent, and contributing to the infringement by others of the '730 patent, Pfizer will suffer irreparable injury. Pfizer has no adequate remedy at law.

Answer:

Denied.

**COUNT II – DECLARATORY JUDGMENT OF
INFRINGEMENT OF THE '730 PATENT**

57. Pfizer incorporates each of the preceding paragraphs 1–56 as if fully set forth herein.

Answer:

Aurobindo incorporates by reference its responses to paragraphs 1–56 as if fully set forth herein.

58. 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 one hand and Aurobindo on the other regarding Aurobindo's infringement, active inducement of infringement, and contribution to the infringement by others of the '730 patent, and/or the validity of the '730 patent.

Answer:

Aurobindo admits there is an actual controversy between Pfizer and Aurobindo relating to the '730 patent. Aurobindo denies the remaining allegations of Paragraph 58.

59. 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 '730 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 '730 patent.

60. 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 '730 patent. Upon 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 that '730 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 '730 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 60.

61. Upon information and belief, Aurobindo's ANDA Product and the use of Aurobindo's ANDA Product are covered by one or more claims of the '730 patent.

Answer:

Denied.

62. As an example, claim 1 of the '730 patent recites:

A crystalline free base of 6-acetyl-8-cyclopentyl-5-methyl-2-(5-piperazin-1-yl-pyridin-2-ylamino)-8H-pyrido[2,3-d]pyrimidin-7-one, having a powder X-ray diffraction pattern comprising peaks at diffraction angles (2θ) of 8.0 ± 0.2 , 10.1 ± 0.2 and 11.5 ± 0.2 and a primary particle size distribution characterized by a D90 value of from about 30 μm to about 65 μm .

Answer:

Aurobindo admits that claim 1 of the '730 patent attached to the Complaint as Exhibit A recites:

A crystalline free base of 6-acetyl-8-cyclopentyl-5-methyl-2-(5-piperazin-1-yl-pyridin-2-ylamino)-8H-pyrido[2,3-d]pyrimidin-7-one, having a powder X-ray diffraction pattern comprising peaks at diffraction angles (2θ) of 8.0 ± 0.2 , 10.1 ± 0.2 and 11.5 ± 0.2 and a primary particle size distribution characterized by a D90 value of from about 30 μm to about 65 μm .

63. Upon information and belief, Aurobindo's ANDA Product infringes claim 1 of the '730 patent, literally or under the doctrine of equivalents.

Answer:

Denied.

64. As an example, Claim 7 of the '730 patent recites:

A crystalline free base of 6-acetyl-8-cyclopentyl-5-methyl-2-(5-piperazin-1-yl-pyridin-2-ylamino)-8H-pyrido[2,3-d]pyrimidin-7-one, having a powder X-ray diffraction pattern comprising peaks at diffraction angles (2θ) of 8.0 ± 0.2 , 10.1 ± 0.2 and 11.5 ± 0.2 and a volume mean diameter characterized by a D[4,3] value of from about 15 μm to about 40 μm .

Answer:

Aurobindo admits that claim 7 of the '730 patent attached to the Complaint as Exhibit A recites:

A crystalline free base of 6-acetyl-8-cyclopentyl-5-methyl-2-(5-piperazin-1-yl-pyridin-2-ylamino)-8H-pyrido[2,3-d]pyrimidin-7-one, having a powder X-ray diffraction pattern comprising peaks at diffraction angles (2θ) of 8.0 ± 0.2 , 10.1 ± 0.2 and 11.5 ± 0.2 and a volume mean diameter characterized by a D[4,3] value of from about 15 μm to about 40 μm .

65. Upon information and belief, Aurobindo's ANDA Product infringes claim 7 of the '730 patent, literally or under the doctrine of equivalents.

Answer:

Denied.

66. As an example, Claim 15 of the '730 patent recites:

A crystalline free base of 6-acetyl-8-cyclopentyl-5-methyl-2-(5-piperazin-1-yl-pyridin-2-ylamino)-8H-pyrido[2,3-d]pyrimidin-7-one, having a powder X-ray diffraction pattern comprising peaks at diffraction angles (2θ) of 8.0 ± 0.2 , 10.1 ± 0.2 and 11.5 ± 0.2 and a volume mean diameter characterized by a D[4,3] value of from about 15 μm to about 30 μm .

Answer:

Aurobindo admits that claim 15 of the '730 patent attached to the Complaint as Exhibit A recites:

A crystalline free base of 6-acetyl-8-cyclopentyl-5-methyl-2-(5-piperazin-1-yl-pyridin-2-ylamino)-8H-pyrido[2,3-d]pyrimidin-7-one, having a powder X-ray diffraction pattern comprising peaks at diffraction angles (2θ) of 8.0 ± 0.2 , 10.1 ± 0.2 and 11.5 ± 0.2 and a volume mean diameter characterized by a D[4,3] value of from about $15\text{ }\mu\text{m}$ to about $30\text{ }\mu\text{m}$.

67. Upon information and belief, Aurobindo's ANDA Product infringes claim 15 of the '730 patent, literally or under the doctrine of equivalents.

Answer:

Denied.

68. Upon 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 68 relate to future conduct to which no final decision has been made, and so Aurobindo denies these allegations.

69. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of Aurobindo's ANDA Product would infringe one or more claims of the '730 patent.

Answer:

Denied.

70. Upon 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 labeling would infringe one or more claims of the '730 patent.

Answer:

Denied.

71. Upon information and belief, Aurobindo plans and intends to, and will, actively induce infringement of the '730 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 '730 patent and specific intent to infringe that patent.

Answer:

Denied.

72. Upon information and belief, Aurobindo knows that Aurobindo's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '730 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. Upon information and belief, Aurobindo plans and intends to, and will, contribute to infringement of the '730 patent immediately and imminently upon approval of Aurobindo's ANDA Product.

Answer:

Denied.

73. Notwithstanding Aurobindo's knowledge of the claims of the '730 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 '730 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 '730 patent. Aurobindo denies the remaining allegations in Paragraph 73.

74. The foregoing actions by Aurobindo constitute and/or will constitute infringement of the '730 patent; active inducement of infringement of the '730 patent; and contribution to the infringement by others of the '730 patent.

Answer:

Denied.

75. Upon information and belief, Aurobindo has acted with full knowledge of the '730 patent and without a reasonable basis for believing that it would not be liable for infringement of the '730 patent; active inducement of infringement of the '730 patent; and/or contribution to the infringement by others of the '730 patent.

Answer:

Denied.

76. Pfizer will be substantially and irreparably damaged by infringement of the '730 patent.

Answer:

Denied.

77. The Court should declare that the commercial manufacture, use, sale, offer for sale and/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 '730 patent, will infringe, induce infringement of, and contribute to the infringement by others of the '730 patent, and that the claims of the '730 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 '730 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

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.

Third Affirmative Defense

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

Fourth 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.

Fifth 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.

Sixth 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 '730 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, and PF PRISM IMB B.V. (collectively “Pfizer” or “Counter-Defendants”) for a declaratory judgment that U.S. Patent No. 10,723,730 (“the ’730 patent”) is invalid and/or not infringed by Aurobindo’s palbociclib product that is the subject of Abbreviated New Drug Application (“ANDA”) No. 213086 (“Aurobindo’s Proposed 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 at 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 IMB B.V. (*besloten venootschap*) 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, PF PRISM IMB B.V. is a wholly-owned subsidiary of Pfizer Inc.

BACKGROUND

7. 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.

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

9. The United States Food and Drug Administration's "Approved Drug Products with Therapeutic Equivalence Evaluation," also known as the "Orange Book," lists the '730 patent as covering IBRANCE® as manufactured under NDA No. 207103.

10. 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 '730 patent is invalid, unenforceable, or will not be infringed by the manufacture, use, or sale of Aurobindo's Proposed ANDA Product.

11. On or about October 14, 2020, Aurobindo sent by FedEx a letter concerning its Paragraph IV certification (the "Notice Letter") to Pfizer Inc. and Warner-Lambert Company LLC.

12. The Notice Letter included a detailed statement of the factual and legal bases for Aurobindo's opinion that the '730 patent is invalid, unenforceable, and/or not infringed by Aurobindo's Proposed ANDA Product.

13. Counterclaim-Defendants have actual knowledge of the contents of the Notice Letters.

JURISDICTION AND VENUE

14. 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.*

15. 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.

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

FIRST COUNTERCLAIM **(Declaration of Non-infringement of the '730 Patent)**

17. Aurobindo incorporates by reference the allegations set forth in Paragraphs 1–16 of the Counterclaims as if fully set forth herein.

18. 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 '730 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.

19. Further, Aurobindo will not infringe, contribute to the infringement of, or induce the infringement of any valid and/or enforceable claim of the '730 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.

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

21. Aurobindo is entitled to a declaration that it does not infringe, directly or indirectly, any valid claim of the '730 patent.

SECOND COUNTERCLAIM
(Declaration of Invalidity of the '730 Patent)

22. Aurobindo incorporates by reference the allegations set forth in Paragraphs 1–21 of the Counterclaims as if fully set forth herein.

23. All claims of the '730 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.

24. For example, as described in the Notice Letter, claims 1-21 of the '730 patent are invalid as obvious under § 103 in light of at least the following prior art: U.S. Patent No. 6,936,612; U.S. Patent No. 7,208,489; U.S. Patent No. 7,456,168; Kale VV, Gadekar S, and Ittadwar AM, *Particle Size Enlargement: Making and Understanding of the Behavior of Powder (Particle) System*, Systemic Reviews in Pharmacy, July-December 2011, Vol. 2, Issue 2, pp. 79-

85; Bauer, *Polymorphism—A Critical Consideration in Pharmaceutical Development, Manufacturing, and Stability*, J. Validation Tech. 15 (2008); Bernstein, J., “Controlling the Polymorphic Form Obtained” in POLYMORPHISM IN MOLECULAR CRYSTALS, Clarendon Press, Oxford (2002); Bernstein, J., Concomitant Polymorphs, 38 ANGEW. CHEM. INT. ED. 3440 (1999); POLYMORPHISM IN PHARMACEUTICAL SOLIDS (ed. Brittain) 1999; Caira, Crystalline Polymorphism of Organic Compounds, DESIGN OF ORGANIC SOLIDS (1998); FDA’s Guidelines for Submitting Supporting Documentation in Drug Applications for the Manufacture of Drug Substance; Guillory, J. Keith, Generation of Polymorphs, Hydrates, Solvates, and Amorphous Solids, Ch. 5 in Polymorphism in Pharmaceutical Solids pp. 183-226 (Brittain, H.G., ed.) (1999); Raw et al., *Regulatory Considerations of Pharmaceutical Solid Polymorphism in Abbreviated New Drug Applications (ANDAS)*, 56 Adv. Drug Deliv. Rev. 397 (2004); Louis J. Ravin & Galen W. Radebaugh, Preformulation, in Remington’s Pharmaceutical Sciences 1473 (Alfonso R. Gennaro et al., eds., 18th ed. 1990); and Wadke, Deodatt A., et al., Preformulation Testing, in 1 Pharmaceutical Dosage Forms: Tablets 1 (Herbert A. Lieberman, Leon Lachman, Joseph B. Schwartz, Eds., 2d. ed. 1989).

25. Aurobindo is entitled to a declaration that the claims of the ’730 patent are invalid.

PRAAYER 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 Aurobindo’s submission of ANDA No. 213086 seeking FDA approval to market palbociclib capsules before the expiry of the ’730 patent has not infringed, and will not infringe, any valid claim of the ’730 patent;
- B. A declaration that the claims of the ’730 patent are invalid;

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 '730 patent;

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 '730 patent against Aurobindo or anyone in privity with Aurobindo; and

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

Dated: December 4, 2020

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