

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

TEVA PHARMACEUTICALS)	
INTERNATIONAL GMBH,)	
CEPHALON, INC., and EAGLE)	
PHARMACEUTICALS, INC.,)	
)	
Plaintiffs,)	
)	
v.)	C.A. No. _____
)	
AUROBINDO PHARMA, LTD.,)	
AUROBINDO PHARMA USA, INC., and)	
EUGIA PHARMA SPECIALITIES LTD.,)	
)	
Defendants.)	
_____)	

COMPLAINT

Plaintiffs Teva Pharmaceuticals International GmbH (“Teva Pharmaceuticals”), Cephalon, Inc. (“Cephalon”) (collectively, with Teva Pharmaceuticals, “Teva”), and Eagle Pharmaceuticals, Inc. (“Eagle”) (collectively, “Plaintiffs”), by their attorneys, for their Complaint, allege as follows:

1. This is an action for patent infringement under the patent laws of the United States, 35 U.S.C., 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 Abbreviated New Drug Application (“ANDA”) No. 214576 to the U.S. Food and Drug Administration (“FDA”) seeking approval to commercially manufacture, use, offer for sale, sell, and/or import a generic version 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 10,052,385 (the “385 patent”) (collectively, the “Patents-in-Suit”).

PARTIES

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

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

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

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 principal 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.

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 principal 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.

7. On information and belief, Defendant Eugia Pharma Specialities Ltd. is a corporation organized and existing under the laws of the India having its corporate offices and 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.

8. On 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.

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 units (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.*

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.

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.

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 manufacture Aurobindo’s ANDA Product; and Aurobindo Pharma USA, Inc. will directly or indirectly market, sell, and distribute Aurobindo’s ANDA Product throughout the United States, including in Delaware. 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 that are nearer than arm's length. On information and belief, Aurobindo Pharma, Ltd., Aurobindo Pharma USA, Inc., and Eugia Pharma Specialities Ltd. participated, assisted, and cooperated in carrying out the acts complained about herein.

13. On 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.

JURISDICTION AND VENUE

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

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.

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 subsidiaries Aurobindo Pharma USA, Inc. and Eugia Pharma Specialities Ltd., 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, and/or has engaged in systematic and continuous business contacts within Delaware.

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.

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.

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.

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.

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.

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.

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

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.

VENUE

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

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).

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.

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.

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.

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.

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

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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

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.

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.

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

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

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

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.

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.

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.

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.

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

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.

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.

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.

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.

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.

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.

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.

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.

**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 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).

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.

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.

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.

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.

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.

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.

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.

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.

**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 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).

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.

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.

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.

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.

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.

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.

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.

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.

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.

**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 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).

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.

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.

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.

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.

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.

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.

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.

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.

**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 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).

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.

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.

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.

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.

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.

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.

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.

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.

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.

**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 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).

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.

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.

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.

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.

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.

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.

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.

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.

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.

**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 preceding paragraphs 1–115 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).

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.

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.

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.

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.

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.

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.

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.

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.

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.

**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 preceding paragraphs 1–126 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).

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.

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.

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.

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.

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.

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.

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.

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.

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.

**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 preceding paragraphs 1–137 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).

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.

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.

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.

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.

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.

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.

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.

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.

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.

**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 preceding paragraphs 1–148 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).

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.

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.

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.

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.

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.

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.

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.

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.

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.

**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 preceding paragraphs 1–159 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).

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.

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.

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.

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.

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.

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.

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.

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.

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.

**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 preceding paragraphs 1–170 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).

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.

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.

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.

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.

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.

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.

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.

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.

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.

**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 preceding paragraphs 1–181 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).

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.

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.

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.

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.

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.

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.

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.

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.

**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 preceding paragraphs 1–191 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).

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.

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.

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.

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.

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.

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.

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.

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.

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.

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

207. Plaintiffs incorporate each of the preceding paragraphs 1–202 as if fully set forth herein.

208. Aurobindo has knowledge of the '707 patent.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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

219. Plaintiffs incorporate each of the preceding paragraphs 1–214 as if fully set forth herein.

220. Aurobindo has knowledge of the '831 patent.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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

231. Plaintiffs incorporate each of the preceding paragraphs 1–226 as if fully set forth herein.

232. Aurobindo has knowledge of the '796 patent.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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

244. Plaintiffs incorporate each of the preceding paragraphs 1–239 as if fully set forth herein.

245. Aurobindo has knowledge of the '797 patent.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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

256. Plaintiffs incorporate each of the preceding paragraphs 1–251 as if fully set forth herein.

257. Aurobindo has knowledge of the '908 patent.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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

269. Plaintiffs incorporate each of the preceding paragraphs 1–264 as if fully set forth herein.

270. Aurobindo has knowledge of the '568 patent.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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

282. Plaintiffs incorporate each of the preceding paragraphs 1–277 as if fully set forth herein.

283. Aurobindo has knowledge of the '887 patent.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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

295. Plaintiffs incorporate each of the preceding paragraphs 1–290 as if fully set forth herein.

296. Aurobindo has knowledge of the '397 patent.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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

308. Plaintiffs incorporate each of the preceding paragraphs 1–303 as if fully set forth herein.

309. Aurobindo has knowledge of the '398 patent.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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

321. Plaintiffs incorporate each of the preceding paragraphs 1–316 as if fully set forth herein.

322. Aurobindo has knowledge of the '399 patent.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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

334. Plaintiffs incorporate each of the preceding paragraphs 1–329 as if fully set forth herein.

335. Aurobindo has knowledge of the '021 patent.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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

347. Plaintiffs incorporate each of the preceding paragraphs 1–342 as if fully set forth herein.

348. Aurobindo has knowledge of the '384 patent.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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

360. Plaintiffs incorporate each of the preceding paragraphs 1–355 as if fully set forth herein.

361. Aurobindo has knowledge of the '533 patent.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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

372. Plaintiffs incorporate each of the preceding paragraphs 1–367 as if fully set forth herein.

373. Aurobindo has knowledge of the '385 patent.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs request the following relief:

(a) A judgment that Aurobindo has infringed, will infringe, and will induce and contribute to infringement of the '707, '831, '796, '797, '908, '568, '887, '397, '398, '399, '021, '384, '533, and '385 patents (the "Patents-in-Suit").

(b) A judgment that the Patents-in-Suit are valid and enforceable;

(c) A judgment pursuant to, among other things, 35 U.S.C. § 271(e)(4)(A) ordering that the effective date of any FDA approval for Aurobindo to make, use, offer for sale, sell, market, distribute, or import Aurobindo's ANDA Product, or any product or compound the making, using, offering for sale, sale, marketing, distribution, or importation of which infringes the Patents-in-Suit, shall not be earlier than the latest of the expiration dates of the Patents-in-Suit, inclusive of any extension(s) and additional period(s) of exclusivity;

(d) A preliminary and permanent injunction pursuant to, among other things, 35 U.S.C. §§ 271(e)(4)(B) and 283 enjoining Aurobindo, its officers, agents, servants, employees and attorneys, and all persons acting in concert with them, from making, using, selling, offering for sale, marketing, distributing, or importing Aurobindo's ANDA Product, or any product the making, using, offering for sale, sale, marketing, distribution, or importation of which infringes the Patents-in-Suit, or the inducement of or the contribution to any of the foregoing, prior to the latest of the expiration dates of the Patents-in-Suit, inclusive of any extension(s) and additional period(s) of exclusivity;

(e) A judgment declaring that making, using, selling, offering for sale, marketing, distributing, or importing Aurobindo's ANDA Product, or any product or compound the making, using, offering for sale, sale, marketing, distribution, or importation of which infringes the Patents-in-Suit, prior to the expiration date of the Patents-in-Suit, respectively, will infringe, actively induce infringement of, and/or contribute to the infringement by others of the Patents-in-Suit;

(f) An award of Plaintiffs' damages or other monetary relief to compensate Plaintiffs if Aurobindo engages in the manufacture, use, offer for sale, sale, marketing, distribution, or importation of Aurobindo's ANDA Product, or any product the making, using, offering for sale, sale, marketing, distribution, or importation of which infringes the Patents-in-Suit, or the inducement of or the contribution to any of the foregoing, prior to the latest of the expiration dates of the Patents-in-Suit, inclusive of any extension(s) and additional period(s) of exclusivity, in accordance with 35 U.S.C. § 271(e)(4)(C);

(g) A declaration that this case is an exceptional case and an award of attorneys' fees pursuant to 35 U.S.C. § 285;

- (h) An award of Plaintiffs’ costs and expenses in this action; and
- (i) Such further and other relief as this Court may deem just and proper.

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