

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

BAYER HEALTHCARE LLC and )  
MEDA PHARMACEUTICALS INC., )  
 )  
Plaintiffs, )  
 )  
v. ) C.A. No. \_\_\_\_\_  
 )  
AUROBINDO PHARMA LTD. and )  
AUROBINDO PHARMA USA, INC., )  
 )  
Defendants. )

**COMPLAINT**

Plaintiffs Bayer HealthCare LLC (“Bayer”) and Meda Pharmaceuticals Inc. (“Meda,” and collectively with Bayer, “Plaintiffs”) file this Complaint for patent infringement against Aurobindo Pharma Ltd. and Aurobindo Pharma USA, Inc. (collectively, “Aurobindo”), and by their attorneys, hereby allege as follows:

1. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, and for a declaratory judgment of patent infringement under 28 U.S.C. §§ 2201 and 2202, that arises out of Aurobindo’s submission of a supplement to an Abbreviated New Drug New Drug Application (“ANDA”) to the U.S. Food and Drug Administration (“FDA”) seeking approval to commercially manufacture, use, offer for sale, sell, and/or import an azelastine hydrochloride nasal spray, 0.2055 mg/spray that Aurobindo has identified as a generic version of Children’s Astepro<sup>®</sup> Allergy (azelastine hydrochloride nasal spray, 205.5 mcg/spray, OTC) (“Aurobindo’s Children’s ANDA Product”) prior to the expiration of U.S. Patent No. 8,071,073 (“the ’073 patent”); U.S. Patent No. 8,518,919 (“the ’919 patent”); and U.S. Patent No. 9,919,050 (“the ’050 patent”). These patents are referred to collectively herein as the “Patents-in-Suit.”

2. Aurobindo notified Plaintiffs by letter dated February 13, 2024 (“Aurobindo’s Notice Letter”) that it had submitted to the FDA a supplement to ANDA No. 216561 (“Aurobindo’s ANDA Supplement”), seeking approval from the FDA to engage in the commercial manufacture, use and/or sale of Aurobindo’s Children’s ANDA Product prior to the expiration of the Patents-in-Suit.

### **PARTIES**

3. Plaintiff Bayer HealthCare LLC is a limited liability company organized and existing under the laws of the States of Delaware, with its principal place of business at 100 Bayer Boulevard, Whippany, New Jersey. Bayer HealthCare LLC is the holder of New Drug Application (“NDA”) No. 213872 for the sale of azelastine hydrochloride nasal solution (0.15%, 205.5 mcg/spray, OTC), which has been approved by the FDA.

4. Plaintiff Meda Pharmaceuticals Inc. is a company organized and existing under the laws of the State of Delaware, with its principal place of business at 1000 Mylan Boulevard, Canonsburg, PA 15317.

5. On information and belief, defendant Aurobindo Pharma Ltd. is a company organized and existing under the laws of the Republic of India with a principal place of business at Mairtri 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 corporation organized and existing under the laws of the State of Delaware with a 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 branded pharmaceutical products for the U.S. market.

7. On information and belief, Aurobindo Pharma USA, Inc. is a wholly owned subsidiary of Aurobindo Pharma Ltd. and is controlled and/or dominated by Aurobindo Pharma Ltd.

8. On information and belief, Aurobindo Pharma Ltd. and Aurobindo Pharma USA, Inc. acted in concert to prepare and submit Aurobindo's ANDA Supplement to the FDA.

### **JURISDICTION**

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

10. This Court has personal jurisdiction over each of Aurobindo Pharma Ltd. and Aurobindo Pharma USA, Inc.

11. Aurobindo Pharma Ltd. is subject to personal jurisdiction in Delaware because, among other things, Aurobindo Pharma Ltd., itself and through its wholly-owned subsidiary 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, Aurobindo Pharma Ltd., itself and through its wholly-owned subsidiary Aurobindo Pharma USA, Inc., develops, manufactures, imports, markets, offers to sell, and/or sells generic drugs throughout the United States, including in the State of Delaware, and therefore transacts business within the State of Delaware, and/or has engaged in systematic and continuous business contacts within the State of Delaware. In addition, Aurobindo Pharma Ltd. is subject to personal jurisdiction in Delaware because, on information and belief, it controls Aurobindo Pharma USA, Inc. and therefore the activities of Aurobindo Pharma USA, Inc. in this jurisdiction are attributed to Aurobindo Pharma Ltd.

12. Aurobindo Pharma USA, Inc. is subject to personal jurisdiction in Delaware because, among other things, it has purposely availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court here. Aurobindo Pharma USA, Inc. is a corporation organized and existing under the laws of the State of Delaware, is qualified to do business in Delaware, and has appointed a registered agent for service of process in Delaware. It therefore has consented to general jurisdiction in Delaware. In addition, on information and belief, Aurobindo Pharma USA, Inc. develops, manufactures, imports, markets, offers to sell, and/or sells generic drugs throughout the United States, including in the State of Delaware and therefore transacts business within the State of Delaware related to Plaintiffs' claims, and/or has engaged in systematic and continuous business contacts within the State of Delaware.

13. On information and belief, Aurobindo knows and intends that following any approval of Aurobindo's Children's ANDA Product, Aurobindo will manufacture and import into the United States Aurobindo's Children's ANDA Product and directly or indirectly market, sell, and distribute Aurobindo's Children's ANDA Product throughout the United States, including in Delaware. On information and belief, following any FDA approval of Aurobindo's Children's ANDA Product, Aurobindo knows and intends that Aurobindo's Children's ANDA Product will be marketed, used, distributed, offered for sale, and sold in the United States and within Delaware. On information and belief, following any FDA approval of Aurobindo's Children's ANDA Product, Aurobindo Pharma Ltd. and Aurobindo Pharma USA, Inc. will act in concert to distribute and sell Aurobindo's Children's ANDA Product throughout the United States, including within Delaware.

14. On information and belief, Aurobindo Pharma Ltd. and Aurobindo Pharma USA, Inc. are agents of each other, and/or operate in concert as integrated parts of the same business group, and enter into agreements with each other that are nearer than arm's length, including with respect to the development, regulatory approval, marketing, sale, offer for sale, and distribution of generic pharmaceutical products throughout the United States, including into Delaware, and including with respect to Aurobindo's Children's ANDA Product at issue. On information and belief, Aurobindo Pharma Ltd. and Aurobindo Pharma USA, Inc. together participated in, assisted, and cooperated in the acts complained of herein.

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

16. On information and belief, Aurobindo, with knowledge of the Hatch-Waxman Act process, directed Aurobindo's Notice Letter to Plaintiffs, entities incorporated in Delaware, and alleged in Aurobindo's Notice Letter that all of the Patents-in-Suit are invalid and/or not infringed. On information and belief, Aurobindo knowingly and deliberately challenged Plaintiffs' patent rights, and knew when it did so that it was triggering the forty-five day period for Plaintiffs to bring an action for patent infringement under the Hatch-Waxman Act.

17. Because Plaintiffs are incorporated in Delaware, Plaintiffs suffer injuries and consequences from Aurobindo challenging Plaintiffs' patent rights in Delaware. On information and belief, Aurobindo knew that it was deliberately challenging the patent rights of Delaware entities and seeking to invalidate intellectual property held in Delaware. Aurobindo has been a

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

18. In addition, this Court has personal jurisdiction over Aurobindo because Aurobindo Pharma Ltd. and Aurobindo Pharma USA, Inc. regularly engage in patent litigation concerning FDA-approved branded drug 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 Court. *See, e.g., Bayer Pharma AG et al. v. Aurobindo Pharma Ltd. et al.*, Case No. 23-1372-RGA, D.I. 15 (D. Del. Feb. 23, 2024); *Pfizer Inc. et al. v. Aurobindo Pharma Ltd.*, Case No. 23-1182-GBW, D.I. 7 (D. Del. Oct. 23, 2023); *Merck KGaA et al. v. Aurobindo Pharma USA, Inc. et al.*, Case No. 23-39-GBW, D.I. 10 (D. Del. Sept. 29, 2023); *Amgen Inc. et al. v. Aurobindo Pharma Ltd. et al.*, Case No. 21-662-MN, D.I. 14 (D. Del. June 10, 2021); *Celgene Corp. v. Aurobindo Pharma Ltd. et al.*, Case No. 21-624-SDW, D.I. 12 (D. Del. Mar. 11, 2021); *Pfizer Inc. et al. v. Aurobindo Pharma Ltd. et al.*, Case No. 21-22-LPS, D.I. 9 (D. Del. Feb. 2, 2021); *Novartis Pharmaceuticals Corp. v. Aurobindo Pharma Ltd. et al.*, Case No. 20-1426-LPS, D.I. 11 (Nov. 16, 2020).

19. On information and belief, if Aurobindo receives approval for Aurobindo's Children's ANDA Product, Aurobindo will directly or indirectly manufacture, market, sell, and/or distribute Aurobindo's Children's ANDA Product within the United States, including in Delaware, consistent with Aurobindo's practices for the marketing and distribution of other generic pharmaceutical products. On information and belief, Aurobindo regularly does business in Delaware, and its practices with other generic pharmaceutical products have involved placing those products into the stream of commerce for distribution throughout the United States, including

in Delaware. On information and belief, Aurobindo's generic pharmaceutical products are used and/or consumed within and throughout the United States, including in Delaware. On information and belief, Aurobindo's Children's ANDA Product will be dispensed by pharmacies located within Delaware, and used by patients in Delaware. Each of these activities would have a substantial effect within Delaware and would constitute infringement of the Patents-in-Suit in the event that Aurobindo's Children's ANDA Product is approved before the Patents-in-Suit expire.

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

21. Alternatively, if Aurobindo Pharma Ltd.'s connections with Delaware, including its connections with Aurobindo Pharma USA, Inc., are found to be insufficient to confer personal jurisdiction, then, upon information and belief, Aurobindo Pharma Ltd. is not subject to jurisdiction in any state's courts of general jurisdiction, and exercising jurisdiction over Aurobindo Pharma Ltd. in Delaware is consistent with the United States Constitution and laws. *See* Fed. R. Civ. P. 4(k)(2).

22. This action is directed to Aurobindo's Children's ANDA Product only. Aurobindo has admitted that Aurobindo's Children's ANDA Product was not the subject of any prior litigation or agreement between Aurobindo, Meda, and Bayer.

**VENUE**

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

24. Venue is proper in this district as to Aurobindo Pharma USA, Inc. pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, Aurobindo Pharma USA, Inc. is a corporation organized and existing under the laws of the State of Delaware and is subject to personal jurisdiction in this judicial district.

**FACTUAL BACKGROUND**

25. Children's Astepro<sup>®</sup> Allergy is an over-the-counter nasal spray containing azelastine hydrochloride (0.15%, 205.5 mcg/spray).

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

**COUNT I – INFRINGEMENT OF THE '073 PATENT**

27. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

28. The '073 patent, entitled "Compositions Comprising Azelastine and Methods of Use Thereof" (attached as Exhibit A), was duly and legally issued on December 6, 2011.

29. Meda is the owner and assignee of the '073 patent.

30. Bayer holds an exclusive license to the '073 patent.

31. In general, the claims of the '073 patent are directed to liquid pharmaceutical compositions comprising azelastine hydrochloride for treating allergic rhinitis or non-allergic vasomotor rhinitis.



32. Children's Astepro<sup>®</sup> Allergy is covered by the '073 patent, including at least claims 2 and 3 of the '073 patent, and the '073 patent has been listed in connection with Children's Astepro<sup>®</sup> Allergy in the FDA's Orange Book.

33. In Aurobindo's Notice Letter, Aurobindo notified Plaintiffs of the submission of Aurobindo's ANDA Supplement to the FDA. The purpose of this submission was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and sale and/or importation of Aurobindo's Children's ANDA Product prior to the expiration of the '073 patent.

34. In Aurobindo's Notice Letter, Aurobindo also notified Plaintiffs that, as part of Aurobindo's ANDA Supplement, Aurobindo had filed certifications of the type described in Section 505(j)(2)(B)(iv) of the FDCA, 21 U.S.C. § 355 (j)(2)(B)(iv), with respect to the '073 patent. On information and belief, Aurobindo submitted Aurobindo's ANDA Supplement to the FDA containing certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '073 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Aurobindo's Children's ANDA Product.

35. According to Aurobindo's Notice Letter, Aurobindo's Children's ANDA Product is a nasal spray solution that contains azelastine hydrochloride. On information and belief, Aurobindo's Children's ANDA Product meets the other limitations of at least claims 2 and 3 of the '073 patent.

36. On information and belief, Aurobindo's Children's ANDA Product and the use of Aurobindo's Children's ANDA Product in accordance with its proposed labeling are covered by at least claims 2 and 3 of the '073 patent.

37. In Aurobindo's Notice Letter, Aurobindo did not contest the infringement of claims 2, 3, 7-12, 14, 15, or 18-28 of the '073 patent on any basis other than the alleged invalidity of those claims.

38. Aurobindo's submission of Aurobindo's ANDA Supplement for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Aurobindo's Children's ANDA Product before the expiration of the '073 patent was an act of infringement of the '073 patent under 35 U.S.C. § 271(e)(2)(A).

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

40. On information and belief, the manufacture, use, sale, offer for sale, or importation of Aurobindo's Children's ANDA Product would infringe, literally and/or under the doctrine of equivalents, one or more claims of the '073 patent, including at least claims 2 and 3 of the '073 patent.

41. On information and belief, the manufacture, use, sale, offer for sale, or importation of Aurobindo's Children's ANDA Product in accordance with, and as directed by, its proposed labeling would infringe one or more claims of the '073 patent, including at least claims 2 and 3 of the '073 patent.

42. On information and belief, Aurobindo plans and intends to, and will, actively induce infringement of the '073 patent when Aurobindo's Children's ANDA Product is approved, and plans and intends to, and will, do so immediately and imminently upon approval. Aurobindo's activities will be done with knowledge of the '073 patent and specific intent to infringe that patent.

43. Notwithstanding Aurobindo's knowledge of the claims of the '073 patent, Aurobindo has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Aurobindo's Children's ANDA Product with its proposed labeling following FDA approval of Aurobindo's Children's ANDA Product prior to the expiration of the '073 patent.

44. The foregoing actions by Aurobindo constitute and/or will constitute infringement of the '073 patent and active inducement of infringement by others of the '073 patent.

45. Plaintiffs will be substantially and irreparably damaged by infringement of the '073 patent.

46. Unless Aurobindo is enjoined from infringing the '073 patent and actively inducing infringement of the '073 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

**COUNT II – DECLARATORY JUDGMENT OF INFRINGEMENT  
OF THE '073 PATENT**

47. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

48. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Plaintiffs on the one hand and Aurobindo on the other regarding Aurobindo's infringement and active inducement of infringement of the '073 patent.

49. The Court should declare that the commercial manufacture, use, sale, offer for sale, or importation of Aurobindo's Children's ANDA Product with its proposed labeling will infringe and induce the infringement of the '073 patent.

**COUNT III – INFRINGEMENT OF THE '919 PATENT**

50. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

51. The '919 patent, entitled, "Compositions Comprising Azelastine and Methods of use Thereof" (attached as Exhibit B), was duly and legally issued on August 27, 2013.

52. Meda is the owner and assignee of the '919 patent.

53. Bayer holds an exclusive license to the '919 patent.

54. In general, the claims of the '919 patent are directed to methods for treating allergic rhinitis and non-allergic vasomotor rhinitis comprising administering a liquid pharmaceutical composition comprising azelastine hydrochloride.

55. The use of Children's Astepro<sup>®</sup> Allergy in accordance with its labeling is covered by the '919 patent, including at least claim 1 of the '919 patent, and the '919 patent has been listed in connection with Children's Astepro<sup>®</sup> Allergy in the FDA's Orange Book.

56. In Aurobindo's Notice Letter, Aurobindo notified Plaintiffs of the submission of Aurobindo's ANDA Supplement to the FDA. The purpose of this submission was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and sale and/or importation of Aurobindo's Children's ANDA Product prior to the expiration of the '919 patent.

57. In Aurobindo's Notice Letter, Aurobindo also notified Plaintiffs that, as part of Aurobindo's ANDA Supplement, Aurobindo had filed certifications of the type described in Section 505(j)(2)(B)(iv) of the FDCA, 21 U.S.C. § 355 (j)(2)(B)(iv), with respect to the '919 patent. On information and belief, Aurobindo submitted Aurobindo's ANDA Supplement to the FDA containing certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '919 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Aurobindo's Children's ANDA Product.

58. According to Aurobindo's Notice Letter, Aurobindo's Children's ANDA Product is a nasal spray solution that contains azelastine hydrochloride. On information and belief, the use of Aurobindo's Children's ANDA Product in accordance with its proposed labeling is covered by at least claim 1 of the '919 patent.

59. In Aurobindo's Notice Letter, Aurobindo did not contest the infringement of claims 1-4, 6-10, or 12-20 of the '919 patent on any basis other than the alleged invalidity of those claims.

60. Aurobindo's submission of Aurobindo's ANDA Supplement for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Aurobindo's Children's ANDA Product before the expiration of the '919 patent was an act of infringement of the '919 patent under 35 U.S.C. § 271(e)(2)(A).

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

62. On information and belief, the manufacture, use, sale, offer for sale, or importation of Aurobindo's Children's ANDA Product in accordance with, and as directed by, its proposed labeling would infringe one or more claims of the '919 patent, including at least claim 1 of the '919 patent.

63. On information and belief, Aurobindo plans and intends to, and will, actively induce infringement of the '919 patent when Aurobindo's Children's ANDA Product is approved, and plans and intends to, and will, do so immediately and imminently upon approval. Aurobindo's activities will be done with knowledge of the '919 patent and specific intent to infringe that patent.

64. On information and belief, Aurobindo knows that Aurobindo's Children's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '919 patent, that Aurobindo's Children's ANDA Product is not a staple article or commodity of commerce, and that Aurobindo's Children's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. On information and belief, Aurobindo plans and intends to, and will, contribute to infringement of the '919 patent immediately and imminently upon approval of Aurobindo's Children's ANDA Product.

65. Notwithstanding Aurobindo's knowledge of the claims of the '919 patent, Aurobindo has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Aurobindo's Children's ANDA Product with its proposed labeling following FDA approval of Aurobindo's Children's ANDA Product prior to the expiration of the '919 patent.

66. The foregoing actions by Aurobindo constitute and/or will constitute infringement of the '919 patent; active inducement of infringement of the '919 patent; and contribution to the infringement by others of the '919 patent.

67. Plaintiffs will be substantially and irreparably damaged by infringement of the '919 patent.

68. Unless Aurobindo is enjoined from infringing the '919 patent, actively inducing infringement of the '919 patent, and contributing to the infringement by others of the '919 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

**COUNT IV – DECLARATORY JUDGMENT OF INFRINGEMENT  
OF THE '919 PATENT**

69. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

70. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Plaintiffs on

the one hand and Aurobindo on the other regarding Aurobindo's infringement, active inducement of infringement, and contribution to the infringement by others of the '919 patent.

71. The Court should declare that the commercial manufacture, use, sale, offer for sale, or importation of Aurobindo's Children's ANDA Product with its proposed labeling will infringe, induce the infringement of, and contribute to the infringement by others of the '919 patent.

**COUNT V – INFRINGEMENT OF THE '050 PATENT**

72. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

73. The '050 patent, entitled "Compositions Comprising Azelastine" (attached as Exhibit C), was duly and legally issued on March 20, 2018.

74. Meda is the owner and assignee of the '050 patent.

75. Bayer holds an exclusive license to the '050 patent.

76. In general, the claims of the '050 patent are directed to liquid intranasal compositions comprising azelastine hydrochloride.

77. Children's Astepro<sup>®</sup> Allergy is covered by the '050 patent, including at least claim 1 of the '050 patent, and the '050 patent has been listed in connection with Children's Astepro<sup>®</sup> Allergy in the FDA's Orange Book.

78. In Aurobindo's Notice Letter, Aurobindo notified Plaintiffs of the submission of Aurobindo's ANDA Supplement to the FDA. The purpose of this submission was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and sale and/or importation of Aurobindo's Children's ANDA Product prior to the expiration of the '050 patent.

79. In Aurobindo's Notice Letter, Aurobindo also notified Plaintiffs that, as part of Aurobindo's ANDA Supplement, Aurobindo had filed certifications of the type described in Section 505(j)(2)(B)(iv) of the FDCA, 21 U.S.C. § 355 (j)(2)(B)(iv), with respect to the '050

patent. On information and belief, Aurobindo submitted Aurobindo's ANDA Supplement to the FDA containing certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '050 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Aurobindo's Children's ANDA Product.

80. According to Aurobindo's Notice Letter, Aurobindo's Children's ANDA Product is a nasal spray solution that contains azelastine hydrochloride. On information and belief, Aurobindo's Children's ANDA Product meets the other limitations of at least claim 1 of the '050 patent.

81. On information and belief, Aurobindo's Children's ANDA Product and the use of Aurobindo's Children's ANDA Product in accordance with its proposed labeling are covered by at least claim 1 of the '050 patent.

82. Aurobindo's submission of Aurobindo's ANDA Supplement for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Aurobindo's Children's ANDA Product before the expiration of the '050 patent was an act of infringement of the '050 patent under 35 U.S.C. § 271(e)(2)(A).

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

84. On information and belief, the manufacture, use, sale, offer for sale, or importation of Aurobindo's Children's ANDA Product would infringe, literally and/or under the doctrine of equivalents, one or more claims of the '050 patent, including at least claim 1 of the '050 patent.

85. In Aurobindo's Notice Letter, Aurobindo did not contest the infringement of claims 1-4 or 6-13 of the '050 patent on any basis other than the alleged invalidity of those claims.



86. Aurobindo's submission of Aurobindo's ANDA Supplement for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Aurobindo's Children's ANDA Product before the expiration of the '050 patent was an act of infringement of the '050 patent under 35 U.S.C. § 271(e)(2)(A).

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

88. On information and belief, the manufacture, use, sale, offer for sale, or importation of Aurobindo's Children's ANDA Product would infringe, literally and/or under the doctrine of equivalents, one or more claims of the '050 patent, including at least claim 1 of the '050 patent.

89. On information and belief, the manufacture, use, sale, offer for sale, or importation of Aurobindo's Children's ANDA Product in accordance with, and as directed by, its proposed labeling would infringe one or more claims of the '050 patent, including at least claim 1 of the '050 patent.

90. On information and belief, Aurobindo plans and intends to, and will, actively induce infringement of the '050 patent when Aurobindo's Children's ANDA Product is approved, and plans and intends to, and will, do so immediately and imminently upon approval. Aurobindo's activities will be done with knowledge of the '050 patent and specific intent to infringe that patent.

91. Notwithstanding Aurobindo's knowledge of the claims of the '050 patent, Aurobindo has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Aurobindo's Children's ANDA Product with its proposed labeling following FDA approval of Aurobindo's Children's ANDA Product prior to the expiration of the '050 patent.

92. The foregoing actions by Aurobindo constitute and/or will constitute infringement of the '050 patent and active inducement of infringement of the '050 patent.

93. Plaintiffs will be substantially and irreparably damaged by infringement of the '050 patent.

94. Unless Aurobindo is enjoined from infringing the '050 patent and actively inducing infringement of the '050 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

**COUNT VI – DECLARATORY JUDGMENT OF INFRINGEMENT  
OF THE '050 PATENT**

95. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

96. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Plaintiffs on the one hand and Aurobindo on the other regarding Aurobindo's infringement and active inducement of infringement of the '050 patent.

97. The Court should declare that the commercial manufacture, use, sale, offer for sale, or importation of Aurobindo's Children's ANDA Product with its proposed labeling will infringe and induce the infringement of the '050 patent.

**PRAYER FOR RELIEF**

WHEREFORE, Plaintiffs request the following relief:

a) A judgment that each of the Patents-in-Suit has been infringed by Aurobindo under 35 U.S.C. § 271(e)(2);

b) A judgment ordering that the effective date of any FDA approval of commercial manufacture, use, or sale of Aurobindo's Children's ANDA Product be not earlier than the latest

of the expiration dates of said patents, inclusive of any extension(s) and additional period(s) of exclusivity;

c) A preliminary and permanent injunction enjoining Aurobindo, and all persons acting in concert with Aurobindo, from the commercial manufacture, use, sale, offer for sale, or importation into the United States of Aurobindo's Children's ANDA Product prior to the expiration of said patents, inclusive of any extension(s) and additional period(s) of exclusivity;

d) A judgment declaring that the commercial manufacture, use, sale, offer for sale or importation of Aurobindo's Children's ANDA Product prior to the expiration of said patents, will infringe, induce the infringement of, and contribute to the infringement by others of, said patents;

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

f) Costs and expenses in this action; and

g) Such further and other relief as this Court may deem just and proper.

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