

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

TEVA PHARMACEUTICALS)	
INTERNATIONAL GMBH,)	
CEPHALON, INC., AND EAGLE)	
PHARMACEUTICALS, INC.,)	
)	
Plaintiffs,)	
)	
v.)	
)	
AUROBINDO PHARMA, LTD.,)	C.A. No. 20-632 (CFC)
AUROBINDO PHARMA USA, INC., AND)	
EUGIA PHARMA SPECIALITIES LTD.,)	
)	
Defendants.)	
)	
)	

**AUROBINDO PHARMA, LTD., AUROBINDO PHARMA USA, INC., AND EUGIA
PHARMA SPECIALITIES 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 Teva Pharmaceuticals International GmbH, Cephalon, Inc., and Eagle Pharmaceuticals, Inc. (collectively “Plaintiffs”) as follows:

1. This is an action for patent infringement under the patent laws of the United States, 35 U.S.C., 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, 35 U.S.C., which arises out of Aurobindo Pharma, Ltd., Aurobindo Pharma USA, Inc., and Eugia Pharma Specialities Ltd.’s (collectively, “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 BENDEKA® (bendamustine

hydrochloride) Injection, 100 mg/4 mL (25 mg/mL), prior to the expiration of U.S. Patent Nos. 8,609,707 (the “’707 patent”); 9,265,831 (the “’831 patent”); 9,572,796 (the “’796 patent”); 9,572,797 (the “’797 patent”); 9,034,908 (the “’908 patent”); 9,144,568 (the “’568 patent”); 9,572,887 (the “’887 patent”); 9,597,397 (the “’397 patent”); 9,597,398 (the “’398 patent”); 9,597,399 (the “’399 patent”); 9,000,021 (the “’021 patent”); 9,579,384 (the “’384 patent”); 10,010,533 (the “’533 patent”); and U.S. Patent No. 10,052,385 (the “’385 patent”) (collectively, 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. 214576 to the U.S. Food and Drug Administration (“FDA”) seeking approval to manufacture, use, offer for sale, sell and/or import generic versions of BENDEKA[®] (bendamustine hydrochloride) Injection, 100 mg/4 mL (25 mg/mL), prior to the expiration of U.S. Patent Nos. 8,609,707 (the “’707 patent”); 9,265,831 (the “’831 patent”); 9,572,796 (the “’796 patent”); 9,572,797 (the “’797 patent”); 9,034,908 (the “’908 patent”); 9,144,568 (the “’568 patent”); 9,572,887 (the “’887 patent”); 9,597,397 (the “’397 patent”); 9,597,398 (the “’398 patent”); 9,597,399 (the “’399 patent”); 9,000,021 (the “’021 patent”); 9,579,384 (the “’384 patent”); 10,010,533 (the “’533 patent”); and U.S. Patent No. 10,052,385 (the “’385 patent”) (together, “the Orange Book Patents”). Aurobindo denies that Plaintiffs are entitled to any relief and denies all remaining allegations of Paragraph 1.

PARTIES

2. Plaintiff Teva Pharmaceuticals is a limited liability company organized and existing under the laws of Switzerland, having its corporate offices and principle place of business at Schlüsselstrasse 12, Jona (SG) 8645, Switzerland.

Answer:

On information and belief, Aurobindo admits the allegation.

3. Plaintiff Cephalon is a corporation organized and existing under the laws of Delaware, having its corporate offices and principle place of business at 145 Brandywine Parkway, West Chester, Pennsylvania 19380.

Answer:

On information and belief, Aurobindo admits the allegation.

4. Plaintiff Eagle is a corporation organized and existing under the laws of Delaware, having its corporate offices and principle place of business at 50 Tice Boulevard, Suite 315, Woodcliff Lake, New Jersey 07677.

Answer:

On information and belief, Aurobindo admits the allegation.

5. On information and belief, Defendant Aurobindo Pharma, Ltd. is a company organized and existing under the laws of India having its corporate offices and principle place of business at Maitri Vihar, Plot # 2, Ameerpet, Hyderabad 500038, Telangana, India. On 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 5.

6. On information and belief, Defendant Aurobindo Pharma USA, Inc. is a company organized and existing under the laws of Delaware having its corporate offices and principle place of business at 279 Princeton-Hightstown Road, East Windsor, New Jersey 08520. On information and belief, Aurobindo Pharma USA, Inc. is in the business of, among other things, manufacturing and selling generic versions of pharmaceutical drug products throughout the United States, including Delaware.

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 at 279 Princeton Hightstown Road, East Windsor, New Jersey 08520. Aurobindo denies the remaining allegations of Paragraph 6.

7. On information and belief, Defendant Eugia Pharma Specialities Ltd. is a company organized and existing under the laws of the [sic] India having its principal place of business at Maitri Vihar, Plot #2, Ameerpet, Hyderabad 500038, Telangana, India. On information and belief, Eugia Pharma Specialities Ltd. is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical drugs throughout the United States, including Delaware.

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 7.

8. Upon information and belief, Aurobindo Pharma USA, Inc. is a wholly-owned subsidiary of Aurobindo Pharma, Ltd., and the U.S. agent for Eugia Pharma Specialities Ltd. On information and belief, Eugia Pharma Specialities Ltd. is a subsidiary of Aurobindo Pharma, Ltd.

Answer:

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

9. On information and belief, Aurobindo Pharma, Ltd. acts in concert with its subsidiaries, including Aurobindo Pharma USA, Inc. and Eugia Pharma Specialities Ltd., to prepare and file ANDAs and similar regulatory submissions. Thus, Aurobindo Pharma, Ltd.’s website states: “The formulation business is systematically organized with a divisional structure, and has a focused team for key international markets. . . . Aurobindo’s 11 units for APIs / intermediates and 15 unites (10 in India, 3 in USA, 1 in Brazil and 1 in Portugal) for formulations are designed to meet the requirements of both advanced as well as emerging market opportunities.” *At a Glance*, Aurobindo Pharma, Ltd., <https://www.aurobindo.com/about-us/at-a-glance/business-overview/> (last accessed May 11, 2020). In addition, Aurobindo’s website states: “Aurobindo exports to over 150 countries across the globe with around 90% of revenues derived from international operations. Our customers include premium multi-national companies. With multiple facilities approved by leading regulatory agencies such as USFDA . . . Aurobindo makes use of

in-house R&D for rapid filing of patents, Drug Master Files (DMFs), Abbreviated New Drug Applications (ANDAs) and formulation dossiers across the world.” *Id.*

Answer:

Aurobindo admits that its website states: “The formulation business is systematically organized with a divisional structure, and has a focused team for key international markets. Leveraging its large manufacturing infrastructure for APIs and formulations, wide and diversified basket of products and confidence in its customers, Aurobindo achieved revenue of USD 2.6 billion in FY2017-18. Aurobindo’s 11 units for APIs / intermediates and 15 unites (10 in India, 3 in USA, 1 in Brazil and 1 in Portugal) for formulations are designed to meet the requirements of both advanced as well as emerging market opportunities.” Aurobindo also admits that its website states: “Aurobindo exports to over 150 countries across the globe with around 90% of revenues derived from international operations. Our customers include premium multi-national companies. With multiple facilities approved by leading regulatory agencies such as USFDA, EU GMP, UK MHRA, South Africa-MCC, Health Canada WHO and Brazil ANVISA, Aurobindo makes use of in-house R&D for rapid filing of patents, Drug Master Files (DMFs), Abbreviated New Drug Applications (ANDAs) and formulation dossiers across the world.” Aurobindo denies the remaining allegations of Paragraph 9.

10. On information and belief, Aurobindo Pharma, Ltd., Aurobindo Pharma USA, Inc., and Eugia Pharma Specialities Ltd. acted in concert to prepare and submit Aurobindo’s ANDA to the FDA.

Answer:

Denied.

11. On information and belief, Aurobindo Pharma, Ltd. actively encouraged Aurobindo Pharma USA, Inc. and Eugia Pharma Specialities Ltd. to prepare and submit Aurobindo's ANDA to the FDA and knew that the filing of Aurobindo's ANDA would infringe the Patents-in-Suit, including because Aurobindo Pharma, Ltd. knew that Aurobindo's ANDA would include a Paragraph IV Certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the Patents-in-Suit.

Answer:

Denied.

12. On information and belief, Aurobindo Pharma, Ltd., Aurobindo Pharma USA, Inc., and Eugia Pharma Specialities Ltd. know and intend that upon approval of Aurobindo's ANDA, Aurobindo Pharma, Ltd. and Eugia Pharma Specialities Ltd. will directly or indirectly market, sell, and distribute Aurobindo's ANDA Product throughout the United States, including in Delaware. On information and belief, Aurobindo Pharma, Ltd., Aurobindo Pharma USA, Inc., and Eugia Pharma Specialities Ltd. 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. On information and belief, Aurobindo Pharma, Ltd., Aurobindo Pharma USA, Inc., and Eugia Pharma Specialities Ltd. participated in, assisted, and cooperated with Aurobindo Pharma USA, Inc. in the acts complained about herein.

Answer:

Paragraph 12 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 12.

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

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.

JURISDICTION AND VENUE

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

Answer:

Paragraph 14 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.

15. Based on the facts and causes alleged herein, and for additional reasons to be further developed through discovery if necessary, this Court has personal Jurisdiction over Aurobindo Pharma, Ltd., Aurobindo Pharma USA, Inc., and Eugia Pharma Specialities Ltd.

Answer:

Paragraph 15 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 15.

16. This Court has personal jurisdiction over Aurobindo Pharma, Ltd. because, among other things, Aurobindo Pharma, Ltd., itself and through its subsidiaries Aurobindo Pharma USA,

Inc. and Eugia Pharma Specialities 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. On information and belief, Aurobindo Pharma, Ltd., itself and through its wholly-owned subsidiaries Aurobindo Pharma USA, Inc. and Eugia Pharma Specialities Ltd., develops, manufactures, imports, markets, offers to sell, and/or sells generic drugs throughout the United States, including in Delaware, and therefore transacts business within Delaware, and/or has engaged in systematic and continuous business contacts within Delaware.

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. In addition, on information and belief, this Court has personal jurisdiction over Aurobindo Pharma, Ltd. because Aurobindo Pharma, Ltd. has named Aurobindo Pharma USA, Inc., a Delaware Company, as its U.S. agent for the purpose of its FDA submissions. By naming Aurobindo Pharma USA, Inc. as its U.S. agent, Aurobindo Pharma, Ltd. has authorized Aurobindo Pharma USA, Inc. to accept service of process on behalf of Aurobindo Pharma, Ltd. in connection with patent infringement lawsuits relating to its FDA submissions. 21 C.F.R. §§ 207.69(b)(4), 314.95(c)(9). Thus, it would not be fundamentally unreasonable or unfair for Aurobindo Pharma, Ltd. to litigate this action in this District

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. In addition, this Court has personal jurisdiction over Aurobindo Pharma, Ltd. because, on information and belief, Aurobindo Pharma, Ltd. controls Aurobindo Pharma USA, Inc. and Eugia Pharma Specialities Ltd., and therefore Aurobindo Pharma USA, Inc.'s and Eugia Pharma Specialities Ltd.'s activities in Delaware are attributable to Aurobindo Pharma, Ltd.

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. This Court has personal jurisdiction over Aurobindo Pharma USA, Inc. 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 Delaware, is qualified to do business in Delaware, and has appointed a registered agent for service of process in Delaware. Therefore, Aurobindo Pharma USA, Inc. has consented to general jurisdiction in Delaware. In addition, on information and belief, Aurobindo Pharma USA, Inc. develops, manufactures, imports, markets, offers to sell, sells, and/or imports generic drugs throughout the United States, including in Delaware, and therefore transacts business within Delaware relating to Plaintiffs' claims, and/or has engaged in systematic and continuous business contacts within 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. This Court has personal jurisdiction over Eugia Pharma Specialities Ltd. because, among other things, Eugia Pharma Specialities Ltd., itself and through its U.S. agent Aurobindo Pharma USA, Inc., has purposefully availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court here. On information and belief, Eugia Pharma Specialities Ltd., itself and through its U.S. agent Aurobindo Pharma USA, Inc., develops, manufactures, imports, markets, offers to sell, sells, and/or imports generic drugs throughout the United States, including in Delaware, and therefore transacts business within Delaware relating to Plaintiffs' claims, and/or has engaged in systematic and continuous business contacts within Delaware.

Answer:

Paragraph 20 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 20.

21. In addition, this Court also has personal jurisdiction over Aurobindo Pharma, Ltd., Aurobindo Pharma USA, Inc., and Eugia Pharma Specialities Ltd. because, among other things, on information and belief: (1) Aurobindo Pharma USA, Inc. and Eugia Pharma Specialities Ltd. filed Aurobindo's ANDA for the purpose of seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Aurobindo's ANDA Product in the United States, including in Delaware; and (2) upon approval of Aurobindo's ANDA, Aurobindo Pharma, Ltd., Aurobindo Pharma USA, Inc., and Eugia Pharma Specialities Ltd. will market, distribute, offer for sale, sell, and/or import Aurobindo's ANDA Product in the United States, including in Delaware, and will derive substantial revenue from the use or consumption of Aurobindo's ANDA Product in Delaware. *See Acorda Therapeutics Inc. v. Mylan Pharm. Inc.*,

817 F.3d 755, 763 (Fed. Cir. 2016). On information and belief, upon approval of Aurobindo's ANDA, Aurobindo's ANDA Product will, among other things, be marketed, distributed, offered for sale, sold, and/or imported in Delaware; prescribed by physicians practicing in Delaware; dispensed by pharmacies located within Delaware; and/or used by patients in Delaware, all of which would have a substantial effect on Delaware.

Answer:

Paragraph 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 the remaining allegations of Paragraph 21.

22. In addition, this Court has personal jurisdiction over Aurobindo Pharma, Ltd., Aurobindo USA, Inc., and Eugia Pharma Specialities Ltd. because they have committed, aided, abetted, induced, contributed to, or participated in the commission of the tortious act of patent infringement that has led and/or will lead to foreseeable harm and injury to Cephalon and Eagle, both Delaware corporations.

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 the remaining allegations of Paragraph 22.

23. In addition, this Court has personal jurisdiction over Aurobindo Pharma, Ltd., Aurobindo USA, Inc., and Eugia Pharma Specialities Ltd. because they regularly engage in patent litigation concerning Aurobindo's ANDA Products in this District, do not contest personal

jurisdiction in this District, and have purposefully availed themselves of the rights and benefits of this Court by asserting claims and/or counterclaims in this District.¹

Answer:

Paragraph 23 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 23.

24. For the above reasons, it would not be unfair or unreasonable for Aurobindo Pharma, Ltd., Aurobindo Pharma USA, Inc., and Eugia Pharma Specialities Ltd. to litigate this action in this District, and the Court has personal jurisdiction over them here.

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 personal jurisdiction solely for the limited purposes of this particular action. Aurobindo denies the remaining allegations of Paragraph 24.

VENUE

25. Plaintiffs incorporate each of the proceeding paragraphs 1–20 as if fully set forth herein.

Answer:

¹ See, e.g., *Pfizer Inc. v. Aziant Drug Research Sols. Pvt. Ltd.*, C.A. No. 19-743-CFC (D. Del. Apr. 7, 2020), D.I. 110, at 53-62 (All Defendants); *Taiho Pharm. Co. v. Eugia Pharma Specialities Ltd.*, C.A. No. 19-2309-CFC (D. Del. Mar. 23, 2020), D.I. 15, at 47-54 (Aurobindo Pharma USA, Inc. and Eugia Pharma Specialities Ltd.); *Millennium Pharm. v. Aurobindo Pharma USA, Inc.*, C.A. No. 19-471-CFC (D. Del. Dec. 26, 2019), D.I. 36, at 26-34 (All Defendants); *Pfizer Inc. v. Aurobindo Pharma, Ltd.*, C.A. No. 19-748-CFC (D. Del. July 8, 2019), D.I. 11, at 51-60 (All Defendants).

Aurobindo incorporates by reference its responses to paragraphs 1–20 as if fully set forth herein.

26. Venue is proper in this District under 28 U.S.C. §§ 1391 and 1400(b) with respect to Aurobindo Pharma, Ltd., at least because, on information and belief, Aurobindo Pharma, Ltd. is a foreign corporation that may be sued in any judicial district in which it is subject to the Court’s personal jurisdiction.

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 under 28 U.S.C. § 1400(b) with respect to Aurobindo Pharma USA, Inc., at least because, on information and belief, Aurobindo Pharma USA, Inc. is a corporation organized and existing under the laws of Delaware and is subject to personal jurisdiction in this 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.

28. Venue is proper in this District under 28 U.S.C. §§ 1391 and 1400(b) with respect to Eugia Pharma Specialities Ltd., at least because, on information and belief, Eugia Pharma Specialities Ltd. is a foreign corporation that may be sued in any judicial district in which it is subject to the Court’s personal jurisdiction.

Answer:

Paragraph 28 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.

BACKGROUND

29. Bendeka®, which contains bendamustine hydrochloride, is an alkylating drug that is indicated for the treatment of patients with (1) chronic lymphocytic leukemia and (2) indolent B-cell non-Hodgkin lymphoma that has progressed during or within six months of treatment with rituximab or a rituximab-containing regimen.

Answer:

On information and belief, Aurobindo admits that Bendeka® contains bendamustine hydrochloride. On information and belief, Aurobindo admits that the prescribing information for Bendeka® provides that it is “an alkylating drug indicated for treatment of patients with: Chronic lymphocytic leukemia (CLL)” and “Indolent C-cell non-Hodgkin’s lymphoma (NHL) that has progressed during or within six months of treatment with rituximab or rituximab-containing regimen.” Aurobindo denies all remaining allegations of paragraph 29.

30. Eagle is the holder of NDA No. 208194 for Bendeka®, which has been approved by the FDA.

Answer:

On information and belief, Aurobindo admits that Eagle is the holder of NDA 208194 for Bendeka®.

31. The ’707 patent, entitled “Formulations of Bendamustine” (Exhibit A), was duly and legally issued on December 17, 2013. Eagle Pharmaceuticals, Inc. is the owner and assignee

of the '707 patent, subject to the exclusive license referenced herein. The '707 patent has been listed in connection with Bendeka® in the Orange Book.

Answer:

Aurobindo admits that the '707 patent on is entitled "Formulations of Bendamustine" and states on its face that it was issued on December 17, 2013, but denies that it is valid and enforceable. On information and belief, Aurobindo also admits that Eagle Pharmaceuticals, Inc. is the owner and assignee of the '707 patent. Aurobindo admits that the '707 patent is listed in connection with Bendeka® in the Orange book, but denies the listing is appropriate. Aurobindo denies any other remaining allegations of paragraph 31.

32. The '831 patent, entitled "Formulations of Bendamustine" (Exhibit B), was duly and legally issued on February 23, 2016. Eagle Pharmaceuticals, Inc. is the owner and assignee of the '831 patent, subject to the exclusive license referenced herein. The '831 patent has been listed in connection with Bendeka® in the Orange Book.

Answer:

Aurobindo admits that the '831 patent on is entitled "Formulations of Bendamustine" and states on its face that it was issued on February 23, 2016, but denies that it is valid and enforceable. On information and belief, Aurobindo also admits that Eagle Pharmaceuticals, Inc. is the owner and assignee of the '831 patent. Aurobindo admits that the '831 patent is listed in connection with Bendeka® in the Orange book, but denies the listing is appropriate. Aurobindo denies any other remaining allegations of paragraph 32.

33. The '796 patent, entitled "Formulations of Bendamustine" (Exhibit C), was duly and legally issued on February 21, 2017. Eagle Pharmaceuticals, Inc. is the owner and assignee of

the '796 patent, subject to the exclusive license referenced herein. The '796 patent has been listed in connection with Bendeka® in the Orange Book.

Answer:

Aurobindo admits that the '796 patent on is entitled "Formulations of Bendamustine" and states on its face that it was issued on February 21, 2017, but denies that it is valid and enforceable. On information and belief, Aurobindo also admits that Eagle Pharmaceuticals, Inc. is the owner and assignee of the '796 patent. Aurobindo admits that the '796 patent is listed in connection with Bendeka® in the Orange book, but denies the listing is appropriate. Aurobindo denies any other remaining allegations of paragraph 33.

34. The '797 patent, entitled "Formulations of Bendamustine" (Exhibit D), was duly and legally issued on February 21, 2017. Eagle Pharmaceuticals, Inc. is the owner and assignee of the '797 patent, subject to the exclusive license referenced herein. The '797 patent has been listed in connection with Bendeka® in the Orange Book.

Answer:

Aurobindo admits that the '797 patent on is entitled "Formulations of Bendamustine" and states on its face that it was issued on February 21, 2017, but denies that it is valid and enforceable. On information and belief, Aurobindo also admits that Eagle Pharmaceuticals, Inc. is the owner and assignee of the '797 patent. Aurobindo admits that the '797 patent is listed in connection with Bendeka® in the Orange book, but denies the listing is appropriate. Aurobindo denies any other remaining allegations of paragraph 34.

35. The '908 patent, entitled "Formulations of Bendamustine" (Exhibit E), was duly and legally issued on May 19, 2015. Eagle Pharmaceuticals, Inc. is the owner and assignee of the

'908 patent, subject to the exclusive license referenced herein. The '908 patent has been listed in connection with Bendeka® in the Orange Book.

Answer:

Aurobindo admits that the '908 patent is entitled "Formulations of Bendamustine" and states on its face that it was issued on May 19, 2015, but denies that it is valid and enforceable. On information and belief, Aurobindo also admits that Eagle Pharmaceuticals, Inc. is the owner and assignee of the '908 patent. Aurobindo admits that the '908 patent is listed in connection with Bendeka® in the Orange Book, but denies the listing is appropriate. Aurobindo denies any other remaining allegations of paragraph 35.

36. The '568 patent, entitled "Formulations of Bendamustine" (Exhibit F), was duly and legally issued on September 29, 2015. Eagle Pharmaceuticals, Inc. is the owner and assignee of the '568 patent, subject to the exclusive license referenced herein. The '568 patent has been listed in connection with Bendeka® in the Orange Book.

Answer:

Aurobindo admits that the '568 patent is entitled "Formulations of Bendamustine" and states on its face that it was issued on September 29, 2015, but denies that it is valid and enforceable. On information and belief, Aurobindo also admits that Eagle Pharmaceuticals, Inc. is the owner and assignee of the '568 patent. Aurobindo admits that the '568 patent is listed in connection with Bendeka® in the Orange Book, but denies the listing is appropriate. Aurobindo denies any other remaining allegations of paragraph 36.

37. The '887 patent, entitled "Formulations of Bendamustine" (Exhibit G), was duly and legally issued on February 21, 2017. Eagle Pharmaceuticals, Inc. is the owner and assignee of

the '887 patent, subject to the exclusive license referenced herein. The '887 patent has been listed in connection with Bendeka® in the Orange Book.

Answer:

Aurobindo admits that the '887 patent is entitled "Formulations of Bendamustine" and states on its face that it was issued on February 21, 2017, but denies that it is valid and enforceable. On information and belief, Aurobindo also admits that Eagle Pharmaceuticals, Inc. is the owner and assignee of the '887 patent. Aurobindo admits that the '887 patent is listed in connection with Bendeka® in the Orange Book, but denies the listing is appropriate. Aurobindo denies any other remaining allegations of paragraph 37.

38. The '397 patent, entitled "Formulations of Bendamustine" (Exhibit H), was duly and legally issued on March 21, 2017. Eagle Pharmaceuticals, Inc. is the owner and assignee of the '397 patent, subject to the exclusive license referenced herein. The '397 patent has been listed in connection with Bendeka® in the Orange Book.

Answer:

Aurobindo admits that the '397 patent is entitled "Formulations of Bendamustine" and states on its face that it was issued on March 21, 2017, but denies that it is valid and enforceable. On information and belief, Aurobindo also admits that Eagle Pharmaceuticals, Inc. is the owner and assignee of the '397 patent. Aurobindo admits that the '397 patent is listed in connection with Bendeka® in the Orange Book, but denies the listing is appropriate. Aurobindo denies any other remaining allegations of paragraph 38.

39. The '398 patent, entitled "Formulations of Bendamustine" (Exhibit I), was duly and legally issued on March 21, 2017. Eagle Pharmaceuticals, Inc. is the owner and assignee of the

'398 patent, subject to the exclusive license referenced herein. The '398 patent has been listed in connection with Bendeka® in the Orange Book.

Answer:

Aurobindo admits that the '398 patent is entitled "Formulations of Bendamustine" and states on its face that it was issued on March 21, 2017, but denies that it is valid and enforceable. On information and belief, Aurobindo also admits that Eagle Pharmaceuticals, Inc. is the owner and assignee of the '398 patent. Aurobindo admits that the '398 patent is listed in connection with Bendeka® in the Orange Book, but denies the listing is appropriate. Aurobindo denies any other remaining allegations of paragraph 39.

40. The '399 patent, entitled "Formulations of Bendamustine" (Exhibit J), was duly and legally issued on March 21, 2017. Eagle Pharmaceuticals, Inc. is the owner and assignee of the '399 patent, subject to the exclusive license referenced herein. The '399 patent has been listed in connection with Bendeka® in the Orange Book.

Answer:

Aurobindo admits that the '399 patent is entitled "Formulations of Bendamustine" and states on its face that it was issued on March 21, 2017, but denies that it is valid and enforceable. On information and belief, Aurobindo also admits that Eagle Pharmaceuticals, Inc. is the owner and assignee of the '399 patent. Aurobindo admits that the '399 patent is listed in connection with Bendeka® in the Orange Book, but denies the listing is appropriate. Aurobindo denies any other remaining allegations of paragraph 40.

41. The '021 patent, entitled "Method of Treating Bendamustine-Responsive Conditions in Patients Requiring Reduced Volumes for Administration" (Exhibit K), was duly and legally issued on April 7, 2015. Eagle Pharmaceuticals, Inc. is the owner and assignee of the '021

patent, subject to the exclusive license referenced herein. The '021 patent has been listed in connection with Bendeka® in the Orange Book.

Answer:

Aurobindo admits that the '021 patent on is entitled “Method of Treating Bendamustine-Responsive Conditions in Patients Requiring Reduced Volumes for Administration” and states on its face that it was issued on April 7, 2015, but denies that it is valid and enforceable. On information and belief, Aurobindo also admits that Eagle Pharmaceuticals, Inc. is the owner and assignee of the '021 patent. Aurobindo admits that the '021 patent is listed in connection with Bendeka® in the Orange book, but denies the listing is appropriate. Aurobindo denies any other remaining allegations of paragraph 41.

42. The '384 patent, entitled “Method of Treating Bendamustine-Responsive Conditions in Patients Requiring Reduced Volumes for Administration” (Exhibit L), was duly and legally issued on February 28, 2017. Eagle Pharmaceuticals, Inc. is the owner and assignee of the '384 patent, subject to the exclusive license referenced herein. The '384 patent has been listed in connection with Bendeka® in the Orange Book.

Answer:

Aurobindo admits that the '384 patent is entitled “Method of Treating Bendamustine-Responsive Conditions in Patients Requiring Reduced Volumes for Administration” and states on its face that it was issued on February 28, 2017, but denies that it is valid and enforceable. On information and belief, Aurobindo also admits that Eagle Pharmaceuticals, Inc. is the owner and assignee of the '384 patent. Aurobindo admits that the '384 patent is listed in connection with Bendeka® in the Orange Book, but denies the listing is appropriate. Aurobindo denies any other remaining allegations of paragraph 42.

43. The '533 patent, entitled "Formulations of Bendamustine" (Exhibit M), was duly and legally issued on July 3, 2018. Eagle Pharmaceuticals, Inc. is the owner and assignee of the '533 patent, subject to the exclusive license referenced herein. The '533 patent has been listed in connection with Bendeka® in the Orange Book.

Answer:

Aurobindo admits that the '533 patent is entitled "Formulations of Bendamustine" and states on its face that it was issued on July 3, 2018, but denies that it is valid and enforceable. On information and belief, Aurobindo also admits that Eagle Pharmaceuticals, Inc. is the owner and assignee of the '533 patent. Aurobindo admits that the '533 patent is listed in connection with Bendeka® in the Orange Book, but denies the listing is appropriate. Aurobindo denies any other remaining allegations of paragraph 43.

44. The '385 patent, entitled "Formulations of Bendamustine" (Exhibit N), was duly and legally issued on August 21, 2018. Eagle Pharmaceuticals, Inc. is the owner and assignee of the '385 patent, subject to the exclusive license referenced herein. The '385 patent has been listed in connection with Bendeka® in the Orange Book.

Answer:

Aurobindo admits that the '385 patent is entitled "Formulations of Bendamustine" and states on its face that it was issued on August 21, 2018, but denies that it is valid and enforceable. On information and belief, Aurobindo also admits that Eagle Pharmaceuticals, Inc. is the owner and assignee of the '385 patent. Aurobindo admits that the '385 patent is listed in connection with Bendeka® in the Orange Book, but denies the listing is appropriate. Aurobindo denies any other remaining allegations of paragraph 44.

45. On or around February 13, 2015, Cephalon executed an exclusive license (the “Eagle License”) to, among other things, the ’707 patent, U.S. Patent Application No. 14/031,879 (which later issued as the ’831 patent); U.S. Patent Application No. 13/838,090 (which later issued as the ’908 patent), U.S. Patent Application No. 13/838,267 (which later issued as the ’021 patent), and all patent rights claiming priority to those patents or patent applications (which include the ’796, ’797, ’568, ’887, ’397, ’398, ’399, ’384, ’533, and ’385 patents), for the commercialization of Eagle’s bendamustine hydrochloride rapid infusion product, EP-3102, which became Bendeka®. The Eagle License provides Cephalon the right to sue for infringement of the licensed patents in the event of, among other things, the filing of an ANDA that makes reference to Bendeka® and seeks approval before expiry of a licensed patent.

Answer:

Aurobindo is without knowledge or information sufficient to form a belief as to the truth of the allegations asserted in paragraph 45 and therefore denies the same.

46. On or around October 14, 2015, Cephalon assigned its rights in the Eagle License to Teva Pharmaceuticals.

Answer:

Aurobindo is without knowledge or information sufficient to form a belief as to the truth of the allegations asserted in paragraph 46 and therefore denies the same.

INFRINGEMENT BY AUROBINDO

47. By letter sent on or around April 6, 2020 (“Aurobindo’s Notice Letter”), Aurobindo Pharma USA, Inc., as U.S. agent for Eugia Pharma Specialities Ltd., notified Teva that it had filed a Paragraph IV Certification with respect to the Patents-in-Suit and was seeking approval from the FDA 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 Patents-in-Suit. On information and belief, Aurobindo's ANDA contains a Paragraph IV Certification asserting that Patents-in-Suit will not be infringed by the manufacture, use, offer for sale, sale, or importation of Aurobindo's ANDA Product, or alternatively, that the Patents-in-Suit are invalid.

Answer:

Aurobindo admits that Aurobindo sent a notice letter dated April 6, 2020 to Teva, Cephalon, and Eagle (the "Notice Letter") pursuant to the Federal Food, Drug, and Cosmetic Act ("FDCA") that Aurobindo had submitted ANDA No. 214576, seeking approval from the FDA to engage in the commercial manufacture, use, and/or sale of a generic Bendamustine Hydrochloride Injection, 25 mg/mL ("Aurobindo's ANDA Product"). Aurobindo denies the remaining allegations of paragraph 47.

48. The purpose of Aurobindo's submission of Aurobindo's ANDA was to obtain approval under the Federal Food, Drug and Cosmetic Act 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 Patents-in-Suit.

Answer:

Aurobindo admits that it submitted ANDA No. 214576 with certifications of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA to obtain approval to engage in the manufacture, use, or sale of Aurobindo's ANDA Product prior to the expiration of the Orange Book Patents. Aurobindo denies any remaining allegations of paragraph 48.

49. In Aurobindo's Notice Letter, Aurobindo stated that the active ingredient of Aurobindo's ANDA Product is bendamustine hydrochloride.

Answer:

Aurobindo admits that it stated in its Notice Letter that bendamustine hydrochloride is the active ingredient in Aurobindo's ANDA Product.

50. In Aurobindo's Notice Letter, Aurobindo stated that the proposed dosage strength of Aurobindo's ANDA Product is 25 mg/mL.

Answer:

Aurobindo admits that it stated in its Notice Letter that 25 mg/mL is the proposed dosage strength of Aurobindo's ANDA Product.

51. On information and belief, Aurobindo's ANDA Product contains propylene glycol, polyethylene glycol, and monothioglycerol in the same or equivalent amounts as Bendeka®.

Answer:

Aurobindo admits that its ANDA Product contains polyethylene glycol, propylene glycol, and monothioglycerol. Aurobindo denies any remaining allegations of paragraph 51.

52. On information and belief, the proposed labeling for Aurobindo's ANDA Product recommends, instructs, and/or promotes administration to patients with chronic lymphocytic leukemia.

Answer:

Denied.

53. On information and belief, the proposed labeling for Aurobindo's ANDA Product recommends, instructs, and/or promotes administration to patients with indolent B-cell non-Hodgkin lymphoma.

Answer:

Denied.

54. On information and belief, the proposed labeling for Aurobindo's ANDA Product recommends, instructs, and/or promotes the administration of Aurobindo's ANDA Product in a volume of about 50 mL or less over a time period of about 10-minutes or less.

Answer:

Denied.

55. In an exchange of correspondence, counsel for Teva and counsel for Aurobindo discussed the terms of Teva's Request for Confidential Access. The parties did not agree on terms under which Teva could review, among other things, Aurobindo's ANDA and certain portions of the Drug Master File referred to therein, and Aurobindo refused to produce other internal documents and materials relevant to infringement.

Answer:

Aurobindo admits that it made an Offer of Confidential Access, and included reasonable and standard terms to produce the relevant portions of the ANDA, but that Plaintiffs refused to negotiate the terms and requested additional materials, such as samples. Aurobindo denies all remaining allegations of paragraph 55.

56. This action is being commenced before the expiration of forty-five days from the date of the receipt of Aurobindo's Notice Letter.

Answer:

Aurobindo admits that this action is being commenced before the expiration of forty-five days following the date of receipt of the Notice Letter.

**COUNT I – INFRINGEMENT BY AUROBINDO
OF U.S. PATENT NO. 8,609,707 UNDER 35 U.S.C. § 271(e)(2)**

57. Plaintiffs incorporate each of the preceding paragraphs 1–52 [sic] as if fully set forth herein.

Answer:

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

58. 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 prior to the expiration of the ’707 patent was an act of infringement of the ’707 patent under 35 U.S.C. § 271(e)(2)(A).

Answer:

Denied.

59. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Aurobindo’s ANDA Product would infringe one or more claims of the ’707 patent, either literally or under the doctrine of equivalents.

Answer:

Denied.

60. 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 FDA approval of Aurobindo’s ANDA.

Answer:

Aurobindo denies the allegations of paragraph 60, as no final decision has been made at this time.

61. On information and belief, the use of Aurobindo's ANDA Product in accordance with and as directed by Aurobindo's proposed labeling for that product would infringe one or more claims of the '707 patent.

Answer:

Denied.

62. On information and belief, Aurobindo plans and intends to, and will, actively induce infringement of the '707 patent when Aurobindo's ANDA is approved, and plans and intends to, and will, do so after approval.

Answer:

Denied.

63. On information and belief, Aurobindo knows that its ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '707 patent and that its ANDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Aurobindo plans and intends to, and will, contribute to infringement of the '707 patent after approval of Aurobindo's ANDA.

Answer:

Denied.

64. The foregoing actions by Aurobindo constitute and/or will constitute infringement of the '707 patent, active inducement of infringement of the '707 patent, and contribution to the infringement by others of the '707 patent.

Answer:

Denied.

65. On information and belief, Aurobindo has acted with full knowledge of the '707 patent and without a reasonable basis for believing that it would not be liable for infringing the '707 patent, actively inducing infringement of the '707 patent, and contributing to the infringement by others of the '707 patent.

Answer:

Denied.

66. Unless Aurobindo is enjoined from infringing the '707 patent, actively inducing infringement of the '707 patent, and contributing to the infringement by others of the '707 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

Answer:

Denied.

**COUNT II – INFRINGEMENT BY AUROBINDO
OF U.S. PATENT NO. 9,265,831 UNDER 35 U.S.C. § 271(e)(2)**

67. Plaintiffs incorporate each of the preceding paragraphs 1–62 [sic] as if fully set forth herein.

Answer:

Aurobindo incorporates by reference its responses to paragraphs 1–66 as if fully set forth herein.

68. 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 prior to the expiration of the '831 patent was an act of infringement of the '831 patent under 35 U.S.C. § 271(e)(2)(A).

Answer:

Denied.

69. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Aurobindo's ANDA Product would infringe one or more claims of the '831 patent, either literally or under the doctrine of equivalents.

Answer:

Denied.

70. 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 FDA approval of Aurobindo's ANDA.

Answer:

Aurobindo denies the allegations of paragraph 70, as no final decision has been made at this time.

71. On information and belief, the use of Aurobindo's ANDA Product in accordance with and as directed by Aurobindo's proposed labeling for that product would infringe one or more claims of the '831 patent.

Answer:

Denied.

72. On information and belief, Aurobindo plans and intends to, and will, actively induce infringement of the '831 patent when Aurobindo's ANDA is approved, and plans and intends to, and will, do so after approval.

Answer:

Denied.

73. On information and belief, Aurobindo knows that its ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '831 patent and that its

ANDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Aurobindo plans and intends to, and will, contribute to infringement of the '831 patent after approval of Aurobindo's ANDA.

Answer:

Denied.

74. The foregoing actions by Aurobindo constitute and/or will constitute infringement of the '831 patent, active inducement of infringement of the '831 patent, and contribution to the infringement by others of the '831 patent.

Answer:

Denied.

75. On information and belief, Aurobindo has acted with full knowledge of the '831 patent and without a reasonable basis for believing that it would not be liable for infringing the '831 patent, actively inducing infringement of the '831 patent, and contributing to the infringement by others of the '831 patent.

Answer:

Denied.

76. Unless Aurobindo is enjoined from infringing the '831 patent, actively inducing infringement of the '831 patent, and contributing to the infringement by others of the '831 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

Answer:

Denied.

**COUNT III – INFRINGEMENT BY AUROBINDO
OF U.S. PATENT NO. 9,572,796 UNDER 35 U.S.C. § 271(e)(2)**

77. Plaintiffs incorporate each of the preceding paragraphs 1–72 [sic] as if fully set forth herein.

Answer:

Aurobindo incorporates by reference its responses to paragraphs 1–76 as if fully set forth herein.

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 prior to the expiration of the ’796 patent was an act of infringement of the ’796 patent under 35 U.S.C. § 271(e)(2)(A).

Answer:

Denied.

79. In its Notice Letter, Aurobindo did not contest that at least some claims of the ’796 patent, including claim 1, cover Aurobindo’s ANDA Product.

Answer:

Aurobindo admits that in its notice letter it discussed that no valid claim of the ’796 patent covers Aurobindo’s ANDA Product. Aurobindo denies any remaining allegations of paragraph 79.

80. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Aurobindo’s ANDA Product would infringe one or more claims of the ’796 patent, either literally or under the doctrine of equivalents.

Answer:

Denied.

81. 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 FDA approval of Aurobindo's ANDA.

Answer:

Aurobindo denies the allegations of paragraph 81, as no final decision has been made at this time.

82. On information and belief, the use of Aurobindo's ANDA Product in accordance with and as directed by Aurobindo's proposed labeling for that product would infringe one or more claims of the '796 patent.

Answer:

Denied.

83. On information and belief, Aurobindo plans and intends to, and will, actively induce infringement of the '796 patent when Aurobindo's ANDA is approved, and plans and intends to, and will, do so after approval.

Answer:

Denied.

84. On information and belief, Aurobindo knows that its ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '796 patent and that its ANDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Aurobindo plans and intends to, and will, contribute to infringement of the '796 patent after approval of Aurobindo's ANDA.

Answer:

Denied.

85. The foregoing actions by Aurobindo constitute and/or will constitute infringement of the '796 patent, active inducement of infringement of the '796 patent, and contribution to the infringement by others of the '796 patent.

Answer:

Denied.

86. On information and belief, Aurobindo has acted with full knowledge of the '796 patent and without a reasonable basis for believing that it would not be liable for infringing the '796 patent, actively inducing infringement of the '796 patent, and contributing to the infringement by others of the '796 patent.

Answer:

Denied.

87. Unless Aurobindo is enjoined from infringing the '796 patent, actively inducing infringement of the '796 patent, and contributing to the infringement by others of the '796 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

Answer:

Denied.

**COUNT IV – INFRINGEMENT BY AUROBINDO
OF U.S. PATENT NO. 9,572,797 UNDER 35 U.S.C. § 271(e)(2)**

88. Plaintiffs incorporate each of the preceding paragraphs 1–83 [sic] as if fully set forth herein.

Answer:

Aurobindo incorporates by reference its responses to Paragraphs 1–87 as if fully set forth herein.

89. 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 prior to the expiration of the '797 patent was an act of infringement of the '797 patent under 35 U.S.C. § 271(e)(2)(A).

Answer:

Denied.

90. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Aurobindo's ANDA Product would infringe one or more claims of the '797 patent, either literally or under the doctrine of equivalents.

Answer:

Denied.

91. 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 FDA approval of Aurobindo's ANDA.

Answer:

Aurobindo denies the allegations of paragraph 91, as no final decision has been made at this time.

92. On information and belief, the use of Aurobindo's ANDA Product in accordance with and as directed by Aurobindo's proposed labeling for that product would infringe one or more claims of the '797 patent.

Answer:

Denied.

93. On information and belief, Aurobindo plans and intends to, and will, actively induce infringement of the '797 patent when Aurobindo's ANDA is approved, and plans and intends to, and will, do so after approval.

Answer:

Denied.

94. On information and belief, Aurobindo knows that its ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '797 patent and that its ANDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Aurobindo plans and intends to, and will, contribute to infringement of the '797 patent after approval of Aurobindo's ANDA.

Answer:

Denied.

95. The foregoing actions by Aurobindo constitute and/or will constitute infringement of the '797 patent, active inducement of infringement of the '797 patent, and contribution to the infringement by others of the '797 patent.

Answer:

Denied.

96. On information and belief, Aurobindo has acted with full knowledge of the '797 patent and without a reasonable basis for believing that it would not be liable for infringing the '797 patent, actively inducing infringement of the '797 patent, and contributing to the infringement by others of the '797 patent.

Answer:

Denied.

97. Unless Aurobindo is enjoined from infringing the '797 patent, actively inducing infringement of the '797 patent, and contributing to the infringement by others of the '797 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

Answer:

Denied.

**COUNT V – INFRINGEMENT BY AUROBINDO
OF U.S. PATENT NO. 9,034,908 UNDER 35 U.S.C. § 271(e)(2)**

98. Plaintiffs incorporate each of the preceding paragraphs 1–93 [sic] as if fully set forth herein.

Answer:

Aurobindo incorporates its responses to Paragraphs 1–97 as if fully set forth herein.

99. 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 prior to the expiration of the '908 patent was an act of infringement of the '908 patent under 35 U.S.C. § 271(e)(2)(A).

Answer:

Denied.

100. In its Notice Letter, Aurobindo did not contest that at least some claims of the '908 patent, including claim 1, cover the use of Aurobindo's ANDA Product as directed by Aurobindo's proposed labeling.

Answer:

Aurobindo admits that in its notice letter it discussed that no valid claim of the '908 patent covers Aurobindo's ANDA Product. Aurobindo denies any remaining allegations of paragraph 100.

101. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Aurobindo's ANDA Product would infringe one or more claims of the '908 patent, either literally or under the doctrine of equivalents.

Answer:

Denied.

102. 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 FDA approval of Aurobindo's ANDA.

Answer:

Aurobindo denies the allegations of paragraph 102, as no final decision has been made at this time.

103. On information and belief, the use of Aurobindo's ANDA Product in accordance with and as directed by Aurobindo's proposed labeling for that product would infringe one or more claims of the '908 patent.

Answer:

Denied.

104. On information and belief, Aurobindo plans and intends to, and will, actively induce infringement of the '908 patent when Aurobindo's ANDA is approved, and plans and intends to, and will, do so after approval.

Answer:

Denied.

105. On information and belief, Aurobindo knows that its ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '908 patent and that its

ANDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Aurobindo plans and intends to, and will, contribute to infringement of the '908 patent after approval of Aurobindo's ANDA.

Answer:

Denied.

106. The foregoing actions by Aurobindo constitute and/or will constitute infringement of the '908 patent, active inducement of infringement of the '908 patent, and contribution to the infringement by others of the '908 patent.

Answer:

Denied.

107. On information and belief, Aurobindo has acted with full knowledge of the '908 patent and without a reasonable basis for believing that it would not be liable for infringing the '908 patent, actively inducing infringement of the '908 patent, and contributing to the infringement by others of the '908 patent.

Answer:

Denied.

108. Unless Aurobindo is enjoined from infringing the '908 patent, actively inducing infringement of the '908 patent, and contributing to the infringement by others of the '908 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

Answer:

Denied.

**COUNT VI – INFRINGEMENT BY AUROBINDO
OF U.S. PATENT NO. 9,144,568 UNDER 35 U.S.C. § 271(e)(2)**

109. Plaintiffs incorporate each of the preceding paragraphs 1–104 [sic] as if fully set forth herein.

Answer:

Aurobindo incorporates by reference its responses to Paragraphs 1–108 as if fully set forth herein.

110. 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 prior to the expiration of the ’568 patent was an act of infringement of the ’568 patent under 35 U.S.C. § 271(e)(2)(A).

Answer:

Denied.

111. In its Notice Letter, Aurobindo did not contest that at least some claims of the ’568 patent, including claim 1, cover the use of Aurobindo’s ANDA Product as directed by Aurobindo’s proposed labeling.

Answer:

Aurobindo admits that in its notice letter it discussed that no valid claim of the ’568 patent covers Aurobindo’s ANDA Product. Aurobindo denies any remaining allegations of paragraph 111.

112. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Aurobindo’s ANDA Product would infringe one or more claims of the ’568 patent, either literally or under the doctrine of equivalents.

Answer:

Denied.

113. 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 FDA approval of Aurobindo's ANDA.

Answer:

Aurobindo denies the allegations of paragraph 113, as no final decision has been made at this time.

114. On information and belief, the use of Aurobindo's ANDA Product in accordance with and as directed by Aurobindo's proposed labeling for that product would infringe one or more claims of the '568 patent.

Answer:

Denied.

115. On information and belief, Aurobindo plans and intends to, and will, actively induce infringement of the '568 patent when Aurobindo's ANDA is approved, and plans and intends to, and will, do so after approval.

Answer:

Denied.

116. On information and belief, Aurobindo knows that its ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '568 patent and that its ANDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Aurobindo plans and intends to, and will, contribute to infringement of the '568 patent after approval of Aurobindo's ANDA.

Answer:

Denied.

117. The foregoing actions by Aurobindo constitute and/or will constitute infringement of the '568 patent, active inducement of infringement of the '568 patent, and contribution to the infringement by others of the '568 patent.

Answer:

Denied.

118. On information and belief, Aurobindo has acted with full knowledge of the '568 patent and without a reasonable basis for believing that it would not be liable for infringing the '568 patent, actively inducing infringement of the '568 patent, and contributing to the infringement by others of the '568 patent.

Answer:

Denied.

119. Unless Aurobindo is enjoined from infringing the '568 patent, actively inducing infringement of the '568 patent, and contributing to the infringement by others of the '568 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

Answer:

Denied.

**COUNT VII – INFRINGEMENT BY AUROBINDO
OF U.S. PATENT NO. 9,572,887 UNDER 35 U.S.C. § 271(e)(2)**

120. Plaintiffs incorporate each of the proceeding paragraphs 1–115 [sic] as if fully set forth herein.

Answer:

Aurobindo incorporates by reference its responses to Paragraphs 1–119 as if fully set forth herein.

121. 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 prior to the expiration of the '887 patent was an act of infringement of the '887 patent under 35 U.S.C. § 271(e)(2)(A).

Answer:

Denied.

122. In its Notice Letter, Aurobindo did not contest that at least some claims of the '887 patent, including claim 1, cover the use of Aurobindo's ANDA Product as directed by Aurobindo's proposed labeling.

Answer:

Aurobindo admits that in its notice letter it discussed that no valid claim of the '887 patent covers Aurobindo's ANDA Product. Aurobindo denies any remaining allegations of paragraph 122.

123. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Aurobindo's ANDA Product would infringe one or more claims of the '887 patent, either literally or under the doctrine of equivalents.

Answer:

Denied.

124. 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 FDA approval of Aurobindo's ANDA.

Answer:

Aurobindo denies the allegations of paragraph 124, as no final decision has been made at this time.

125. On information and belief, the use of Aurobindo's ANDA Product in accordance with and as directed by Aurobindo's proposed labeling for that product would infringe one or more claims of the '887 patent.

Answer:

Denied.

126. On information and belief, Aurobindo plans and intends to, and will, actively induce infringement of the '887 patent when Aurobindo's ANDA is approved, and plans and intends to, and will, do so after approval.

Answer:

Denied.

127. On information and belief, Aurobindo knows that its ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '887 patent and that its ANDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Aurobindo plans and intends to, and will, contribute to infringement of the '887 patent after approval of Aurobindo's ANDA.

Answer:

Denied.

128. The foregoing actions by Aurobindo constitute and/or will constitute infringement of the '887 patent, active inducement of infringement of the '887 patent, and contribution to the infringement by others of the '887 patent.

Answer:

Denied.

129. On information and belief, Aurobindo has acted with full knowledge of the '887 patent and without a reasonable basis for believing that it would not be liable for infringing the '887 patent, actively inducing infringement of the '887 patent, and contributing to the infringement by others of the '887 patent.

Answer:

Denied.

130. Unless Aurobindo is enjoined from infringing the '887 patent, actively inducing infringement of the '887 patent, and contributing to the infringement by others of the '887 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

Answer:

Denied.

**COUNT VIII – INFRINGEMENT BY AUROBINDO
OF U.S. PATENT NO. 9,597,397 UNDER 35 U.S.C. § 271(e)(2)**

131. Plaintiffs incorporate each of the proceeding paragraphs 1–126 [sic] as if fully set forth herein.

Answer:

Aurobindo incorporates by reference its responses to Paragraphs 1–130 as if fully set forth herein.

132. 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 prior to the expiration of the '397 patent was an act of infringement of the '397 patent under 35 U.S.C. § 271(e)(2)(A).

Answer:

Denied.

133. In its Notice Letter, Aurobindo did not contest that at least some claims of the '397 patent, including claim 1, cover the use of Aurobindo's ANDA Product as directed by Aurobindo's proposed labeling.

Answer:

Aurobindo admits that in its notice letter it discussed that no valid claim of the '397 patent covers Aurobindo's ANDA Product. Aurobindo denies any remaining allegations of paragraph 133.

134. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Aurobindo's ANDA Product would infringe one or more claims of the '397 patent, either literally or under the doctrine of equivalents.

Answer:

Denied.

135. 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 FDA approval of Aurobindo's ANDA.

Answer:

Aurobindo denies the allegations of paragraph 135, as no final decision has been made at this time.

136. On information and belief, the use of Aurobindo's ANDA Product in accordance with and as directed by Aurobindo's proposed labeling for that product would infringe one or more claims of the '397 patent.

Answer:

Denied.

137. On information and belief, Aurobindo plans and intends to, and will, actively induce infringement of the '397 patent when Aurobindo's ANDA is approved, and plans and intends to, and will, do so after approval.

Answer:

Denied.

138. On information and belief, Aurobindo knows that its ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '397 patent and that its ANDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Aurobindo plans and intends to, and will, contribute to infringement of the '397 patent after approval of Aurobindo's ANDA.

Answer:

Denied.

139. The foregoing actions by Aurobindo constitute and/or will constitute infringement of the '397 patent, active inducement of infringement of the '397 patent, and contribution to the infringement by others of the '397 patent.

Answer:

Denied.

140. On information and belief, Aurobindo has acted with full knowledge of the '397 patent and without a reasonable basis for believing that it would not be liable for infringing the '397 patent, actively inducing infringement of the '397 patent, and contributing to the infringement by others of the '397 patent.

Answer:

Denied.

141. Unless Aurobindo is enjoined from infringing the '397 patent, actively inducing infringement of the '397 patent, and contributing to the infringement by others of the '397 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

Answer:

Denied.

**COUNT IX – INFRINGEMENT BY AUROBINDO
OF U.S. PATENT NO. 9,597,398 UNDER 35 U.S.C. § 271(e)(2)**

142. Plaintiffs incorporate each of the proceeding paragraphs 1–137 [sic] as if fully set forth herein.

Answer:

Aurobindo incorporates by reference its responses to Paragraphs 1–141 as if fully set forth herein.

143. 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 prior to the expiration of the '398 patent was an act of infringement of the '398 patent under 35 U.S.C. § 271(e)(2)(A).

Answer:

Denied.

144. In its Notice Letter, Aurobindo did not contest that at least some claims of the '398 patent, including claim 1, cover the use of Aurobindo's ANDA Product as directed by Aurobindo's proposed labeling.

Answer:

Aurobindo admits that in its notice letter it discussed that no valid claim of the '398 patent covers Aurobindo's ANDA Product. Aurobindo denies any remaining allegations of paragraph 144.

145. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Aurobindo's ANDA Product would infringe one or more claims of the '398 patent, either literally or under the doctrine of equivalents.

Answer:

Denied.

146. 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 FDA approval of Aurobindo's ANDA.

Answer:

Aurobindo denies the allegations of paragraph 146, as a final decision has not been made at this time.

147. On information and belief, the use of Aurobindo's ANDA Product in accordance with and as directed by Aurobindo's proposed labeling for that product would infringe one or more claims of the '398 patent.

Answer:

Denied.

148. On information and belief, Aurobindo plans and intends to, and will, actively induce infringement of the '398 patent when Aurobindo's ANDA is approved, and plans and intends to, and will, do so after approval.

Answer:

Denied.

149. On information and belief, Aurobindo knows that its ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '398 patent and that its ANDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Aurobindo plans and intends to, and will, contribute to infringement of the '398 patent after approval of Aurobindo's ANDA.

Answer:

Denied.

150. The foregoing actions by Aurobindo constitute and/or will constitute infringement of the '398 patent, active inducement of infringement of the '398 patent, and contribution to the infringement by others of the '398 patent.

Answer:

Denied.

151. On information and belief, Aurobindo has acted with full knowledge of the '398 patent and without a reasonable basis for believing that it would not be liable for infringing the '398 patent, actively inducing infringement of the '398 patent, and contributing to the infringement by others of the '398 patent.

Answer:

Denied.

152. Unless Aurobindo is enjoined from infringing the '398 patent, actively inducing infringement of the '398 patent, and contributing to the infringement by others of the '398 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

Answer:

Denied.

**COUNT X – INFRINGEMENT BY AUROBINDO
OF U.S. PATENT NO. 9,597,399 UNDER 35 U.S.C. § 271(e)(2)**

153. Plaintiffs incorporate each of the proceeding paragraphs 1–148 [sic] as if fully set forth herein.

Answer:

Aurobindo incorporates by reference its responses to Paragraphs 1–152 as if fully set forth herein.

154. 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 prior to the expiration of the ’399 patent was an act of infringement of the ’399 patent under 35 U.S.C. § 271(e)(2)(A).

Answer:

Denied.

155. In its Notice Letter, Aurobindo did not contest that at least some claims of the ’399 patent, including claim 1, cover the use of Aurobindo’s ANDA Product as directed by Aurobindo’s proposed labeling.

Answer:

Aurobindo admits that in its notice letter it discussed that no valid claim of the ’399 patent covers Aurobindo’s ANDA Product. Aurobindo denies any remaining allegations of paragraph 155.

156. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Aurobindo’s ANDA Product would infringe one or more claims of the ’399 patent, either literally or under the doctrine of equivalents.

Answer:

Denied.

157. 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 FDA approval of Aurobindo's ANDA.

Answer:

Aurobindo denies the allegations of paragraph 157, as no final decision has been made at this time.

158. On information and belief, the use of Aurobindo's ANDA Product in accordance with and as directed by Aurobindo's proposed labeling for that product would infringe one or more claims of the '399 patent.

Answer:

Denied.

159. On information and belief, Aurobindo plans and intends to, and will, actively induce infringement of the '399 patent when Aurobindo's ANDA is approved, and plans and intends to, and will, do so after approval.

Answer:

Denied.

160. On information and belief, Aurobindo knows that its ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '399 patent and that its ANDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Aurobindo plans and intends to, and will, contribute to infringement of the '399 patent after approval of Aurobindo's ANDA.

Answer:

Denied.

161. The foregoing actions by Aurobindo constitute and/or will constitute infringement of the '399 patent, active inducement of infringement of the '399 patent, and contribution to the infringement by others of the '399 patent.

Answer:

Denied.

162. On information and belief, Aurobindo has acted with full knowledge of the '399 patent and without a reasonable basis for believing that it would not be liable for infringing the '399 patent, actively inducing infringement of the '399 patent, and contributing to the infringement by others of the '399 patent.

Answer:

Denied.

163. Unless Aurobindo is enjoined from infringing the '399 patent, actively inducing infringement of the '399 patent, and contributing to the infringement by others of the '399 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

Answer:

Denied.

**COUNT XI – INFRINGEMENT BY AUROBINDO
OF U.S. PATENT NO. 9,000,021 UNDER 35 U.S.C. § 271(e)(2)**

164. Plaintiffs incorporate each of the proceeding paragraphs 1–159 [sic] as if fully set forth herein.

Answer:

Aurobindo incorporates by reference its responses to Paragraphs 1–163 as if fully set forth herein.

165. 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 prior to the expiration of the ’021 patent was an act of infringement of the ’021 patent under 35 U.S.C. § 271(e)(2)(A).

Answer:

Denied.

166. In its Notice Letter, Aurobindo did not contest that at least some claims of the ’021 patent, including claim 1, cover the use of Aurobindo’s ANDA Product as directed by Aurobindo’s proposed labeling.

Answer:

Aurobindo admits that in its notice letter it discussed that no valid claim of the ’021 patent covers Aurobindo’s ANDA Product. Aurobindo denies any remaining allegations of paragraph 166.

167. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Aurobindo’s ANDA Product would infringe one or more claims of the ’021 patent, either literally or under the doctrine of equivalents.

Answer:

Denied.

168. 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 FDA approval of Aurobindo’s ANDA.

Answer:

Aurobindo denies the allegations of paragraph 168, as a final decision has not been made at this time.

169. On information and belief, the use of Aurobindo's ANDA Product in accordance with and as directed by Aurobindo's proposed labeling for that product would infringe one or more claims of the '021 patent.

Answer:

Denied.

170. On information and belief, Aurobindo plans and intends to, and will, actively induce infringement of the '021 patent when Aurobindo's ANDA is approved, and plans and intends to, and will, do so after approval.

Answer:

Denied.

171. On information and belief, Aurobindo knows that its ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '021 patent and that its ANDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Aurobindo plans and intends to, and will, contribute to infringement of the '021 patent after approval of Aurobindo's ANDA.

Answer:

Denied.

172. The foregoing actions by Aurobindo constitute and/or will constitute infringement of the '021 patent, active inducement of infringement of the '021 patent, and contribution to the infringement by others of the '021 patent.

Answer:

Denied.

173. On information and belief, Aurobindo has acted with full knowledge of the '021 patent and without a reasonable basis for believing that it would not be liable for infringing the '021 patent, actively inducing infringement of the '021 patent, and contributing to the infringement by others of the '021 patent.

Answer:

Denied.

174. Unless Aurobindo is enjoined from infringing the '021 patent, actively inducing infringement of the '021 patent, and contributing to the infringement by others of the '021 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

Answer:

Denied.

**COUNT XII – INFRINGEMENT BY AUROBINDO
OF U.S. PATENT NO. 9,579,384 UNDER 35 U.S.C. § 271(e)(2)**

175. Plaintiffs incorporate each of the proceeding paragraphs 1–170 [sic] as if fully set forth herein.

Answer:

Aurobindo incorporates by reference its responses to Paragraphs 1–174 as if fully set forth herein.

176. 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 prior to the expiration of the '384 patent was an act of infringement of the '384 patent under 35 U.S.C. § 271(e)(2)(A).

Answer:

Denied.

177. In its Notice Letter, Aurobindo did not contest that at least some claims of the '384 patent, including claim 1, cover the use of Aurobindo's ANDA Product as directed by Aurobindo's proposed labeling.

Answer:

Aurobindo admits that in its notice letter it discussed that no valid claim of the '384 patent covers Aurobindo's ANDA Product. Aurobindo denies any remaining allegations of paragraph 177.

178. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Aurobindo's ANDA Product would infringe one or more claims of the '384 patent, either literally or under the doctrine of equivalents.

Answer:

Denied.

179. 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 FDA approval of Aurobindo's ANDA.

Answer:

Aurobindo denies the allegations of paragraph 179, as a final decision has not been made at this time.

180. On information and belief, the use of Aurobindo's ANDA Product in accordance with and as directed by Aurobindo's proposed labeling for that product would infringe one or more claims of the '384 patent.

Answer:

Denied.

181. On information and belief, Aurobindo plans and intends to, and will, actively induce infringement of the '384 patent when Aurobindo's ANDA is approved, and plans and intends to, and will, do so after approval.

Answer:

Denied.

182. On information and belief, Aurobindo knows that its ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '384 patent and that its ANDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Aurobindo plans and intends to, and will, contribute to infringement of the '384 patent after approval of Aurobindo's ANDA.

Answer:

Denied.

183. The foregoing actions by Aurobindo constitute and/or will constitute infringement of the '384 patent, active inducement of infringement of the '384 patent, and contribution to the infringement by others of the '384 patent.

Answer:

Denied.

184. On information and belief, Aurobindo has acted with full knowledge of the '384 patent and without a reasonable basis for believing that it would not be liable for infringing the '384 patent, actively inducing infringement of the '384 patent, and contributing to the infringement by others of the '384 patent.

Answer:

Denied.

185. Unless Aurobindo is enjoined from infringing the '384 patent, actively inducing infringement of the '384 patent, and contributing to the infringement by others of the '384 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

Answer:

Denied.

**COUNT XIII – INFRINGEMENT BY AUROBINDO
OF U.S. PATENT NO. 10,010,533 UNDER 35 U.S.C. § 271(e)(2)**

186. Plaintiffs incorporate each of the proceeding paragraphs 1–181 [sic] as if fully set forth herein.

Answer:

Aurobindo incorporates by reference its responses to Paragraphs 1–185 as if fully set forth herein.

187. 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 prior to the expiration of the '533 patent was an act of infringement of the '533 patent under 35 U.S.C. § 271(e)(2)(A).

Answer:

Denied.

188. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Aurobindo's ANDA Product would infringe one or more claims of the '533 patent, either literally or under the doctrine of equivalents.

Answer:

Denied.

189. 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 FDA approval of Aurobindo's ANDA.

Answer:

Aurobindo denies the allegations of paragraph 189, as a final decision has not been made at this time.

190. On information and belief, the use of Aurobindo's ANDA Product in accordance with and as directed by Aurobindo's proposed labeling for that product would infringe one or more claims of the '533 patent.

Answer:

Denied.

191. On information and belief, Aurobindo plans and intends to, and will, actively induce infringement of the '533 patent when Aurobindo's ANDA is approved, and plans and intends to, and will, do so after approval.

Answer:

Denied.

192. On information and belief, Aurobindo knows that its ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '533 patent and that its ANDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Aurobindo plans and intends to, and will, contribute to infringement of the '533 patent after approval of Aurobindo's ANDA.

Answer:

Denied.

193. The foregoing actions by Aurobindo constitute and/or will constitute infringement of the '533 patent, active inducement of infringement of the '533 patent, and contribution to the infringement by others of the '533 patent.

Answer:

Denied.

194. On information and belief, Aurobindo has acted with full knowledge of the '533 patent and without a reasonable basis for believing that it would not be liable for infringing the '533 patent, actively inducing infringement of the '533 patent, and contributing to the infringement by others of the '533 patent.

Answer:

Denied.

195. Unless Aurobindo is enjoined from infringing the '533 patent, actively inducing infringement of the '533 patent, and contributing to the infringement by others of the '533 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

Answer:

Denied.

**COUNT XIV – INFRINGEMENT BY AUROBINDO
OF U.S. PATENT NO. 10,052,385 UNDER 35 U.S.C. § 271(e)(2)**

196. Plaintiffs incorporate each of the proceeding paragraphs 1–191 [sic] as if fully set forth herein.

Answer:

Aurobindo incorporates by reference its responses to Paragraphs 1–195 as if fully set forth herein.

197. 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 prior to the expiration of the '385 patent was an act of infringement of the '385 patent under 35 U.S.C. § 271(e)(2)(A).

Answer:

Denied.

198. In its Notice Letter, Aurobindo did not contest that at least some claims of the '385 patent, including claim 1, cover the use of Aurobindo's ANDA Product as directed by Aurobindo's proposed labeling.

Answer:

Aurobindo admits that in its notice letter it discussed that no valid claim of the '385 patent covers Aurobindo's ANDA Product. Aurobindo denies any remaining allegations of paragraph 198.

199. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Aurobindo's ANDA Product would infringe one or more claims of the '385 patent, either literally or under the doctrine of equivalents.

Answer:

Denied.

200. 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 FDA approval of Aurobindo's ANDA.

Answer:

Aurobindo denies the allegations of paragraph 200, as a final decision has not been made at this time.

201. On information and belief, the use of Aurobindo's ANDA Product in accordance with and as directed by Aurobindo's proposed labeling for that product would infringe one or more claims of the '385 patent.

Answer:

Denied.

202. On information and belief, Aurobindo plans and intends to, and will, actively induce infringement of the '385 patent when Aurobindo's ANDA is approved, and plans and intends to, and will, do so after approval.

Answer:

Denied.

203. On information and belief, Aurobindo knows that its ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '385 patent and that its ANDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Aurobindo plans and intends to, and will, contribute to infringement of the '385 patent after approval of Aurobindo's ANDA.

Answer:

Denied.

204. The foregoing actions by Aurobindo constitute and/or will constitute infringement of the '385 patent, active inducement of infringement of the '385 patent, and contribution to the infringement by others of the '385 patent.

Answer:

Denied.

205. On information and belief, Aurobindo has acted with full knowledge of the '385 patent and without a reasonable basis for believing that it would not be liable for infringing the '385 patent, actively inducing infringement of the '385 patent, and contributing to the infringement by others of the '385 patent.

Answer:

Denied.

206. Unless Aurobindo is enjoined from infringing the '385 patent, actively inducing infringement of the '385 patent, and contributing to the infringement by others of the '385 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

Answer:

Denied.

**COUNT XV – DECLARATORY JUDGEMENT OF INFRINGEMENT
BY AUROBINDO OF U.S. PATENT NO. 8,609,707**

207. Plaintiffs incorporate each of the proceeding paragraphs 1–202 [sic] as if fully set forth herein.

Answer:

Aurobindo incorporates by reference its responses to Paragraphs 1–205 as if fully set forth herein.

208. Aurobindo has knowledge of the '707 patent.

Answer:

Admitted.

209. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Aurobindo's ANDA Product would infringe one or more claims of the '707 patent, either literally or under the doctrine of equivalents.

Answer:

Denied.

210. 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 with its proposed labeling upon FDA approval of Aurobindo's ANDA.

Answer:

Aurobindo denies the allegations of paragraph 210, as a final decision has not been made at this time.

211. On information and belief, the use of Aurobindo's ANDA Product in accordance with and as directed by Aurobindo's proposed labeling for that product would infringe one or more claims of the '707 patent.

Answer:

Denied.

212. On information and belief, Aurobindo plans and intends to, and will, actively induce infringement of the '707 patent when Aurobindo's ANDA is approved, and plans and intends to, and will, do so after approval.

Answer:

Denied.

213. On information and belief, Aurobindo knows that its ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '707 patent and that its

ANDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Aurobindo plans and intends to, and will, contribute to infringement of the '707 patent after approval of Aurobindo's ANDA.

Answer:

Denied.

214. The foregoing actions by Aurobindo constitute and/or will constitute infringement of the '707 patent, active inducement of infringement of the '707 patent, and contribution to the infringement by others of the '707 patent.

Answer:

Denied.

215. On information and belief, Aurobindo has acted without a reasonable basis for believing that it would not be liable for infringing the '707 patent, actively inducing infringement of the '707 patent, and contributing to the infringement by others of the '707 patent.

Answer:

Denied.

216. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and Aurobindo regarding whether Aurobindo's manufacture, use, sale, offer for sale, or importation into the United States of Aurobindo's ANDA Product with its proposed labeling according to Aurobindo's ANDA will infringe one or more claims of the '707 patent and whether one or more claims of the '707 patent are valid.

Answer:

Denied.

217. Plaintiffs should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of Aurobindo's ANDA Product with its proposed labeling would infringe, actively induce the infringement of, and contribute to the infringement by others of the '707 patent and that the claims of the '707 patent are valid.

Answer:

Denied.

218. Aurobindo should be enjoined from infringing the '707 patent, actively inducing infringement of the '707 patent, and contributing to the infringement by others of the '707 patent; otherwise Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

Answer:

Denied.

**COUNT XVI – DECLARATORY JUDGEMENT OF INFRINGEMENT
BY AUROBINDO OF U.S. PATENT NO. 9,265,831**

219. Plaintiffs incorporate each of the proceeding paragraphs 1–214 [sic] as if fully set forth herein.

Answer:

Aurobindo incorporates by reference its responses to Paragraphs 1–218 as if fully set forth herein.

220. Aurobindo has knowledge of the '831 patent.

Answer:

Admitted.

221. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Aurobindo's ANDA Product would infringe one or more claims of the '831 patent, either literally or under the doctrine of equivalents.

Answer:

Denied.

222. 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 with its proposed labeling upon FDA approval of Aurobindo's ANDA.

Answer:

Aurobindo denies the allegations of paragraph 222, as a final decision has not been made at this time.

223. On information and belief, the use of Aurobindo's ANDA Product in accordance with and as directed by Aurobindo's proposed labeling for that product would infringe one or more claims of the '831 patent.

Answer:

Denied.

224. On information and belief, Aurobindo plans and intends to, and will, actively induce infringement of the '831 patent when Aurobindo's ANDA is approved, and plans and intends to, and will, do so after approval.

Answer:

Denied.

225. On information and belief, Aurobindo knows that its ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '831 patent and that its ANDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Aurobindo plans and intends to, and will, contribute to infringement of the '831 patent after approval of Aurobindo's ANDA.

Answer:

Denied.

226. The foregoing actions by Aurobindo constitute and/or will constitute infringement of the '831 patent, active inducement of infringement of the '831 patent, and contribution to the infringement by others of the '831 patent.

Answer:

Denied.

227. On information and belief, Aurobindo has acted without a reasonable basis for believing that it would not be liable for infringing the '831 patent, actively inducing infringement of the '831 patent, and contributing to the infringement by others of the '831 patent.

Answer:

Denied.

228. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and Aurobindo regarding whether Aurobindo's manufacture, use, sale, offer for sale, or importation into the United States of Aurobindo's ANDA Product with its proposed labeling according to Aurobindo's ANDA will infringe one or more claims of the '831 patent and whether one or more claims of the '831 patent are valid.

Answer:

Denied.

229. Plaintiffs should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of Aurobindo's ANDA Product with its proposed labeling would infringe, actively induce the infringement of, and contribute to the infringement by others of the '831 patent and that the claims of the '831 patent are valid.

Answer:

Denied.

230. Aurobindo should be enjoined from infringing the '831 patent, actively inducing infringement of the '831 patent, and contributing to the infringement by others of the '831 patent; otherwise Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

Answer:

Denied.

**COUNT XVII – DECLARATORY JUDGEMENT OF INFRINGEMENT
BY AUROBINDO OF U.S. PATENT NO. 9,572,796**

231. Plaintiffs incorporate each of the proceeding paragraphs 1–226 [sic] as if fully set forth herein.

Answer:

Aurobindo incorporates by reference its responses to Paragraphs 1–230 as if fully set forth herein.

232. Aurobindo has knowledge of the '796 patent.

Answer:

Admitted.

233. In its Notice Letter, Aurobindo did not contest that at least some claims of the '796 patent, including claim 1, cover Aurobindo's ANDA Product.

Answer:

Aurobindo admits that in its notice letter it discussed that no valid claim of the '796 patent covers Aurobindo's ANDA Product. Aurobindo denies any remaining allegations of paragraph 233.

234. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Aurobindo's ANDA Product would infringe one or more claims of the '796 patent, either literally or under the doctrine of equivalents.

Answer:

Aurobindo admits that in its notice letter it discussed that no valid claim of the '385 patent covers Aurobindo's ANDA Product. Aurobindo denies any remaining allegations of paragraph 198.

235. 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 with its proposed labeling upon FDA approval of Aurobindo's ANDA.

Answer:

Aurobindo denies the allegations of paragraph 235, as a final decision has not been made at this time.

236. On information and belief, the use of Aurobindo's ANDA Product in accordance with and as directed by Aurobindo's proposed labeling for that product would infringe one or more claims of the '796 patent.

Answer:

Denied.

237. On information and belief, Aurobindo plans and intends to, and will, actively induce infringement of the '796 patent when Aurobindo's ANDA is approved, and plans and intends to, and will, do so after approval.

Answer:

Denied.

238. On information and belief, Aurobindo knows that its ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '796 patent and that its ANDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Aurobindo plans and intends to, and will, contribute to infringement of the '796 patent after approval of Aurobindo's ANDA.

Answer:

Denied.

239. The foregoing actions by Aurobindo constitute and/or will constitute infringement of the '796 patent, active inducement of infringement of the '796 patent, and contribution to the infringement by others of the '796 patent.

Answer:

Denied.

240. On information and belief, Aurobindo has acted without a reasonable basis for believing that it would not be liable for infringing the '796 patent, actively inducing infringement of the '796 patent, and contributing to the infringement by others of the '796 patent.

Answer:

Denied.

241. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and Aurobindo regarding whether Aurobindo's manufacture, use, sale, offer for sale, or importation into the United States of Aurobindo's ANDA Product with its proposed labeling according to Aurobindo's ANDA will infringe one or more claims of the '796 patent and whether one or more claims of the '796 patent are valid.

Answer:

Denied.

242. Plaintiffs should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of Aurobindo's ANDA Product with its proposed labeling would infringe, actively induce the infringement of, and contribute to the infringement by others of the '796 patent and that the claims of the '796 patent are valid.

Answer:

Denied.

243. Aurobindo should be enjoined from infringing the '796 patent, actively inducing infringement of the '796 patent, and contributing to the infringement by others of the '796 patent; otherwise Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

Answer:

Denied.

**COUNT XVIII – DECLARATORY JUDGEMENT OF INFRINGEMENT
BY AUROBINDO OF U.S. PATENT NO. 9,572,797**

244. Plaintiffs incorporate each of the proceeding paragraphs 1–239 [sic] as if fully set forth herein.

Answer:

Aurobindo incorporates by reference its responses to Paragraphs 1–243 as if fully set forth herein.

245. Aurobindo has knowledge of the '797 patent.

Answer:

Admitted.

246. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Aurobindo's ANDA Product would infringe one or more claims of the '797 patent, either literally or under the doctrine of equivalents.

Answer:

Denied.

247. 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 with its proposed labeling upon FDA approval of Aurobindo's ANDA.

Answer:

Aurobindo denies the allegations of paragraph 247, as a final decision has not been made at this time.

248. On information and belief, the use of Aurobindo's ANDA Product in accordance with and as directed by Aurobindo's proposed labeling for that product would infringe one or more claims of the '797 patent.

Answer:

Denied.

249. On information and belief, Aurobindo plans and intends to, and will, actively induce infringement of the '797 patent when Aurobindo's ANDA is approved, and plans and intends to, and will, do so after approval.

Answer:

Denied.

250. On information and belief, Aurobindo knows that its ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '797 patent and that its

ANDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Aurobindo plans and intends to, and will, contribute to infringement of the '797 patent after approval of Aurobindo's ANDA.

Answer:

Denied.

251. The foregoing actions by Aurobindo constitute and/or will constitute infringement of the '797 patent, active inducement of infringement of the '797 patent, and contribution to the infringement by others of the '797 patent.

Answer:

Denied.

252. On information and belief, Aurobindo has acted without a reasonable basis for believing that it would not be liable for infringing the '797 patent, actively inducing infringement of the '797 patent, and contributing to the infringement by others of the '797 patent.

Answer:

Denied.

253. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and Aurobindo regarding whether Aurobindo's manufacture, use, sale, offer for sale, or importation into the United States of Aurobindo's ANDA Product with its proposed labeling according to Aurobindo's ANDA will infringe one or more claims of the '797 patent and whether one or more claims of the '797 patent are valid.

Answer:

Denied.

254. Plaintiffs should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of Aurobindo's ANDA Product with its proposed labeling would infringe, actively induce the infringement of, and contribute to the infringement by others of the '797 patent and that the claims of the '797 patent are valid.

Answer:

Denied.

255. Aurobindo should be enjoined from infringing the '797 patent, actively inducing infringement of the '797 patent, and contributing to the infringement by others of the '797 patent; otherwise Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

Answer:

Denied.

**COUNT XIX – DECLARATORY JUDGEMENT OF INFRINGEMENT
BY AUROBINDO OF U.S. PATENT NO. 9,034,908**

256. Plaintiffs incorporate each of the proceeding paragraphs 1–251 [sic] as if fully set forth herein.

Answer:

Aurobindo incorporates by reference its responses to Paragraphs 1–255 as if fully set forth herein.

257. Aurobindo has knowledge of the '908 patent.

Answer:

Admitted.

258. In its Notice Letter, Aurobindo did not contest that at least some claims of the '908 patent, including claim 1, cover the use of Aurobindo's ANDA Product as directed by Aurobindo's proposed labeling.

Answer:

Aurobindo admits that in its notice letter it discussed that no valid claim of the '908 patent covers Aurobindo's ANDA Product. Aurobindo denies any remaining allegations of paragraph 258.

259. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Aurobindo's ANDA Product would infringe one or more claims of the '908 patent, either literally or under the doctrine of equivalents.

Answer:

Denied.

260. 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 with its proposed labeling upon FDA approval of Aurobindo's ANDA.

Answer:

Aurobindo denies the allegations of paragraph 260, as a final decision has not been made at this time.

261. On information and belief, the use of Aurobindo's ANDA Product in accordance with and as directed by Aurobindo's proposed labeling for that product would infringe one or more claims of the '908 patent.

Answer:

Denied.

262. On information and belief, Aurobindo plans and intends to, and will, actively induce infringement of the '908 patent when Aurobindo's ANDA is approved, and plans and intends to, and will, do so after approval.

Answer:

Denied.

263. On information and belief, Aurobindo knows that its ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '908 patent and that its ANDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Aurobindo plans and intends to, and will, contribute to infringement of the '908 patent after approval of Aurobindo's ANDA.

Answer:

Denied.

264. The foregoing actions by Aurobindo constitute and/or will constitute infringement of the '908 patent, active inducement of infringement of the '908 patent, and contribution to the infringement by others of the '908 patent.

Answer:

Denied.

265. On information and belief, Aurobindo has acted without a reasonable basis for believing that it would not be liable for infringing the '908 patent, actively inducing infringement of the '908 patent, and contributing to the infringement by others of the '908 patent.

Answer:

Denied.

266. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and Aurobindo regarding whether Aurobindo's manufacture, use, sale, offer for sale, or importation into the United States of Aurobindo's ANDA Product with its proposed

labeling according to Aurobindo's ANDA will infringe one or more claims of the '908 patent and whether one or more claims of the '908 patent are valid.

Answer:

Denied.

267. Plaintiffs should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of Aurobindo's ANDA Product with its proposed labeling would infringe, actively induce the infringement of, and contribute to the infringement by others of the '908 patent and that the claims of the '908 patent are valid.

Answer:

Denied.

268. Aurobindo should be enjoined from infringing the '908 patent, actively inducing infringement of the '908 patent, and contributing to the infringement by others of the '908 patent; otherwise Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

Answer:

Denied.

**COUNT XX – DECLARATORY JUDGEMENT OF INFRINGEMENT
BY AUROBINDO OF U.S. PATENT NO. 9,144,568**

269. Plaintiffs incorporate each of the proceeding paragraphs 1–264 [sic] as if fully set forth herein.

Answer:

Aurobindo incorporates by reference its responses to Paragraphs 1–268 as if fully set forth herein.

270. Aurobindo has knowledge of the '568 patent.

Answer:

Admitted.

271. In its Notice Letter, Aurobindo did not contest that at least some claims of the '568 patent, including claim 1, cover the use of Aurobindo's ANDA Product as directed by Aurobindo's proposed labeling.

Answer:

Aurobindo admits that in its notice letter it discussed that no valid claim of the '568 patent covers Aurobindo's ANDA Product. Aurobindo denies any remaining allegations of paragraph 271.

272. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Aurobindo's ANDA Product would infringe one or more claims of the '568 patent, either literally or under the doctrine of equivalents.

Answer:

Denied.

273. 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 with its proposed labeling upon FDA approval of Aurobindo's ANDA.

Answer:

Aurobindo denies the allegations of paragraph 273, as a final decision has not been made at this time.

274. On information and belief, the use of Aurobindo's ANDA Product in accordance with and as directed by Aurobindo's proposed labeling for that product would infringe one or more claims of the '568 patent.

Answer:

Denied.

275. On information and belief, Aurobindo plans and intends to, and will, actively induce infringement of the '568 patent when Aurobindo's ANDA is approved, and plans and intends to, and will, do so after approval.

Answer:

Denied.

276. On information and belief, Aurobindo knows that its ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '568 patent and that its ANDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Aurobindo plans and intends to, and will, contribute to infringement of the '568 patent after approval of Aurobindo's ANDA.

Answer:

Denied.

277. The foregoing actions by Aurobindo constitute and/or will constitute infringement of the '568 patent, active inducement of infringement of the '568 patent, and contribution to the infringement by others of the '568 patent.

Answer:

Denied.

278. On information and belief, Aurobindo has acted without a reasonable basis for believing that it would not be liable for infringing the '568 patent, actively inducing infringement of the '568 patent, and contributing to the infringement by others of the '568 patent.

Answer:

Denied.

279. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and Aurobindo regarding whether Aurobindo's manufacture, use, sale, offer for sale, or importation into the United States of Aurobindo's ANDA Product with its proposed labeling according to Aurobindo's ANDA will infringe one or more claims of the '568 patent and whether one or more claims of the '568 patent are valid.

Answer:

Denied.

280. Plaintiffs should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of Aurobindo's ANDA Product with its proposed labeling would infringe, actively induce the infringement of, and contribute to the infringement by others of the '568 patent and that the claims of the '568 patent are valid.

Answer:

Denied.

281. Aurobindo should be enjoined from infringing the '568 patent, actively inducing infringement of the '568 patent, and contributing to the infringement by others of the '568 patent; otherwise Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

Answer:

Denied.

**COUNT XXI – DECLARATORY JUDGEMENT OF INFRINGEMENT
BY AUROBINDO OF U.S. PATENT NO. 9,572,887**

282. Plaintiffs incorporate each of the proceeding paragraphs 1–277 [sic] as if fully set forth herein.

Answer:

Aurobindo incorporates by reference its responses to Paragraphs 1–281 as if fully set forth herein.

283. Aurobindo has knowledge of the '887 patent.

Answer:

Admitted.

284. In its Notice Letter, Aurobindo did not contest that at least some claims of the '887 patent, including claim 1, cover the use of Aurobindo's ANDA Product as directed by Aurobindo's proposed labeling.

Answer:

Aurobindo admits that in its notice letter it discussed that no valid claim of the '887 patent covers Aurobindo's ANDA Product. Aurobindo denies any remaining allegations of paragraph 284.

285. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Aurobindo's ANDA Product would infringe one or more claims of the '887 patent, either literally or under the doctrine of equivalents.

Answer:

Denied.

286. 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 with its proposed labeling upon FDA approval of Aurobindo's ANDA.

Answer:

Aurobindo denies the allegations of paragraph 286, as a final decision has not been made at this time.

287. On information and belief, the use of Aurobindo's ANDA Product in accordance with and as directed by Aurobindo's proposed labeling for that product would infringe one or more claims of the '887 patent.

Answer:

Denied.

288. On information and belief, Aurobindo plans and intends to, and will, actively induce infringement of the '887 patent when Aurobindo's ANDA is approved, and plans and intends to, and will, do so after approval.

Answer:

Denied.

289. On information and belief, Aurobindo knows that its ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '887 patent and that its ANDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Aurobindo plans and intends to, and will, contribute to infringement of the '887 patent after approval of Aurobindo's ANDA.

Answer:

Denied.

290. The foregoing actions by Aurobindo constitute and/or will constitute infringement of the '887 patent, active inducement of infringement of the '887 patent, and contribution to the infringement by others of the '887 patent.

Answer:

Denied.

291. On information and belief, Aurobindo has acted without a reasonable basis for believing that it would not be liable for infringing the '887 patent, actively inducing infringement of the '887 patent, and contributing to the infringement by others of the '887 patent.

Answer:

Denied.

292. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and Aurobindo regarding whether Aurobindo's manufacture, use, sale, offer for sale, or importation into the United States of Aurobindo's ANDA Product with its proposed labeling according to Aurobindo's ANDA will infringe one or more claims of the '887 patent and whether one or more claims of the '887 patent are valid.

Answer:

Denied.

293. Plaintiffs should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of Aurobindo's ANDA Product with its proposed labeling would infringe, actively induce the infringement of, and contribute to the infringement by others of the '887 patent and that the claims of the '887 patent are valid.

Answer:

Denied.

294. Aurobindo should be enjoined from infringing the '887 patent, actively inducing infringement of the '887 patent, and contributing to the infringement by others of the '887 patent; otherwise Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

Answer:

Denied.

**COUNT XXII – DECLARATORY JUDGEMENT OF INFRINGEMENT
BY AUROBINDO OF U.S. PATENT NO. 9,597,397**

295. Plaintiffs incorporate each of the proceeding paragraphs 1–290 [sic] as if fully set forth herein.

Answer:

Aurobindo incorporates by reference its responses to Paragraphs 1–294 as if fully set forth herein.

296. Aurobindo has knowledge of the '397 patent.

Answer:

Admitted.

297. In its Notice Letter, Aurobindo did not contest that at least some claims of the '397 patent, including claim 1, cover the use of Aurobindo's ANDA Product as directed by Aurobindo's proposed labeling.

Answer:

Aurobindo admits that in its notice letter it discussed that no valid claim of the '397 patent covers Aurobindo's ANDA Product. Aurobindo denies any remaining allegations of paragraph 297.

298. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Aurobindo's ANDA Product would infringe one or more claims of the '397 patent, either literally or under the doctrine of equivalents.

Answer:

Denied.

299. 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 with its proposed labeling upon FDA approval of Aurobindo's ANDA.

Answer:

Aurobindo denies the allegations of paragraph 299, as a final decision has not been made at this time.

300. On information and belief, the use of Aurobindo's ANDA Product in accordance with and as directed by Aurobindo's proposed labeling for that product would infringe one or more claims of the '397 patent.

Answer:

Denied.

301. On information and belief, Aurobindo plans and intends to, and will, actively induce infringement of the '397 patent when Aurobindo's ANDA is approved, and plans and intends to, and will, do so after approval.

Answer:

Denied.

302. On information and belief, Aurobindo knows that its ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '397 patent and that its ANDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Aurobindo plans and intends to, and will, contribute to infringement of the '397 patent after approval of Aurobindo's ANDA.

Answer:

Denied.

303. The foregoing actions by Aurobindo constitute and/or will constitute infringement of the '397 patent, active inducement of infringement of the '397 patent, and contribution to the infringement by others of the '397 patent.

Answer:

Denied.

304. On information and belief, Aurobindo has acted without a reasonable basis for believing that it would not be liable for infringing the '397 patent, actively inducing infringement of the '397 patent, and contributing to the infringement by others of the '397 patent.

Answer:

Denied.

305. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and Aurobindo regarding whether Aurobindo's manufacture, use, sale, offer for sale, or importation into the United States of Aurobindo's ANDA Product with its proposed labeling according to Aurobindo's ANDA will infringe one or more claims of the '397 patent and whether one or more claims of the '397 patent are valid.

Answer:

Denied.

306. Plaintiffs should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of Aurobindo's ANDA Product with its proposed labeling would infringe, actively induce the infringement of, and contribute to the infringement by others of the '397 patent and that the claims of the '397 patent are valid.

Answer:

Denied.

307. Aurobindo should be enjoined from infringing the '397 patent, actively inducing infringement of the '397 patent, and contributing to the infringement by others of the '397 patent; otherwise Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

Answer:

Denied.

**COUNT XXIII – DECLARATORY JUDGEMENT OF INFRINGEMENT
BY AUROBINDO OF U.S. PATENT NO. 9,597,398**

308. Plaintiffs incorporate each of the proceeding paragraphs 1–303 [sic] as if fully set forth herein.

Answer:

Aurobindo incorporates by reference its responses to Paragraphs 1–307 as if fully set forth herein.

309. Aurobindo has knowledge of the '398 patent.

Answer:

Admitted.

310. In its Notice Letter, Aurobindo did not contest that at least some claims of the '398 patent, including claim 1, cover the use of Aurobindo's ANDA Product as directed by Aurobindo's proposed labeling.

Answer:

Aurobindo admits that in its notice letter it discussed that no valid claim of the '398 patent covers Aurobindo's ANDA Product. Aurobindo denies any remaining allegations of paragraph 310.

311. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Aurobindo's ANDA Product would infringe one or more claims of the '398 patent, either literally or under the doctrine of equivalents.

Answer:

Denied.

312. 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 with its proposed labeling upon FDA approval of Aurobindo's ANDA.

Answer:

Aurobindo denies the allegations of paragraph 312, as a final decision has not been made at this time.

313. On information and belief, the use of Aurobindo's ANDA Product in accordance with and as directed by Aurobindo's proposed labeling for that product would infringe one or more claims of the '398 patent.

Answer:

Denied.

314. On information and belief, Aurobindo plans and intends to, and will, actively induce infringement of the '398 patent when Aurobindo's ANDA is approved, and plans and intends to, and will, do so after approval.

Answer:

Denied.

315. On information and belief, Aurobindo knows that its ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '398 patent and that its

ANDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Aurobindo plans and intends to, and will, contribute to infringement of the '398 patent after approval of Aurobindo's ANDA.

Answer:

Denied.

316. The foregoing actions by Aurobindo constitute and/or will constitute infringement of the '398 patent, active inducement of infringement of the '398 patent, and contribution to the infringement by others of the '398 patent.

Answer:

Denied.

317. On information and belief, Aurobindo has acted without a reasonable basis for believing that it would not be liable for infringing the '398 patent, actively inducing infringement of the '398 patent, and contributing to the infringement by others of the '398 patent.

Answer:

Denied.

318. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and Aurobindo regarding whether Aurobindo's manufacture, use, sale, offer for sale, or importation into the United States of Aurobindo's ANDA Product with its proposed labeling according to Aurobindo's ANDA will infringe one or more claims of the '398 patent and whether one or more claims of the '398 patent are valid.

Answer:

Denied.

319. Plaintiffs should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of Aurobindo's ANDA Product with its proposed labeling would infringe, actively induce the infringement of, and contribute to the infringement by others of the '398 patent and that the claims of the '398 patent are valid.

Answer:

Denied.

320. Aurobindo should be enjoined from infringing the '398 patent, actively inducing infringement of the '398 patent, and contributing to the infringement by others of the '398 patent; otherwise Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

Answer:

Denied.

**COUNT XXIV – DECLARATORY JUDGEMENT OF INFRINGEMENT
BY AUROBINDO OF U.S. PATENT NO. 9,597,399**

321. Plaintiffs incorporate each of the proceeding paragraphs 1–316 [sic] as if fully set forth herein.

Answer:

Aurobindo incorporates by reference its responses to Paragraphs 1–320 as if fully set forth herein.

322. Aurobindo has knowledge of the '399 patent.

Answer:

Admitted.

323. In its Notice Letter, Aurobindo did not contest that at least some claims of the '399 patent, including claim 1, cover the use of Aurobindo's ANDA Product as directed by Aurobindo's proposed labeling.

Answer:

Aurobindo admits that in its notice letter it discussed that no valid claim of the '399 patent covers Aurobindo's ANDA Product. Aurobindo denies any remaining allegations of paragraph 323.

324. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Aurobindo's ANDA Product would infringe one or more claims of the '399 patent, either literally or under the doctrine of equivalents.

Answer:

Denied.

325. 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 with its proposed labeling upon FDA approval of Aurobindo's ANDA.

Answer:

Aurobindo denies the allegations of paragraph 325, as a final decision has not been made at this time.

326. On information and belief, the use of Aurobindo's ANDA Product in accordance with and as directed by Aurobindo's proposed labeling for that product would infringe one or more claims of the '399 patent.

Answer:

Denied.

327. On information and belief, Aurobindo plans and intends to, and will, actively induce infringement of the '399 patent when Aurobindo's ANDA is approved, and plans and intends to, and will, do so after approval.

Answer:

Denied.

328. On information and belief, Aurobindo knows that its ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '399 patent and that its ANDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Aurobindo plans and intends to, and will, contribute to infringement of the '399 patent after approval of Aurobindo's ANDA.

Answer:

Denied.

329. The foregoing actions by Aurobindo constitute and/or will constitute infringement of the '399 patent, active inducement of infringement of the '399 patent, and contribution to the infringement by others of the '399 patent.

Answer:

Denied.

330. On information and belief, Aurobindo has acted without a reasonable basis for believing that it would not be liable for infringing the '399 patent, actively inducing infringement of the '399 patent, and contributing to the infringement by others of the '399 patent.

Answer:

Denied.

331. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and Aurobindo regarding whether Aurobindo's manufacture, use, sale, offer for sale, or importation into the United States of Aurobindo's ANDA Product with its proposed

labeling according to Aurobindo's ANDA will infringe one or more claims of the '399 patent and whether one or more claims of the '399 patent are valid.

Answer:

Denied.

332. Plaintiffs should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of Aurobindo's ANDA Product with its proposed labeling would infringe, actively induce the infringement of, and contribute to the infringement by others of the '399 patent and that the claims of the '399 patent are valid.

Answer:

Denied.

333. Aurobindo should be enjoined from infringing the '399 patent, actively inducing infringement of the '399 patent, and contributing to the infringement by others of the '399 patent; otherwise Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

Answer:

Denied.

**COUNT XXV – DECLARATORY JUDGEMENT OF INFRINGEMENT
BY AUROBINDO OF U.S. PATENT NO. 9,000,021**

334. Plaintiffs incorporate each of the proceeding paragraphs 1–329 [sic] as if fully set forth herein.

Answer:

Aurobindo incorporates by reference its responses to Paragraphs 1–333 as if fully set forth herein.

335. Aurobindo has knowledge of the '021 patent.

Answer:

Admitted.

336. In its Notice Letter, Aurobindo did not contest that at least some claims of the '021 patent, including claim 1, cover the use of Aurobindo's ANDA Product as directed by Aurobindo's proposed labeling.

Answer:

Aurobindo admits that in its notice letter it discussed that no valid claim of the '021 patent covers Aurobindo's ANDA Product. Aurobindo denies any remaining allegations of paragraph 336.

337. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Aurobindo's ANDA Product would infringe one or more claims of the '021 patent, either literally or under the doctrine of equivalents.

Answer:

Denied.

338. 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 with its proposed labeling upon FDA approval of Aurobindo's ANDA.

Answer:

Aurobindo denies the allegations of paragraph 338, as a final decision has not been made at this time.

339. On information and belief, the use of Aurobindo's ANDA Product in accordance with and as directed by Aurobindo's proposed labeling for that product would infringe one or more claims of the '021 patent.

Answer:

Denied.

340. On information and belief, Aurobindo plans and intends to, and will, actively induce infringement of the '021 patent when Aurobindo's ANDA is approved, and plans and intends to, and will, do so after approval.

Answer:

Denied.

341. On information and belief, Aurobindo knows that its ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '021 patent and that its ANDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Aurobindo plans and intends to, and will, contribute to infringement of the '021 patent after approval of Aurobindo's ANDA.

Answer:

Denied.

342. The foregoing actions by Aurobindo constitute and/or will constitute infringement of the '021 patent, active inducement of infringement of the '021 patent, and contribution to the infringement by others of the '021 patent.

Answer:

Denied.

343. On information and belief, Aurobindo has acted without a reasonable basis for believing that it would not be liable for infringing the '021 patent, actively inducing infringement of the '021 patent, and contributing to the infringement by others of the '021 patent.

Answer:

Denied.

344. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and Aurobindo regarding whether Aurobindo's manufacture, use, sale, offer for sale, or importation into the United States of Aurobindo's ANDA Product with its proposed labeling according to Aurobindo's ANDA will infringe one or more claims of the '021 patent and whether one or more claims of the '021 patent are valid.

Answer:

Denied.

345. Plaintiffs should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of Aurobindo's ANDA Product with its proposed labeling would infringe, actively induce the infringement of, and contribute to the infringement by others of the '021 patent and that the claims of the '021 patent are valid.

Answer:

Denied.

346. Aurobindo should be enjoined from infringing the '021 patent, actively inducing infringement of the '021 patent, and contributing to the infringement by others of the '021 patent; otherwise Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

Answer:

Denied.

**COUNT XXVI – DECLARATORY JUDGEMENT OF INFRINGEMENT
BY AUROBINDO OF U.S. PATENT NO. 9,579,384**

347. Plaintiffs incorporate each of the proceeding paragraphs 1–342 [sic] as if fully set forth herein.

Answer:

Aurobindo incorporates by reference its responses to Paragraphs 1–346 as if fully set forth herein.

348. Aurobindo has knowledge of the '384 patent.

Answer:

Admitted.

349. In its Notice Letter, Aurobindo did not contest that at least some claims of the '384 patent, including claim 1, cover the use of Aurobindo's ANDA Product as directed by Aurobindo's proposed labeling.

Answer:

Aurobindo admits that in its notice letter it discussed that no valid claim of the '384 patent covers Aurobindo's ANDA Product. Aurobindo denies any remaining allegations of paragraph 349.

350. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Aurobindo's ANDA Product would infringe one or more claims of the '384 patent, either literally or under the doctrine of equivalents.

Answer:

Denied.

351. 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 with its proposed labeling upon FDA approval of Aurobindo's ANDA.

Answer:

Aurobindo denies the allegations of paragraph 351, as a final decision has not been made at this time.

352. On information and belief, the use of Aurobindo's ANDA Product in accordance with and as directed by Aurobindo's proposed labeling for that product would infringe one or more claims of the '384 patent.

Answer:

Denied.

353. On information and belief, Aurobindo plans and intends to, and will, actively induce infringement of the '384 patent when Aurobindo's ANDA is approved, and plans and intends to, and will, do so after approval.

Answer:

Denied.

354. On information and belief, Aurobindo knows that its ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '384 patent and that its ANDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Aurobindo plans and intends to, and will, contribute to infringement of the '384 patent after approval of Aurobindo's ANDA.

Answer:

Denied.

355. The foregoing actions by Aurobindo constitute and/or will constitute infringement of the '384 patent, active inducement of infringement of the '384 patent, and contribution to the infringement by others of the '384 patent.

Answer:

Denied.

356. On information and belief, Aurobindo has acted without a reasonable basis for believing that it would not be liable for infringing the '384 patent, actively inducing infringement of the '384 patent, and contributing to the infringement by others of the '384 patent.

Answer:

Denied.

357. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and Aurobindo regarding whether Aurobindo's manufacture, use, sale, offer for sale, or importation into the United States of Aurobindo's ANDA Product with its proposed labeling according to Aurobindo's ANDA will infringe one or more claims of the '384 patent and whether one or more claims of the '384 patent are valid.

Answer:

Denied.

358. Plaintiffs should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of Aurobindo's ANDA Product with its proposed labeling would infringe, actively induce the infringement of, and contribute to the infringement by others of the '384 patent and that the claims of the '384 patent are valid.

Answer:

Denied.

359. Aurobindo should be enjoined from infringing the '384 patent, actively inducing infringement of the '384 patent, and contributing to the infringement by others of the '384 patent; otherwise Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

Answer:

Denied.

**COUNT XXVII – DECLARATORY JUDGEMENT OF INFRINGEMENT
BY AUROBINDO OF U.S. PATENT NO. 10,010,533**

360. Plaintiffs incorporate each of the proceeding paragraphs 1–355 [sic] as if fully set forth herein.

Answer:

Aurobindo incorporates by reference its responses to Paragraphs 1–359 as if fully set forth herein.

361. Aurobindo has knowledge of the '533 patent.

Answer:

Admitted.

362. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Aurobindo's ANDA Product would infringe one or more claims of the '533 patent, either literally or under the doctrine of equivalents.

Answer:

Denied.

363. 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 with its proposed labeling upon FDA approval of Aurobindo's ANDA.

Answer:

Aurobindo denies the allegations of paragraph 363, as a final decision has not been made at this time.

364. On information and belief, the use of Aurobindo's ANDA Product in accordance with and as directed by Aurobindo's proposed labeling for that product would infringe one or more claims of the '533 patent.

Answer:

Denied.

365. On information and belief, Aurobindo plans and intends to, and will, actively induce infringement of the '533 patent when Aurobindo's ANDA is approved, and plans and intends to, and will, do so after approval.

Answer:

Denied.

366. On information and belief, Aurobindo knows that its ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '533 patent and that its ANDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Aurobindo plans and intends to, and will, contribute to infringement of the '533 patent after approval of Aurobindo's ANDA.

Answer:

Denied.

367. The foregoing actions by Aurobindo constitute and/or will constitute infringement of the '533 patent, active inducement of infringement of the '533 patent, and contribution to the infringement by others of the '533 patent.

Answer:

Denied.

368. On information and belief, Aurobindo has acted without a reasonable basis for believing that it would not be liable for infringing the '533 patent, actively inducing infringement of the '533 patent, and contributing to the infringement by others of the '533 patent.

Answer:

Denied.

369. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and Aurobindo regarding whether Aurobindo's manufacture, use, sale, offer for sale, or importation into the United States of Aurobindo's ANDA Product with its proposed labeling according to Aurobindo's ANDA will infringe one or more claims of the '533 patent and whether one or more claims of the '533 patent are valid.

Answer:

Denied.

370. Plaintiffs should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of Aurobindo's ANDA Product with its proposed labeling would infringe, actively induce the infringement of, and contribute to the infringement by others of the '533 patent and that the claims of the '533 patent are valid.

Answer:

Denied.

371. Aurobindo should be enjoined from infringing the '533 patent, actively inducing infringement of the '533 patent, and contributing to the infringement by others of the '533 patent; otherwise Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

Answer:

Denied.

**COUNT XXVIII – DECLARATORY JUDGEMENT OF INFRINGEMENT
BY AUROBINDO OF U.S. PATENT NO. 10,052,385**

372. Plaintiffs incorporate each of the proceeding paragraphs 1–367 [sic] as if fully set forth herein.

Answer:

Aurobindo incorporates by reference its responses to Paragraphs 1–371 as if fully set forth herein.

373. Aurobindo has knowledge of the '385 patent.

Answer:

Admitted.

374. In its Notice Letter, Aurobindo did not contest that at least some claims of the '385 patent, including claim 1, cover the use of Aurobindo's ANDA Product as directed by Aurobindo's proposed labeling.

Answer:

Aurobindo admits that in its notice letter it discussed that no valid claim of the '385 patent covers Aurobindo's ANDA Product. Aurobindo denies any remaining allegations of paragraph 374.

375. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Aurobindo's ANDA Product would infringe one or more claims of the '385 patent, either literally or under the doctrine of equivalents.

Answer:

Denied.

376. 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 with its proposed labeling upon FDA approval of Aurobindo's ANDA.

Answer:

Aurobindo denies the allegations of paragraph 376, as a final decision has not been made at this time.

377. On information and belief, the use of Aurobindo's ANDA Product in accordance with and as directed by Aurobindo's proposed labeling for that product would infringe one or more claims of the '385 patent.

Answer:

Denied.

378. On information and belief, Aurobindo plans and intends to, and will, actively induce infringement of the '385 patent when Aurobindo's ANDA is approved, and plans and intends to, and will, do so after approval.

Answer:

Denied.

379. On information and belief, Aurobindo knows that its ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '533 patent and that its ANDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Aurobindo plans and intends to, and will, contribute to infringement of the '385 patent after approval of Aurobindo's ANDA.

Answer:

Denied.

380. The foregoing actions by Aurobindo constitute and/or will constitute infringement of the '533 patent, active inducement of infringement of the '385 patent, and contribution to the infringement by others of the '385 patent.

Answer:

Denied.

381. On information and belief, Aurobindo has acted without a reasonable basis for believing that it would not be liable for infringing the '385 patent, actively inducing infringement of the '385 patent, and contributing to the infringement by others of the '385 patent.

Answer:

Denied.

382. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and Aurobindo regarding whether Aurobindo's manufacture, use, sale, offer for sale, or importation into the United States of Aurobindo's ANDA Product with its proposed labeling according to Aurobindo's ANDA will infringe one or more claims of the '385 patent and whether one or more claims of the '385 patent are valid.

Answer:

Denied.

383. Plaintiffs should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of Aurobindo's ANDA Product with its proposed labeling would infringe, actively induce the infringement of, and contribute to the infringement by others of the '385 patent and that the claims of the '385 patent are valid.

Answer:

Denied.

384. Aurobindo should be enjoined from infringing the '385 patent, actively inducing infringement of the '385 patent, and contributing to the infringement by others of the '385 patent; otherwise Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

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 '707 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 '831 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 '796 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

The claims of the '797 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.

Fifth Affirmative Defense

The claims of the '908 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.

Sixth Affirmative Defense

The claims of the '568 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.

Seventh Affirmative Defense

The claims of the '887 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.

Eighth Affirmative Defense

The claims of the '397 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.

Ninth Affirmative Defense

The claims of the '398 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.

Tenth Affirmative Defense

The claims of the '399 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.

Eleventh Affirmative Defense

The claims of the '021 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.

Twelfth Affirmative Defense

The claims of the '384 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.

Thirteenth Affirmative Defense

The claims of the '533 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.

Fourteenth Affirmative Defense

The claims of the '385 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.

Fifteenth 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.

Sixteenth Affirmative Defense

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

Seventeenth 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.

Eighteenth 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.

Nineteenth Affirmative Defense

The manufacture, use, or sale of Aurobindo's ANDA Product described in ANDA No. 214576 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 '707 patent, either literally or under the doctrine of equivalents.

Twentieth Affirmative Defense

The manufacture, use, or sale of Aurobindo's ANDA Product described in ANDA No. 214576 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 '831 patent, either literally or under the doctrine of equivalents.

Twenty-first Affirmative Defense

The manufacture, use, or sale of Aurobindo's ANDA Product described in ANDA No. 214576 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 '796 patent, either literally or under the doctrine of equivalents.

Twenty-second Affirmative Defense

The manufacture, use, or sale of Aurobindo's ANDA Product described in ANDA No. 214576 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 '797 patent, either literally or under the doctrine of equivalents.

Twenty-third Affirmative Defense

The manufacture, use, or sale of Aurobindo's ANDA Product described in ANDA No. 214576 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 '908 patent, either literally or under the doctrine of equivalents.

Twenty-fourth Affirmative Defense

The manufacture, use, or sale of Aurobindo's ANDA Product described in ANDA No. 214576 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 '568 patent, either literally or under the doctrine of equivalents.

Twenty-fifth Affirmative Defense

The manufacture, use, or sale of Aurobindo's ANDA Product described in ANDA No. 214576 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 '887 patent, either literally or under the doctrine of equivalents.

Twenty-sixth Affirmative Defense

The manufacture, use, or sale of Aurobindo's ANDA Product described in ANDA No. 214576 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 '397 patent, either literally or under the doctrine of equivalents.

Twenty-seventh Affirmative Defense

The manufacture, use, or sale of Aurobindo's ANDA Product described in ANDA No. 214576 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 '796 patent, either literally or under the doctrine of equivalents.

Twenty-eighth Affirmative Defense

The manufacture, use, or sale of Aurobindo's ANDA Product described in ANDA No. 214576 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 '398 patent, either literally or under the doctrine of equivalents.

Twenty-ninth Affirmative Defense

The manufacture, use, or sale of Aurobindo's ANDA Product described in ANDA No. 214576 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 '399 patent, either literally or under the doctrine of equivalents.

Thirtieth Affirmative Defense

The manufacture, use, or sale of Aurobindo's ANDA Product described in ANDA No. 214576 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 '021 patent, either literally or under the doctrine of equivalents.

Thirty-first Affirmative Defense

The manufacture, use, or sale of Aurobindo's ANDA Product described in ANDA No. 214576 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 '384 patent, either literally or under the doctrine of equivalents.

Thirty-second Affirmative Defense

The manufacture, use, or sale of Aurobindo's ANDA Product described in ANDA No. 214576 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 '533 patent, either literally or under the doctrine of equivalents.

Thirty-third Affirmative Defense

The manufacture, use, or sale of Aurobindo's ANDA Product described in ANDA No. 214576 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 '385 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 Teva Pharmaceuticals International GmbH, Cephalon, Inc., and Eagle Pharmaceuticals, Inc. (collectively “Plaintiffs”) for a declaratory judgment that U.S. Patent Nos. 8,609,707 (the “’707 patent”); 9,265,831 (the “’831 patent”); 9,572,796 (the “’796 patent”); 9,572,797 (the “’797 patent”); 9,034,908 (the “’908 patent”); 9,144,568 (the “’568 patent”); 9,572,887 (the “’887 patent”); 9,597,397 (the “’397 patent”); 9,597,398 (the “’398 patent”); 9,597,399 (the “’399 patent”); 9,000,021 (the “’021 patent”); 9,579,384 (the “’384 patent”); 10,010,533 (the “’533 patent”); and U.S. Patent No. 10,052,385 (the “’385 patent”) (collectively the “Asserted Patents”) are invalid and/or not infringed by Aurobindo’s bendamustine hydrochloride product that is the subject of Abbreviated New Drug Application (“ANDA”) No. 214576 (“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 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 2 of the Counterclaim-Defendants' Complaint, Counterclaim-Defendant Teva Pharmaceuticals International GmbH ("Teva") is a limited liability company organized and existing under the laws of Switzerland, having its principle place of business at Schlüsselstrasse 12, Jona (SG) 8645, Switzerland.

5. On information and belief, and based on Paragraph 3 of Counterclaim-Defendants' Complaint, Counterclaim-Defendant Cephalon, Inc. ("Cephalon") is a corporation organized and existing under the laws of the State of Delaware, having its principle place of business at 145 Brandywine Parkway, West Chester, Pennsylvania 19380. On information and belief, Cephalon is a wholly-owned subsidiary of Teva.

6. On information and belief, and based on Paragraph 4 of the Counterclaim-Defendants' Complaint, Counterclaim-Defendant Eagle Pharmaceuticals, Inc. ("Eagle") is a corporation organized under the laws of the State of Delaware, having its principle place of business at 50 Tice Boulevard, Suite 315, Woodcliff Lake, New Jersey 07677.

BACKGROUND

7. Aurobindo filed ANDA No. 214576 with the FDA seeking approval to market bendamustine hydrochloride injection, referencing the approved New Drug Application ("NDA") for BENDEKA[®], NDA No. 208194.

8. On information and belief, Eagle is the current holder of NDA No. 208194.

9. 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 BENDEKA[®] as manufactured under NDA No. 208194.

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 Asserted Patents are invalid, unenforceable, or will not be infringed by the manufacture, use, or sale of Aurobindo’s Proposed ANDA Product.

11. On or about April 6, 2020, Aurobindo sent by FedEx a letter concerning its Paragraph IV certification (the “Notice Letter”) to Teva, Cephalon, and Eagle.

12. 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.

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

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 ’707 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 '707 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 '707 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 '707 patent.

SECOND COUNTERCLAIM
(Declaration of Invalidity of the '707 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 '707 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, independent claims 1, 14, and 15 of the '707 patent are invalid as obvious under § 103 in light of at least the following prior art: Drager *et al.*, U.S. Patent No. 8,344,006; Olthoff *et al.*, DD 159289 (March 2, 1983); Tait *et al.*,

WO200202125; Alam et al., U.S. Patent No. 4,879,286; Boylan *et al.*, *Parenteral Products*, MODERN PHARMACEUTICS (2002); and/or Nema *et al.*, *Excipients and Their Use in Injectable Products*, 51 PDA J. PHARM. SCI. & TECH. 166 (1997).

25. Aurobindo is entitled to a declaration that the claims of the '707 patent are invalid.

THIRD COUNTERCLAIM
(Declaration of Non-infringement of the '831 Patent)

26. Aurobindo incorporates by reference the allegations set forth in Paragraphs 1–25 of the Counterclaims as if fully set forth herein.

27. 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 '831 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.

28. Further, Aurobindo will not infringe, contribute to the infringement of, or induce the infringement of any valid and/or enforceable claim of the '831 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.

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

30. Aurobindo is entitled to a declaration that it does not infringe, directly or indirectly, any valid claim of the '831 patent.

FOURTH COUNTERCLAIM
(Declaration of Invalidity of the '831 Patent)

31. Aurobindo incorporates by reference the allegations set forth in Paragraphs 1–30 of the Counterclaims as if fully set forth herein.

32. All claims of the '831 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.

33. For example, as described in the Notice Letter, independent claim 1 of the '831 patent are invalid as obvious under § 103 in light of at least the following prior art: Drager *et al.*, U.S. Patent No. 8,344,006; Olthoff *et al.*, DD 159289 (March 2, 1983); Tait *et al.*, WO200202125; Alam *et al.*, U.S. Patent No. 4,879,286; Boylan *et al.*, *Parenteral Products*, MODERN PHARMACEUTICS (2002); and/or Nema *et al.*, *Excipients and Their Use in Injectable Products*, 51 PDA J. PHARM. SCI. & TECH. 166 (1997).

34. Aurobindo is entitled to a declaration that the claims of the '831 patent are invalid.

FIFTH COUNTERCLAIM
(Declaration of Non-infringement of the '796 Patent)

35. Aurobindo incorporates by reference the allegations set forth in Paragraphs 1–34 of the Counterclaims as if fully set forth herein.

36. 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 '796 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.

37. Further, Aurobindo will not infringe, contribute to the infringement of, or induce the infringement of any valid and/or enforceable claim of the '796 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.

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

39. Aurobindo is entitled to a declaration that it does not infringe, directly or indirectly, any valid claim of the '796 patent.

SIXTH COUNTERCLAIM
(Declaration of Invalidity of the '796 Patent)

40. Aurobindo incorporates by reference the allegations set forth in Paragraphs 1–39 of the Counterclaims as if fully set forth herein.

41. All claims of the '796 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.

42. For example, as described in the Notice Letter, independent claims 1 and 14 of the '796 patent are invalid as obvious under § 103 in light of at least the following prior art: Drager *et al.*, U.S. Patent No. 8,344,006; Olthoff *et al.*, DD 159289 (March 2, 1983); Tait *et al.*, WO200202125; Alam *et al.*, U.S. Patent No. 4,879,286; Boylan *et al.*, *Parenteral Products*, MODERN PHARMACEUTICS (2002); and/or Nema *et al.*, *Excipients and Their Use in Injectable Products*, 51 PDA J. PHARM. SCI. & TECH. 166 (1997).

43. Aurobindo is entitled to a declaration that the claims of the '796 patent are invalid.

SEVENTH COUNTERCLAIM
(Declaration of Non-infringement of the '797 Patent)

44. Aurobindo incorporates by reference the allegations set forth in Paragraphs 1–43 of the Counterclaims as if fully set forth herein.

45. 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 ’797 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.

46. Further, Aurobindo will not infringe, contribute to the infringement of, or induce the infringement of any valid and/or enforceable claim of the ’797 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.

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

48. Aurobindo is entitled to a declaration that it does not infringe, directly or indirectly, any valid claim of the ’797 patent.

EIGHTH COUNTERCLAIM
(Declaration of Invalidity of the ’797 Patent)

49. Aurobindo incorporates by reference the allegations set forth in Paragraphs 1–48 of the Counterclaims as if fully set forth herein.

50. All claims of the ’797 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.

51. For example, as described in the Notice Letter, independent claims 1 and 16 of the '797 patent are invalid as obvious under § 103 in light of at least the following prior art: Drager *et al.*, U.S. Patent No. 8,344,006; Olthoff *et al.*, DD 159289 (March 2, 1983); Tait *et al.*, WO200202125; Alam *et al.*, U.S. Patent No. 4,879,286; Boylan *et al.*, *Parenteral Products*, MODERN PHARMACEUTICS (2002); and/or Nema *et al.*, *Excipients and Their Use in Injectable Products*, 51 PDA J. PHARM. SCI. & TECH. 166 (1997).

52. Aurobindo is entitled to a declaration that the claims of the '797 patent are invalid.

NINTH COUNTERCLAIM
(Declaration of Non-infringement of the '908 Patent)

53. Aurobindo incorporates by reference the allegations set forth in Paragraphs 1–52 of the Counterclaims as if fully set forth herein.

54. 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 '908 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.

55. Further, Aurobindo will not infringe, contribute to the infringement of, or induce the infringement of any valid and/or enforceable claim of the '908 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.

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

57. Aurobindo is entitled to a declaration that it does not infringe, directly or indirectly, any valid claim of the '908 patent.

TENTH COUNTERCLAIM
(Declaration of Invalidity of the '908 Patent)

58. Aurobindo incorporates by reference the allegations set forth in Paragraphs 1–57 of the Counterclaims as if fully set forth herein.

59. All claims of the '908 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.

60. For example, as described in the Notice Letter, independent claim 1 of the '908 patent are invalid as obvious under § 103 in light of at least the following prior art: Palepu *et al.*, U.S. Publication No. US 2011/0184036; Treanda® Label (2009); Preiss *et al.*, *Studies on the Pharmacokinetics of Bendamustine (Cytostasan®) in Humans*, 40 PHARMAZIE 782 (1985) and Preiss *et al.*, *Pharmacological and Clinical Data of Bendamustine*, 17th International Cancer Congress (1998); Barth *et al.*, *Bendamustine Plus Rituximab (B-R) Is Significantly Superior to CHOP-R as First-Line Therapy in Indolent and Mantle-Cell Lymphoma*, 12 ONKOLOGISCHE PHARMAZIE 4 (2010); Schoffski *et al.*, *Repeated Administration of Short Infusions of Bendamustine: A Phase I Study in Patients with Advanced Progressive Solid Tumors*, 126 J. CANCER RES. CLIN. ONCOL. 41 (2000) and Schoffski *et al.*, *Weekly Administration of Bendamustine: A Phase I Study in Patients with Advanced Progressive Solid Tumors*, 11 ANNALS OF ONCOL. 729 (2000); and/or Olthoff *et al.*, DD 159289 (March 2, 1983).

61. Aurobindo is entitled to a declaration that the claims of the '908 patent are invalid.

ELEVENTH COUNTERCLAIM
(Declaration of Non-infringement of the '568 Patent)

62. Aurobindo incorporates by reference the allegations set forth in Paragraphs 1–61 of the Counterclaims as if fully set forth herein.

63. 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 ’568 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.

64. Further, Aurobindo will not infringe, contribute to the infringement of, or induce the infringement of any valid and/or enforceable claim of the ’568 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.

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

66. Aurobindo is entitled to a declaration that it does not infringe, directly or indirectly, any valid claim of the ’568 patent.

TWELFTH COUNTERCLAIM
(Declaration of Invalidity of the ’568 Patent)

67. Aurobindo incorporates by reference the allegations set forth in Paragraphs 1–66 of the Counterclaims as if fully set forth herein.

68. All claims of the ’568 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.

69. For example, as described in the Notice Letter, independent claim 1 of the '568 patent are invalid as obvious under § 103 in light of at least the following prior art: Palepu *et al.*, U.S. Publication No. US 2011/0184036; Treanda® Label (2009); Preiss *et al.*, *Studies on the Pharmacokinetics of Bendamustine (Cytostasan®) in Humans*, 40 PHARMAZIE 782 (1985) and Preiss *et al.*, *Pharmacological and Clinical Data of Bendamustine*, 17th International Cancer Congress (1998); Barth *et al.*, *Bendamustine Plus Rituximab (B-R) Is Significantly Superior to CHOP-R as First-Line Therapy in Indolent and Mantle-Cell Lymphoma*, 12 ONKOLOGISCHE PHARMAZIE 4 (2010); Schoffski *et al.*, *Repeated Administration of Short Infusions of Bendamustine: A Phase I Study in Patients with Advanced Progressive Solid Tumors*, 126 J. CANCER RES. CLIN. ONCOL. 41 (2000) and Schoffski *et al.*, *Weekly Administration of Bendamustine: A Phase I Study in Patients with Advanced Progressive Solid Tumors*, 11 ANNALS OF ONCOL. 729 (2000); and/or Olthoff *et al.*, DD 159289 (March 2, 1983).

70. Aurobindo is entitled to a declaration that the claims of the '568 patent are invalid.

THIRTEENTH COUNTERCLAIM
(Declaration of Non-infringement of the '887 Patent)

71. Aurobindo incorporates by reference the allegations set forth in Paragraphs 1–70 of the Counterclaims as if fully set forth herein.

72. 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 '887 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.

73. Further, Aurobindo will not infringe, contribute to the infringement of, or induce the infringement of any valid and/or enforceable claim of the '887 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.

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

75. Aurobindo is entitled to a declaration that it does not infringe, directly or indirectly, any valid claim of the '887 patent.

FOURTEENTH COUNTERCLAIM
(Declaration of Invalidity of the '887 Patent)

76. Aurobindo incorporates by reference the allegations set forth in Paragraphs 1–75 of the Counterclaims as if fully set forth herein.

77. All claims of the '887 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.

78. For example, as described in the Notice Letter, independent claim 1 of the '887 patent are invalid as obvious under § 103 in light of at least the following prior art: Palepu *et al.*, U.S. Publication No. US 2011/0184036; Treanda® Label (2009); Preiss *et al.*, *Studies on the Pharmacokinetics of Bendamustine (Cytostasan®) in Humans*, 40 PHARMAZIE 782 (1985) and Preiss *et al.*, *Pharmacological and Clinical Data of Bendamustine*, 17th International Cancer Congress (1998); Barth *et al.*, *Bendamustine Plus Rituximab (B-R) Is Significantly Superior to CHOP-R as First-Line Therapy in Indolent and Mantle-Cell Lymphoma*, 12 ONKOLOGISCHE PHARMAZIE 4 (2010); Schoffski *et al.*, *Repeated Administration of Short Infusions of Bendamustine: A Phase I Study in Patients with Advanced Progressive Solid Tumors*, 126 J. CANCER RES. CLIN. ONCOL. 41 (2000) and Schoffski *et al.*, *Weekly Administration of*

Bendamustine: A Phase I Study in Patients with Advanced Progressive Solid Tumors, 11 ANNALS OF ONCOL. 729 (2000); and/or Olthoff et al., DD 159289 (March 2, 1983).

79. Aurobindo is entitled to a declaration that the claims of the '887 patent are invalid.

FIFTEENTH COUNTERCLAIM
(Declaration of Non-infringement of the '397 Patent)

80. Aurobindo incorporates by reference the allegations set forth in Paragraphs 1–79 of the Counterclaims as if fully set forth herein.

81. 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 '397 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.

82. Further, Aurobindo will not infringe, contribute to the infringement of, or induce the infringement of any valid and/or enforceable claim of the '397 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.

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

84. Aurobindo is entitled to a declaration that it does not infringe, directly or indirectly, any valid claim of the '397 patent.

SIXTEENTH COUNTERCLAIM
(Declaration of Invalidity of the '397 Patent)

85. Aurobindo incorporates by reference the allegations set forth in Paragraphs 1–84 of the Counterclaims as if fully set forth herein.

86. All claims of the '397 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.

87. For example, as described in the Notice Letter, independent claim 1 of the '397 patent are invalid as obvious under § 103 in light of at least the following prior art: Palepu *et al.*, U.S. Publication No. US 2011/0184036; Treanda® Label (2009); Preiss *et al.*, *Studies on the Pharmacokinetics of Bendamustine (Cytostasan®) in Humans*, 40 PHARMAZIE 782 (1985) and Preiss *et al.*, *Pharmacological and Clinical Data of Bendamustine*, 17th International Cancer Congress (1998); Barth *et al.*, *Bendamustine Plus Rituximab (B-R) Is Significantly Superior to CHOP-R as First-Line Therapy in Indolent and Mantle-Cell Lymphoma*, 12 ONKOLOGISCHE PHARMAZIE 4 (2010); Schoffski *et al.*, *Repeated Administration of Short Infusions of Bendamustine: A Phase I Study in Patients with Advanced Progressive Solid Tumors*, 126 J. CANCER RES. CLIN. ONCOL. 41 (2000) and Schoffski *et al.*, *Weekly Administration of Bendamustine: A Phase I Study in Patients with Advanced Progressive Solid Tumors*, 11 ANNALS OF ONCOL. 729 (2000); and/or Olthoff *et al.*, DD 159289 (March 2, 1983).

88. Aurobindo is entitled to a declaration that the claims of the '397 patent are invalid.

SEVENTEENTH COUNTERCLAIM
(Declaration of Non-infringement of the '398 Patent)

89. Aurobindo incorporates by reference the allegations set forth in Paragraphs 1–88 of the Counterclaims as if fully set forth herein.

90. 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 '398 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.

91. Further, Aurobindo will not infringe, contribute to the infringement of, or induce the infringement of any valid and/or enforceable claim of the '398 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.

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

93. Aurobindo is entitled to a declaration that it does not infringe, directly or indirectly, any valid claim of the '398 patent.

EIGHTEENTH COUNTERCLAIM
(Declaration of Invalidity of the '398 Patent)

94. Aurobindo incorporates by reference the allegations set forth in Paragraphs 1–93 of the Counterclaims as if fully set forth herein.

95. All claims of the '398 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.

96. For example, as described in the Notice Letter, claims 1 and 9 of the '398 patent are invalid as obvious under § 103 in light of at least the following prior art: Palepu *et al.*, U.S. Publication No. US 2011/0184036; Treanda® Label (2009); Preiss *et al.*, *Studies on the Pharmacokinetics of Bendamustine (Cytostasan®) in Humans*, 40 PHARMAZIE 782 (1985) and Preiss *et al.*, *Pharmacological and Clinical Data of Bendamustine*, 17th International Cancer Congress (1998); Barth *et al.*, *Bendamustine Plus Rituximab (B-R) Is Significantly Superior to*

CHOP-R as First-Line Therapy in Indolent and Mantle-Cell Lymphoma, 12 ONKOLOGISCHE PHARMAZIE 4 (2010); Schoffski *et al.*, *Repeated Administration of Short Infusions of Bendamustine: A Phase I Study in Patients with Advanced Progressive Solid Tumors*, 126 J. CANCER RES. CLIN. ONCOL. 41 (2000) and Schoffski *et al.*, *Weekly Administration of Bendamustine: A Phase I Study in Patients with Advanced Progressive Solid Tumors*, 11 ANNALS OF ONCOL. 729 (2000); and/or Olthoff *et al.*, DD 159289 (March 2, 1983).

97. Aurobindo is entitled to a declaration that the claims of the '399 patent are invalid.

NINETEENTH COUNTERCLAIM
(Declaration of Non-infringement of the '399 Patent)

98. Aurobindo incorporates by reference the allegations set forth in Paragraphs 1–97 of the Counterclaims as if fully set forth herein.

99. 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 '399 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.

100. Further, Aurobindo will not infringe, contribute to the infringement of, or induce the infringement of any valid and/or enforceable claim of the '399 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.

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

102. Aurobindo is entitled to a declaration that it does not infringe, directly or indirectly, any valid claim of the '399 patent.

TWENTIETH COUNTERCLAIM
(Declaration of Invalidity of the '399 Patent)

103. Aurobindo incorporates by reference the allegations set forth in Paragraphs 1–102 of the Counterclaims as if fully set forth herein.

104. All claims of the '399 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.

105. For example, as described in the Notice Letter, independent claim 1 of the '399 patent are invalid as obvious under § 103 in light of at least the following prior art: Palepu *et al.*, U.S. Publication No. US 2011/0184036; Treanda® Label (2009); Preiss *et al.*, *Studies on the Pharmacokinetics of Bendamustine (Cytostasan®) in Humans*, 40 PHARMAZIE 782 (1985) and Preiss *et al.*, *Pharmacological and Clinical Data of Bendamustine*, 17th International Cancer Congress (1998); Barth *et al.*, *Bendamustine Plus Rituximab (B-R) Is Significantly Superior to CHOP-R as First-Line Therapy in Indolent and Mantle-Cell Lymphoma*, 12 ONKOLOGISCHE PHARMAZIE 4 (2010); Schoffski *et al.*, *Repeated Administration of Short Infusions of Bendamustine: A Phase I Study in Patients with Advanced Progressive Solid Tumors*, 126 J. CANCER RES. CLIN. ONCOL. 41 (2000) and Schoffski *et al.*, *Weekly Administration of Bendamustine: A Phase I Study in Patients with Advanced Progressive Solid Tumors*, 11 ANNALS OF ONCOL. 729 (2000); and/or Olthoff *et al.*, DD 159289 (March 2, 1983).

106. Aurobindo is entitled to a declaration that the claims of the '399 patent are invalid.

TWENTY-FIRST COUNTERCLAIM
(Declaration of Non-infringement of the '021 Patent)

107. Aurobindo incorporates by reference the allegations set forth in Paragraphs 1–106 of the Counterclaims as if fully set forth herein.

108. 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 '021 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.

109. Further, Aurobindo will not infringe, contribute to the infringement of, or induce the infringement of any valid and/or enforceable claim of the '021 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.

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

111. Aurobindo is entitled to a declaration that it does not infringe, directly or indirectly, any valid claim of the '021 patent.

TWENTY-SECOND COUNTERCLAIM
(Declaration of Invalidity of the '021 Patent)

112. Aurobindo incorporates by reference the allegations set forth in Paragraphs 1–111 of the Counterclaims as if fully set forth herein.

113. All claims of the '021 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.

114. For example, as described in the Notice Letter, independent claims 1, 28, and 29 of the '021 patent are invalid as obvious under § 103 in light of at least the following prior art: Palepu *et al.*, U.S. Publication No. US 2011/0184036; Treanda® Label (2009); Preiss *et al.*, *Studies on the Pharmacokinetics of Bendamustine (Cytostasan®) in Humans*, 40 PHARMAZIE 782 (1985) and Preiss *et al.*, *Pharmacological and Clinical Data of Bendamustine*, 17th International Cancer Congress (1998); Barth *et al.*, *Bendamustine Plus Rituximab (B-R) Is Significantly Superior to CHOP-R as First-Line Therapy in Indolent and Mantle-Cell Lymphoma*, 12 ONKOLOGISCHE PHARMAZIE 4 (2010); Schoffski *et al.*, *Repeated Administration of Short Infusions of Bendamustine: A Phase I Study in Patients with Advanced Progressive Solid Tumors*, 126 J. CANCER RES. CLIN. ONCOL. 41 (2000) and Schoffski *et al.*, *Weekly Administration of Bendamustine: A Phase I Study in Patients with Advanced Progressive Solid Tumors*, 11 ANNALS OF ONCOL. 729 (2000); and/or Olthoff *et al.*, DD 159289 (March 2, 1983).

115. Aurobindo is entitled to a declaration that the claims of the '021 patent are invalid.

TWENTY-THIRD COUNTERCLAIM
(Declaration of Non-infringement of the '384 Patent)

116. Aurobindo incorporates by reference the allegations set forth in Paragraphs 1–115 of the Counterclaims as if fully set forth herein.

117. 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 '384 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.

118. Further, Aurobindo will not infringe, contribute to the infringement of, or induce the infringement of any valid and/or enforceable claim of the '384 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.

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

120. Aurobindo is entitled to a declaration that it does not infringe, directly or indirectly, any valid claim of the '384 patent.

TWENTY-FOURTH COUNTERCLAIM
(Declaration of Invalidity of the '384 Patent)

121. Aurobindo incorporates by reference the allegations set forth in Paragraphs 1–120 of the Counterclaims as if fully set forth herein.

122. All claims of the '384 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.

123. For example, as described in the Notice Letter, independent claims 1 and 23 of the '384 patent are invalid as obvious under § 103 in light of at least the following prior art: Palepu *et al.*, U.S. Publication No. US 2011/0184036; Treanda® Label (2009); Preiss *et al.*, *Studies on the Pharmacokinetics of Bendamustine (Cytostasan®) in Humans*, 40 PHARMAZIE 782 (1985) and Preiss *et al.*, *Pharmacological and Clinical Data of Bendamustine*, 17th International Cancer Congress (1998); Barth *et al.*, *Bendamustine Plus Rituximab (B-R) Is Significantly Superior to CHOP-R as First-Line Therapy in Indolent and Mantle-Cell Lymphoma*, 12 ONKOLOGISCHE PHARMAZIE 4 (2010); Schoffski *et al.*, *Repeated Administration of Short Infusions of Bendamustine: A Phase I Study in Patients with Advanced Progressive Solid Tumors*, 126 J. CANCER RES. CLIN. ONCOL. 41 (2000) and Schoffski *et al.*, *Weekly Administration of*

Bendamustine: A Phase I Study in Patients with Advanced Progressive Solid Tumors, 11 ANNALS OF ONCOL. 729 (2000); and/or Olthoff et al., DD 159289 (March 2, 1983).

124. Aurobindo is entitled to a declaration that the claims of the '384 patent are invalid.

TWENTY-FIFTH COUNTERCLAIM
(Declaration of Non-infringement of the '533 Patent)

125. Aurobindo incorporates by reference the allegations set forth in Paragraphs 1–124 of the Counterclaims as if fully set forth herein.

126. 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 '533 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.

127. Further, Aurobindo will not infringe, contribute to the infringement of, or induce the infringement of any valid and/or enforceable claim of the '533 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.

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

129. Aurobindo is entitled to a declaration that it does not infringe, directly or indirectly, any valid claim of the '533 patent.

TWENTY-SIXTH COUNTERCLAIM
(Declaration of Invalidity of the '533 Patent)

130. Aurobindo incorporates by reference the allegations set forth in Paragraphs 1–129 of the Counterclaims as if fully set forth herein.

131. All claims of the '533 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.

132. For example, as described in the Notice Letter, independent claims 1, 7, and 16 of the '533 patent are invalid as obvious under § 103 in light of at least the following prior art: Drager *et al.*, U.S. Patent No. 8,344,006; Olthoff *et al.*, DD 159289 (March 2, 1983); Tait *et al.*, WO200202125; Alam *et al.*, U.S. Patent No. 4,879,286; Boylan *et al.*, *Parenteral Products*, MODERN PHARMACEUTICS (2002); and/or Nema *et al.*, *Excipients and Their Use in Injectable Products*, 51 PDA J. PHARM. SCI. & TECH. 166 (1997).

133. Aurobindo is entitled to a declaration that the claims of the '533 patent are invalid.

TWENTY-SEVENTH COUNTERCLAIM
(Declaration of Non-infringement of the '385 Patent)

134. Aurobindo incorporates by reference the allegations set forth in Paragraphs 1–133 of the Counterclaims as if fully set forth herein.

135. 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 '385 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.

136. Further, Aurobindo will not infringe, contribute to the infringement of, or induce the infringement of any valid and/or enforceable claim of the '385 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.

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

138. Aurobindo is entitled to a declaration that it does not infringe, directly or indirectly, any valid claim of the '385 patent.

TWENTY-EIGHTH COUNTERCLAIM
(Declaration of Invalidity of the '385 Patent)

139. Aurobindo incorporates by reference the allegations set forth in Paragraphs 1–138 of the Counterclaims as if fully set forth herein.

140. All claims of the '385 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.

141. For example, as described in the Notice Letter, independent claim 1 of the '385 patent are invalid as obvious under § 103 in light of at least the following prior art: Palepu *et al.*, U.S. Publication No. US 2011/0184036; Treanda® Label (2009); Preiss *et al.*, *Studies on the Pharmacokinetics of Bendamustine (Cytostasan®) in Humans*, 40 PHARMAZIE 782 (1985) and Preiss *et al.*, *Pharmacological and Clinical Data of Bendamustine*, 17th International Cancer Congress (1998); Barth *et al.*, *Bendamustine Plus Rituximab (B-R) Is Significantly Superior to CHOP-R as First-Line Therapy in Indolent and Mantle-Cell Lymphoma*, 12 ONKOLOGISCHE PHARMAZIE 4 (2010); Schoffski *et al.*, *Repeated Administration of Short Infusions of Bendamustine: A Phase I Study in Patients with Advanced Progressive Solid Tumors*, 126 J. CANCER RES. CLIN. ONCOL. 41 (2000) and Schoffski *et al.*, *Weekly Administration of Bendamustine: A Phase I Study in Patients with Advanced Progressive Solid Tumors*, 11 ANNALS OF ONCOL. 729 (2000); and/or Olthoff *et al.*, DD 159289 (March 2, 1983).

142. Aurobindo is entitled to a declaration that the claims of the '385 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. 214576 seeking FDA approval to market bendamustine hydrochloride injection 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 bendamustine hydrochloride product that is the subject of ANDA No. 214576 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. 214576 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 20, 2020

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