IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BOEHRINGER INGELHEIM PHARMACEUTICALS INC. and BOEHRINGER INGELHEIM INTERNATIONAL GMBH,	)	
Plaintiffs,	)	
v.	)	
	)	C.A. No. _____
ANOBRI PHARMACEUTICALS US, LLC, NANCHANG ANOVENT PHARMACEUTICAL CO., LTD., and SHANGHAI ANOVENT PHARMACEUTICAL CO., LTD.	)	
Defendants.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Boehringer Ingelheim Pharmaceuticals, Inc. and Boehringer Ingelheim International GmbH (collectively, "Plaintiffs"), by their undersigned attorneys, bring this action against Anobri Pharmaceuticals US, LLC (formerly known as Anovent Pharmaceutical (U.S.), LLC), NanChang Anovent Pharmaceutical Co., Ltd., and Shanghai Anovent Pharmaceutical Co., Ltd. (collectively, "Defendants"), and hereby allege as follows:

NATURE OF THE ACTION

1. This action for patent infringement, brought pursuant to the patent laws of the United States, 35 U.S.C. § 1, *et seq*., and in particular under 35 U.S.C §§ 271 (a–c and e), arises from Defendants' submission of Abbreviated New Drug Application (ANDA) No. 216581 to the United States Food and Drug Administration (FDA). Through this ANDA, Defendants seek approval to market a generic version of the pharmaceutical product SPIRIVA® Respimat® prior to the expiration of United States Patent Nos. 7,284,474 ("the '474 patent"), 7,896,264 ("the

'264 patent"), 7,396,341 ("the '6,341 patent"), 9,027,967 ("the '967 patent"), 7,837,235 ("the '235 patent"), and 8,733,341 ("the '3,341 patent") (collectively, "the patents-in-suit"). Plaintiffs seek injunctive relief against infringement, attorneys' fees, and any other relief the Court deems just and proper.

2. This is also an action under 28 U.S.C. §§ 2201–02 for a declaratory judgment of patent infringement arising under the patent laws of the United States, 35 U.S.C. §§ 1, *et seq.*, and in particular under 35 U.S.C. § 271.

THE PARTIES

3. Boehringer Ingelheim Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 900 Ridgebury Road, Ridgefield, Connecticut 06877.

4. Boehringer Ingelheim International GmbH is a private limited liability company organized and existing under the laws of Germany, having a principal place of business at Binger Strasse 173, 55216 Ingelheim, Germany.

5. On information and belief, Shanghai Anovent Pharmaceutical Co., Ltd. is a corporation organized and existing under the laws of China, having a place of business at Room 1019, Yi Building, No. 555, Dongchuan Road, Minhang District, Shanghai, Shanghai 20000-0, China.

6. On information and belief, NanChang Anovent Pharmaceutical Co., Ltd. is a corporation organized and existing under the laws of China, having a place of business at Building B1, Lianbo Science and Technology Park, No. 888, Jingka NanChang 330052.

7. On information and belief, NanChang Anovent Pharmaceutical Co., Ltd. is a subsidiary of Shanghai Anovent Pharmaceutical Co., Ltd.

8. On information and belief, Anobri Pharmaceuticals US, LLC is a limited liability company organized and existing under the laws of Delaware, having its principal place of business at One Gateway Center, Suite 2600, Newark, New Jersey 07102.

9. On information and belief, Anobri Pharmaceuticals US, LLC is a wholly owned subsidiary of NanChang Anovent Pharmaceutical Co., Ltd.

10. On information and belief, Anobri Pharmaceuticals US, LLC amended its certificate of formation in Delaware on May 22, 2023, changing its name from Anovent Pharmaceutical (U.S.), LLC.

11. On information and belief, Anobri Pharmaceuticals US, LLC, in collaboration with NanChang Anovent Pharmaceutical Co., Ltd. and Shanghai Anovent Pharmaceutical Co., Ltd., prepared and submitted ANDA No. 216581 ("Defendants' ANDA"), and they continue to collaborate in seeking FDA approval of Defendants' ANDA.

12. On information and belief, Defendants intend to commercially manufacture, market, offer for sale, and sell the product described in Defendants' ANDA (the "ANDA Product") throughout the United States, including in the State of Delaware, in the event FDA approves Defendants' ANDA.

JURISDICTION AND VENUE

13. This civil action for patent infringement arises under the patent laws of the United States, including 35 U.S.C. § 271, and alleges infringement of the patents-in-suit. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338, and 2201–02.

14. On information and belief, this Court has personal jurisdiction over Anobri Pharmaceuticals US, LLC because it is a Delaware limited liability company and is the agent of NanChang Anovent Pharmaceutical Co., Ltd. and Shanghai Anovent Pharmaceutical Co., Ltd. On

information and belief, Anobri Pharmaceuticals US, LLC is acting as the agent of NanChang Anovent Pharmaceutical Co., Ltd. and Shanghai Anovent Pharmaceutical Co., Ltd. with respect to Defendants' ANDA.

15. On information and belief, this Court has personal jurisdiction over NanChang Anovent Pharmaceutical Co., Ltd. and Shanghai Anovent Pharmaceutical Co., Ltd. because the requirements of Federal Rule of Civil Procedure 4(k)(2) are met: (a) Plaintiffs' claims arise under federal law; (b) NanChang Anovent Pharmaceutical Co., Ltd. and Shanghai Anovent Pharmaceutical Co., Ltd. are foreign defendants not subject to general personal jurisdiction in the courts of any state; and (c) NanChang Anovent Pharmaceutical Co., Ltd. and Shanghai Anovent Pharmaceutical Co., Ltd. have sufficient contacts with the United States as a whole, including, but not limited to, preparing and submitting ANDAs to FDA and/or manufacturing, importing, offering to sell, and/or selling pharmaceutical products to be distributed throughout the United States, such that this Court's exercise of jurisdiction over NanChang Anovent Pharmaceutical Co., Ltd. and Shanghai Anovent Pharmaceutical Co., Ltd. satisfies due process.

16. On information and belief, this Court also has jurisdiction over Defendants because, *inter alia*, this action arises from actions of Defendants directed toward Delaware and because Defendants have purposefully availed themselves of the rights and benefits of Delaware law by engaging in systematic and continuous contacts with Delaware.

17. On information and belief, Defendants have committed, aided, abetted, contributed to, and/or participated in the commission of acts of patent infringement that will lead to foreseeable harm and injury to Plaintiffs, which manufacture SPIRIVA® Respimat® for sale and use throughout the United States, including this Judicial District. On information and belief, Anobri Pharmaceuticals US, LLC has submitted, caused to be submitted, or aided and abetted in the

preparation or submission of Defendants' ANDA. On information and belief, in the event that FDA approves Defendants' ANDA, Anobri Pharmaceuticals US, LLC, with the participation of NanChang Anovent Pharmaceutical Co., Ltd. and Shanghai Anovent Pharmaceutical Co., Ltd., intends to commercially manufacture, import, market, offer for sale, and sell the ANDA Product throughout the United States and in this Judicial District.

18. At least because, on information and belief, Anobri Pharmaceuticals US, LLC is a Delaware limited liability company, venue is proper in this Judicial District as to Anobri Pharmaceuticals US, LLC pursuant to 28 U.S.C. § 1400(b).

19. At least because, on information and belief, NanChang Anovent Pharmaceutical Co., Ltd. and Shanghai Anovent Pharmaceutical Co., Ltd. are foreign corporations, venue is proper in this Judicial District as to NanChang Anovent Pharmaceutical Co., Ltd. and Shanghai Anovent Pharmaceutical Co., Ltd. pursuant to 28 U.S.C. §§ 1391(c)(3) and 1400(b).

PLAINTIFFS' APPROVED SPIRIVA® RESPIMAT® DRUG PRODUCT AND PATENTS-IN-SUIT

20. Plaintiffs make and sell SPIRIVA® Respimat®, a product that is used as an anticholinergic agent indicated for the long-term, once-daily, maintenance treatment of bronchospasm associated with chronic obstructive pulmonary disease (COPD), and for reducing COPD exacerbations. A true and correct copy of the prescribing label for SPIRIVA® Respimat® is attached hereto as Exhibit A.

21. Boehringer Ingelheim Pharmaceuticals, Inc. is the holder of New Drug Application (NDA) No. 021936 for SPIRIVA® Respimat® and a licensee of the patents-in-suit. FDA first approved NDA No. 021936 for SPIRIVA® Respimat® in September 2014.

22. Boehringer Ingelheim International GmbH owns the ’474 patent, which is listed in the Approved Drug Products With Therapeutic Equivalence Evaluations (an FDA publication commonly known as the “Orange Book”) for SPIRIVA® Respimat®.

23. The ’474 patent is entitled “Piston-Pumping System having O-ring Seal Properties” and was duly and lawfully issued by the USPTO on October 23, 2007. The ’474 patent is attached hereto as Exhibit B.

24. Boehringer Ingelheim International GmbH owns the ’264 patent, which is listed in the Orange Book for SPIRIVA® Respimat®.

25. The ’264 patent is entitled “Microstructured High Pressure Nozzle with Built-in Filter Function” and was duly and lawfully issued by the USPTO on March 1, 2011. The ’264 patent is attached hereto as Exhibit C.

26. Boehringer Ingelheim International GmbH owns the ’6,341 patent, which is listed in the Orange Book for SPIRIVA® Respimat®.

27. The ’6,341 patent is entitled “Blocking Device for a Locking Stressing Mechanism having a Spring-Actuated Output Drive Device” and was duly and lawfully issued by the USPTO on July 8, 2008. The ’6,341 patent is attached hereto as Exhibit D.

28. Boehringer Ingelheim International GmbH owns the ’967 patent, which is listed in the Orange Book for SPIRIVA® Respimat®.

29. The ’967 patent is entitled “Device for Clamping a Fluidic Component” and was duly and lawfully issued by the USPTO on May 12, 2015. The ’967 patent is attached hereto as Exhibit E.

30. Boehringer Ingelheim International GmbH owns the ’235 patent, which is listed in the Orange Book for SPIRIVA® Respimat®.

31. The ’235 patent is entitled “Device for Clamping a Fluidic Component” and was duly and lawfully issued by the USPTO on November 23, 2010. The ’235 patent is attached hereto as Exhibit F.

32. Boehringer Ingelheim International GmbH owns the ’3,341 patent, which is listed in the Orange Book for SPIRIVA® Respimat®.

33. The ’3,341 patent is entitled “Atomizer and Method of Atomizing Fluid with a Nozzle Rinsing Mechanism” and was duly and lawfully issued by the USPTO on May 27, 2014. The ’3,341 patent is attached hereto as Exhibit G.

DEFENDANTS’ ANDA

34. On information and belief, Defendants have submitted or caused to be submitted Defendants’ ANDA to FDA under 21 U.S.C. § 355(j), in order to obtain approval to engage in the commercial manufacture, use, or sale of tiotropium bromide inhalation spray as a purported generic version of SPIRIVA® Respimat® prior to the expiration of the patents-in-suit.

35. On information and belief, on or about May 18, 2023, Defendants mailed Plaintiffs a letter regarding “notice and information required by 21 U.S.C. §§ 355(j)(2)(B)(i) and (ii)” (“Notice Letter”). The Notice Letter represented that Defendants had submitted to FDA Defendants’ ANDA and a purported Paragraph IV certification to obtain approval to engage in the commercial manufacture, use, or sale of the product described in Defendants’ ANDA before the expiration of the patents-in-suit, which are listed in the Orange Book for SPIRIVA® Respimat®. Hence, Defendants’ purpose in submitting Defendants’ ANDA is to manufacture and market the ANDA Product before the expiration of the patents-in-suit.

36. The only dosage form referenced in Defendants’ Notice Letter is tiotropium bromide inhalation spray, 2.5 mcg/actuation.

37. Defendants' Notice Letter contained a purported detailed statement of the factual and legal bases for Defendants' Paragraph IV certification ("Detailed Statement").

38. The Detailed Statement conclusorily alleges that the '474 patent will not be infringed by the commercial manufacture, use, or sale of the ANDA Product.

39. The Detailed Statement conclusorily alleges that the '264 patent will not be infringed by the commercial manufacture, use, or sale of the ANDA Product.

40. The Detailed Statement conclusorily alleges that the '6,341 patent will not be infringed by the commercial manufacture, use, or sale of the ANDA Product.

41. The Detailed Statement alleges that the '967 patent is invalid.

42. The Detailed Statement alleges that the '235 patent is invalid.

43. The Detailed Statement conclusorily alleges that the '3,341 patent will not be infringed by the commercial manufacture, use, or sale of the ANDA Product.

44. Defendants' Notice Letter contained a purported offer of confidential access ("Defendants' Offer"). Defendants' Offer did not permit any of Plaintiffs' in-house attorneys to access Defendants' ANDA. Defendants' Offer also did not permit scientific consultants to access Defendants' ANDA. In addition, Defendants' Offer contained provisions that unreasonably restricted counsel receiving access to Defendants' ANDA. The restrictions that Defendants' Offer placed on access to Defendants' ANDA contravene 21 U.S.C. § 355(j)(5)(C)(i)(III), which states that an offer of confidential access "shall contain such restrictions as to persons entitled to access, and on the use and disposition of any information accessed, as would apply had a protective order been entered for the purpose of protecting trade secrets and other confidential business information." Outside counsel for Plaintiffs negotiated in good faith with counsel for Defendants and were ultimately able to reach agreement on the terms of confidential access to Defendants'

ANDA. Following that agreement, however, Defendants produced only limited information about the proposed inhaler from Defendants' ANDA and unreasonably refused to produce other portions of Defendants' ANDA. Defendants also unreasonably refused to provide samples of the proposed inhaler. Defendants further unreasonably objected to a scientific consultant identified by Plaintiffs. Defendants thus have not provided reasonable access to Defendants' ANDA, and Defendants' actions have impeded Plaintiffs' ability to evaluate Defendants' contentions that the proposed inhaler does not infringe certain of the patents-in-suit.

45. On information and belief, Defendants have participated in the preparation and submission of Defendants' ANDA, have provided material support to the preparation and submission of Defendants' ANDA, and intend to support the further prosecution of Defendants' ANDA.

46. On information and belief, if FDA approves Defendants' ANDA, Defendants will manufacture, offer for sale, or sell the ANDA Product within the United States, including within Delaware, or will import the ANDA Product into the United States, including Delaware.

47. Alternatively, on information and belief, if FDA approves Defendants' ANDA, Defendants will actively induce or contribute to the manufacture, use, offer for sale, or sale of the ANDA Product within the United States, including within Delaware, or will import the ANDA Product into the United States, including Delaware. On information and belief, Defendants' ANDA Product is especially adapted for a use that infringes one or more claims of the patents-in-suit and there is no substantial noninfringing use for Defendants' ANDA Product.

48. This action is being filed within forty-five days of Plaintiffs' receipt of the Notice Letter, pursuant to 21 U.S.C. § 355(j)(5)(B)(iii).

COUNT I
INFRINGEMENT OF THE ’474 PATENT

49. Plaintiffs incorporate by reference paragraphs 1–48 as if fully set forth herein.

50. On information and belief, Defendants have submitted or caused the submission of Defendants’ ANDA to FDA and continue to seek FDA approval of Defendants’ ANDA.

51. Defendants have infringed the ’474 patent under 35 U.S.C. § 271(e)(2)(A) by submitting Defendants’ ANDA with a Paragraph IV certification and seeking FDA approval of Defendants’ ANDA prior to the expiration of the ’474 patent.

52. On information and belief, if Defendants’ ANDA is approved, Defendants and their affiliates will make, offer for sale, sell, import, or otherwise distribute the ANDA Product in the United States, including in the State of Delaware, directly infringing one or more claims of the ’474 patent.

53. Defendants’ commercial manufacture, use, offer for sale, sale, or importation into the United States of the ANDA Product would actively induce and/or contribute to the infringement of the ’474 patent. Accordingly, unless enjoined by this Court, upon FDA approval of ANDA No. 216581, Defendants will make, use, offer to sell, or sell the ANDA Product within the United States, or will import the ANDA Product into the United States, and will thereby contribute to the infringement of and/or induce the infringement of one or more claims of the ’474 patent.

54. Defendants had actual knowledge of the ’474 patent prior to submitting Defendants’ ANDA and were aware that the submission of Defendants’ ANDA with the request for FDA approval prior to the expiration of the ’474 patent would constitute an act of infringement of the ’474 patent. Defendants had no reasonable basis for asserting that the commercial

manufacture, use, offer for sale, or sale of the ANDA Product will not directly infringe, contribute to the infringement of, and/or induce the infringement of the ’474 patent.

55. In addition, Defendants submitted Defendants’ ANDA without adequate justification for asserting the ’474 patent to be invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of the ANDA Product. Defendants’ conduct in certifying invalidity, unenforceability, and/or non-infringement with respect to the ’474 patent thus renders this case “exceptional” under 35 U.S.C. § 285.

56. Plaintiffs will be irreparably harmed if Defendants are not enjoined from infringing and from actively inducing or contributing to the infringement of the ’474 patent. Plaintiffs do not have an adequate remedy at law and, considering the balance of hardships between Plaintiffs and Defendants, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT II
INFRINGEMENT OF THE ’264 PATENT

57. Plaintiffs incorporate by reference paragraphs 1–56 as if fully set forth herein.

58. On information and belief, Defendants have submitted or caused the submission of Defendants’ ANDA to FDA and continue to seek FDA approval of Defendants’ ANDA.

59. Defendants have infringed the ’264 patent under 35 U.S.C. § 271(e)(2)(A) by submitting Defendants’ ANDA with a Paragraph IV certification and seeking FDA approval of Defendants’ ANDA prior to the expiration of the ’264 patent.

60. On information and belief, if Defendants’ ANDA is approved, Defendants and their affiliates will make, offer for sale, sell, import, or otherwise distribute the ANDA Product in the United States, including in the State of Delaware, directly infringing one or more claims of the ’264 patent.

61. Defendants' commercial manufacture, use, offer for sale, sale, or importation into the United States of the ANDA Product would actively induce and/or contribute to the infringement of the '264 patent. Accordingly, unless enjoined by this Court, upon FDA approval of ANDA No. 216581, Defendants will make, use, offer to sell, or sell the ANDA Product within the United States, or will import the ANDA Product into the United States, and will thereby contribute to the infringement of and/or induce the infringement of one or more claims of the '264 patent.

62. Defendants had actual knowledge of the '264 patent prior to submitting Defendants' ANDA and were aware that the submission of Defendants' ANDA with the request for FDA approval prior to the expiration of the '264 patent would constitute an act of infringement of the '264 patent. Defendants had no reasonable basis for asserting that the commercial manufacture, use, offer for sale, or sale of the ANDA Product will not directly infringe, contribute to the infringement of, and/or induce the infringement of the '264 patent.

63. In addition, Defendants submitted Defendants' ANDA without adequate justification for asserting the '264 patent to be invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of the ANDA Product. Defendants' conduct in certifying invalidity, unenforceability, and/or non-infringement with respect to the '264 patent thus renders this case "exceptional" under 35 U.S.C. § 285.

64. Plaintiffs will be irreparably harmed if Defendants are not enjoined from infringing and from actively inducing or contributing to the infringement of the '264 patent. Plaintiffs do not have an adequate remedy at law and, considering the balance of hardships between Plaintiffs and Defendants, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT III
INFRINGEMENT OF THE ’6,341 PATENT

65. Plaintiffs incorporate by reference paragraphs 1–64 as if fully set forth herein.

66. On information and belief, Defendants have submitted or caused the submission of Defendants’ ANDA to FDA and continue to seek FDA approval of Defendants’ ANDA.

67. Defendants have infringed the ’6,341 patent under 35 U.S.C. § 271(e)(2)(A) by submitting Defendants’ ANDA with a Paragraph IV certification and seeking FDA approval of Defendants’ ANDA prior to the expiration of the ’6,341 patent.

68. On information and belief, if Defendants’ ANDA is approved, Defendants and their affiliates will make, offer for sale, sell, import, or otherwise distribute the ANDA Product in the United States, including in the State of Delaware, directly infringing one or more claims of the ’6,341 patent.

69. Defendants’ commercial manufacture, use, offer for sale, sale, or importation into the United States of the ANDA Product would actively induce and/or contribute to the infringement of the ’6,341 patent. Accordingly, unless enjoined by this Court, upon FDA approval of ANDA No. 216581, Defendants will make, use, offer to sell, or sell the ANDA Product within the United States, or will import the ANDA Product into the United States, and will thereby contribute to the infringement of and/or induce the infringement of one or more claims of the ’6,341 patent.

70. Defendants had actual knowledge of the ’6,341 patent prior to submitting Defendants’ ANDA and were aware that the submission of Defendants’ ANDA with the request for FDA approval prior to the expiration of the ’6,341 patent would constitute an act of infringement of the ’6,341 patent. Defendants had no reasonable basis for asserting that the

commercial manufacture, use, offer for sale, or sale of the ANDA Product will not directly infringe, contribute to the infringement of, and/or induce the infringement of the ’6,341 patent.

71. In addition, Defendants submitted Defendants’ ANDA without adequate justification for asserting the ’6,341 patent to be invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of the ANDA Product. Defendants’ conduct in certifying invalidity, unenforceability, and/or non-infringement with respect to the ’6,341 patent thus renders this case “exceptional” under 35 U.S.C. § 285.

72. Plaintiffs will be irreparably harmed if Defendants are not enjoined from infringing and from actively inducing or contributing to the infringement of the ’6,341 patent. Plaintiffs do not have an adequate remedy at law and, considering the balance of hardships between Plaintiffs and Defendants, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT IV
INFRINGEMENT OF THE ’967 PATENT

73. Plaintiffs incorporate by reference paragraphs 1–72 as if fully set forth herein.

74. On information and belief, Defendants have submitted or caused the submission of Defendants’ ANDA to FDA and continue to seek FDA approval of Defendants’ ANDA.

75. Defendants have infringed the ’967 patent under 35 U.S.C. § 271(e)(2)(A) by submitting Defendants’ ANDA with a Paragraph IV certification and seeking FDA approval of Defendants’ ANDA prior to the expiration of the ’967 patent.

76. On information and belief, if Defendants’ ANDA is approved, Defendants and their affiliates will make, offer for sale, sell, import, or otherwise distribute the ANDA Product in the United States, including in the State of Delaware, directly infringing one or more claims of the ’967 patent.

77. Defendants' commercial manufacture, use, offer for sale, sale, or importation into the United States of the ANDA Product would actively induce and/or contribute to the infringement of the '967 patent. Accordingly, unless enjoined by this Court, upon FDA approval of ANDA No. 216581, Defendants will make, use, offer to sell, or sell the ANDA Product within the United States, or will import the ANDA Product into the United States, and will thereby contribute to the infringement of and/or induce the infringement of one or more claims of the '967 patent.

78. Defendants had actual knowledge of the '967 patent prior to submitting Defendants' ANDA and were aware that the submission of Defendants' ANDA with the request for FDA approval prior to the expiration of the '967 patent would constitute an act of infringement of the '967 patent. Defendants had no reasonable basis for asserting that the commercial manufacture, use, offer for sale, or sale of the ANDA Product will not directly infringe, contribute to the infringement of, and/or induce the infringement of the '967 patent.

79. In addition, Defendants submitted Defendants' ANDA without adequate justification for asserting the '967 patent to be invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of the ANDA Product. Defendants' conduct in certifying invalidity, unenforceability, and/or non-infringement with respect to the '967 patent thus renders this case "exceptional" under 35 U.S.C. § 285.

80. Plaintiffs will be irreparably harmed if Defendants are not enjoined from infringing and from actively inducing or contributing to the infringement of the '967 patent. Plaintiffs do not have an adequate remedy at law and, considering the balance of hardships between Plaintiffs and Defendants, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT V
INFRINGEMENT OF THE ’235 PATENT

81. Plaintiffs incorporate by reference paragraphs 1–80 as if fully set forth herein.

82. On information and belief, Defendants have submitted or caused the submission of Defendants’ ANDA to FDA and continue to seek FDA approval of Defendants’ ANDA.

83. Defendants have infringed the ’235 patent under 35 U.S.C. § 271(e)(2)(A) by submitting Defendants’ ANDA with a Paragraph IV certification and seeking FDA approval of Defendants’ ANDA prior to the expiration of the ’235 patent.

84. On information and belief, if Defendants’ ANDA is approved, Defendants and their affiliates will make, offer for sale, sell, import, or otherwise distribute the ANDA Product in the United States, including in the State of Delaware, directly infringing one or more claims of the ’235 patent.

85. Defendants’ commercial manufacture, use, offer for sale, sale, or importation into the United States of the ANDA Product would actively induce and/or contribute to the infringement of the ’235 patent. Accordingly, unless enjoined by this Court, upon FDA approval of ANDA No. 216581, Defendants will make, use, offer to sell, or sell the ANDA Product within the United States, or will import the ANDA Product into the United States, and will thereby contribute to the infringement of and/or induce the infringement of one or more claims of the ’235 patent.

86. Defendants had actual knowledge of the ’235 patent prior to submitting Defendants’ ANDA and was aware that the submission of Defendants’ ANDA with the request for FDA approval prior to the expiration of the ’235 patent would constitute an act of infringement of the ’235 patent. Defendants had no reasonable basis for asserting that the commercial

manufacture, use, offer for sale, or sale of the ANDA Product will not directly infringe, contribute to the infringement of, and/or induce the infringement of the ’235 patent.

87. In addition, Defendants submitted Defendants’ ANDA without adequate justification for asserting the ’235 patent to be invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of the ANDA Product. Defendants’ conduct in certifying invalidity, unenforceability, and/or non-infringement with respect to the ’235 patent thus renders this case “exceptional” under 35 U.S.C. § 285.

88. Plaintiffs will be irreparably harmed if Defendants are not enjoined from infringing and from actively inducing or contributing to the infringement of the ’235 patent. Plaintiffs do not have an adequate remedy at law and, considering the balance of hardships between Plaintiffs and Defendants, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT VI
INFRINGEMENT OF THE ’3,341 PATENT

89. Plaintiffs incorporate by reference paragraphs 1–88 as if fully set forth herein.

90. On information and belief, Defendants have submitted or caused the submission of Defendants’ ANDA to FDA and continue to seek FDA approval of Defendants’ ANDA.

91. Defendants have infringed the ’3,341 patent under 35 U.S.C. § 271(e)(2)(A) by submitting Defendants’ ANDA with a Paragraph IV certification and seeking FDA approval of Defendants’ ANDA prior to the expiration of the ’3,341 patent.

92. On information and belief, if Defendants’ ANDA is approved, Defendants and their affiliates will make, offer for sale, sell, import, or otherwise distribute the ANDA Product in the United States, including in the State of Delaware, directly infringing one or more claims of the ’3,341 patent.

93. Defendants' commercial manufacture, use, offer for sale, sale, or importation into the United States of the ANDA Product would actively induce and/or contribute to the infringement of the '3,341 patent. Accordingly, unless enjoined by this Court, upon FDA approval of ANDA No. 216581, Defendants will make, use, offer to sell, or sell the ANDA Product within the United States, or will import the ANDA Product into the United States, and will thereby contribute to the infringement of and/or induce the infringement of one or more claims of the '3,341 patent.

94. Defendants had actual knowledge of the '3,341 patent prior to submitting Defendants' ANDA and were aware that the submission of Defendants' ANDA with the request for FDA approval prior to the expiration of the '3,341 patent would constitute an act of infringement of the '3,341 patent. Defendants had no reasonable basis for asserting that the commercial manufacture, use, offer for sale, or sale of the ANDA Product will not directly infringe, contribute to the infringement of, and/or induce the infringement of the '3,341 patent.

95. In addition, Defendants submitted Defendants' ANDA without adequate justification for asserting the '3,341 patent to be invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of the ANDA Product. Defendants' conduct in certifying invalidity, unenforceability, and/or non-infringement with respect to the '3,341 patent thus renders this case "exceptional" under 35 U.S.C. § 285.

96. Plaintiffs will be irreparably harmed if Defendants are not enjoined from infringing and from actively inducing or contributing to the infringement of the '3,341 patent. Plaintiffs do not have an adequate remedy at law and, considering the balance of hardships between Plaintiffs and Defendants, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT VII
DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '474 PATENT

97. Plaintiffs incorporate by reference paragraphs 1–96 as if fully set forth herein.

98. Plaintiffs' claims also arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

99. On information and belief, if Defendants' ANDA is approved, the ANDA Product will be made, offered for sale, sold, or otherwise distributed in the United States, including in the State of Delaware, by or through Defendants and their affiliates.

100. On information and belief, Defendants know that healthcare professionals or patients will use the ANDA Product in accordance with the labeling sought by Defendants' ANDA, and Defendants will therefore contribute to the infringement of and/or induce the infringement of one or more claims of the '474 patent under one or more of 35 U.S.C. §§ 271(a), (b), and (c).

101. On information and belief, Defendants' infringing activity, including the commercial manufacture, use, offer to sell, sale, or importation of the ANDA Product complained of herein will begin immediately after FDA approves Defendants' ANDA. Any such conduct before the '474 patent expires will contribute to the infringement of and/or induce the infringement of one or more claims of the '474 patent under one or more of 35 U.S.C. §§ 271(a), (b), and (c).

102. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiffs and Defendants concerning liability for the infringement of the '474 patent for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

103. Plaintiffs will be substantially and irreparably harmed by Defendants' infringing activities unless those activities are enjoined by this Court. Plaintiffs have no adequate remedy at law.

104. This case is exceptional, and Plaintiffs are entitled to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT VIII
DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '264 PATENT

105. Plaintiffs incorporate by reference paragraphs 1–104 as if fully set forth herein.

106. Plaintiffs' claims also arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

107. On information and belief, if Defendants' ANDA is approved, the ANDA Product will be made, offered for sale, sold, or otherwise distributed in the United States, including in the State of Delaware, by or through Defendants and their affiliates.

108. On information and belief, Defendants know that healthcare professionals or patients will use the ANDA Product in accordance with the labeling sought by Defendants' ANDA, and Defendants will therefore contribute to the infringement of and/or induce the infringement of one or more claims of the '264 patent under one or more of 35 U.S.C. §§ 271(a), (b), and (c).

109. On information and belief, Defendants' infringing activity, including the commercial manufacture, use, offer to sell, sale, or importation of the ANDA Product complained of herein will begin immediately after FDA approves Defendants' ANDA. Any such conduct before the '264 patent expires will contribute to the infringement of and/or induce the infringement of one or more claims of the '264 patent under one or more of 35 U.S.C. §§ 271(a), (b), and (c).

110. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiffs and Defendants concerning liability for the infringement of the ’264 patent for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

111. Plaintiffs will be substantially and irreparably harmed by Defendants’ infringing activities unless those activities are enjoined by this Court. Plaintiffs have no adequate remedy at law.

112. This case is exceptional, and Plaintiffs are entitled to an award of attorneys’ fees under 35 U.S.C. § 285.

COUNT IX
DECLARATORY JUDGMENT OF INFRINGEMENT OF THE ’6,341 PATENT

113. Plaintiffs incorporate by reference paragraphs 1–112 as if fully set forth herein.

114. Plaintiffs’ claims also arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

115. On information and belief, if Defendants’ ANDA is approved, the ANDA Product will be made, offered for sale, sold, or otherwise distributed in the United States, including in the State of Delaware, by or through Defendants and their affiliates.

116. On information and belief, Defendants know that healthcare professionals or patients will use the ANDA Product in accordance with the labeling sought by Defendants’ ANDA, and Defendants will therefore contribute to the infringement of and/or induce the infringement of one or more claims of the ’6,341 patent under one or more of 35 U.S.C. §§ 271(a), (b), and (c).

117. On information and belief, Defendants’ infringing activity, including the commercial manufacture, use, offer to sell, sale, or importation of the ANDA Product complained

of herein will begin immediately after FDA approves Defendants' ANDA. Any such conduct before the '6,341 patent expires will contribute to the infringement of and/or induce the infringement of one or more claims of the '6,341 patent under one or more of 35 U.S.C. §§ 271(a), (b), and (c).

118. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiffs and Defendants concerning liability for the infringement of the '6,341 patent for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

119. Plaintiffs will be substantially and irreparably harmed by Defendants' infringing activities unless those activities are enjoined by this Court. Plaintiffs have no adequate remedy at law.

120. This case is exceptional, and Plaintiffs are entitled to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT X
DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '967 PATENT

121. Plaintiffs incorporate by reference paragraphs 1–120 as if fully set forth herein.

122. Plaintiffs' claims also arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

123. On information and belief, if Defendants' ANDA is approved, the ANDA Product will be made, offered for sale, sold, or otherwise distributed in the United States, including in the State of Delaware, by or through Defendants and their affiliates.

124. On information and belief, Defendants know that healthcare professionals or patients will use the ANDA Product in accordance with the labeling sought by Defendants' ANDA, and Defendants will therefore contribute to the infringement of and/or induce the

infringement of one or more claims of the ’967 patent under one or more of 35 U.S.C. §§ 271(a), (b), and (c).

125. On information and belief, Defendants’ infringing activity, including the commercial manufacture, use, offer to sell, sale, or importation of the ANDA Product complained of herein will begin immediately after FDA approves Defendants’ ANDA. Any such conduct before the ’967 patent expires will contribute to the infringement of and/or induce the infringement of one or more claims of the ’967 patent under one or more of 35 U.S.C. §§ 271(a), (b), and (c).

126. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiffs and Defendants concerning liability for the infringement of the ’967 patent for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

127. Plaintiffs will be substantially and irreparably harmed by Defendants’ infringing activities unless those activities are enjoined by this Court. Plaintiffs have no adequate remedy at law.

128. This case is exceptional, and Plaintiffs are entitled to an award of attorneys’ fees under 35 U.S.C. § 285.

COUNT XI
DECLARATORY JUDGMENT OF INFRINGEMENT OF THE ’235 PATENT

129. Plaintiffs incorporate by reference paragraphs 1–128 as if fully set forth herein.

130. Plaintiffs’ claims also arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

131. On information and belief, if Defendants’ ANDA is approved, the ANDA Product will be made, offered for sale, sold, or otherwise distributed in the United States, including in the State of Delaware, by or through Defendants and their affiliates.

132. On information and belief, Defendants know that healthcare professionals or patients will use the ANDA Product in accordance with the labeling sought by Defendants' ANDA, and Defendants will therefore contribute to the infringement of and/or induce the infringement of one or more claims of the '235 patent under one or more of 35 U.S.C. §§ 271(a), (b), and (c).

133. On information and belief, Defendants' infringing activity, including the commercial manufacture, use, offer to sell, sale, or importation of the ANDA Product complained of herein will begin immediately after FDA approves Defendants' ANDA. Any such conduct before the '235 patent expires will contribute to the infringement of and/or induce the infringement of one or more claims of the '235 patent under one or more of 35 U.S.C. §§ 271(a), (b), (c), (f), and (g).

134. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiffs and Defendants concerning liability for the infringement of the '235 patent for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

135. Plaintiffs will be substantially and irreparably harmed by Defendants' infringing activities unless those activities are enjoined by this Court. Plaintiffs have no adequate remedy at law.

136. This case is exceptional, and Plaintiffs are entitled to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT XII
DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '3,341 PATENT

137. Plaintiffs incorporate by reference paragraphs 1–136 as if fully set forth herein.

138. Plaintiffs' claims also arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

139. On information and belief, if Defendants' ANDA is approved, the ANDA Product will be made, offered for sale, sold, or otherwise distributed in the United States, including in the State of Delaware, by or through Defendants and their affiliates.

140. On information and belief, Defendants know that healthcare professionals or patients will use the ANDA Product in accordance with the labeling sought by Defendants' ANDA, and Defendants will therefore contribute to the infringement of and/or induce the infringement of one or more claims of the '3,341 patent under one or more of 35 U.S.C. §§ 271(a), (b), (c), (f), and (g).

141. On information and belief, Defendants' infringing activity, including the commercial manufacture, use, offer to sell, sale, or importation of the ANDA Product complained of herein will begin immediately after FDA approves Defendants' ANDA. Any such conduct before the '3,341 patent expires will contribute to the infringement of and/or induce the infringement of one or more claims of the '3,341 patent under one or more of 35 U.S.C. §§ 271(a), (b), (c), (f), and (g).

142. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiffs and Defendants concerning liability for the infringement of the '3,341 patent for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

143. Plaintiffs will be substantially and irreparably harmed by Defendants' infringing activities unless those activities are enjoined by this Court. Plaintiffs have no adequate remedy at law.

144. This case is exceptional, and Plaintiffs are entitled to an award of attorneys' fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

Wherefore, Plaintiffs respectfully request the following relief:

A. A judgment that Defendants have infringed one or more claims of the '474, '264, '6,341, '967, '235 and '3,341 patents under 35 U.S.C. § 271(e)(2)(A);

B. A declaratory judgment that, under one or more of 35 U.S.C. §§ 271(a), (b), and (c), Defendants' commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of the ANDA Product, or inducing or contributing to such conduct, would constitute infringement of one or more claims of the '474, '264, '6,341, '967, '235 and '3,341 patents;

C. A permanent injunction, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining Defendants, their affiliates and subsidiaries, and all persons and entities acting in concert with Defendants, from commercially manufacturing, using, offering for sale, or selling or importing any product that infringes the '474, '264, '6,341, '967, '235, and '3,341 patents, including the ANDA Product described in ANDA No. 216581;

D. The entry of an order, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any FDA approval of ANDA No. 216581 shall be no earlier than the expiration date of the '474, '264, '6,341, '967, '235, and '3,341 patents, or any later expiration of exclusivity for the '474, '264, '6,341, '967, '235, and '3,341 patents, including any extensions or regulatory exclusivities;

E. A declaration under 28 U.S.C. § 2201 that if Defendants, their officers, agents, servants, employees, licensees, representatives, and attorneys, and any other persons acting or attempting to act in active concert or participation with them or acting on their behalf, engage in the commercial manufacture, use, offer for sale, sale and/or importation of the product described

in ANDA No. 216581, it will constitute an act of direct and/or indirect infringement of the '474, '264, '6,341, '967, '235, and '3,341 patents;

F. An award of damages or other relief, pursuant to 35 U.S.C. § 271(e)(4)(C), if Defendants engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the ANDA Product, or any product that infringes the '474, '264, '6,341, '967, '235, and '3,341 patents, or induces or contributes to such conduct, prior to the expiration of the '474, '264, '6,341, '967, '235, and '3,341 patents, or any later expiration of exclusivity for the '474, '264, '6,341, '967, '235, and '3,341 patents, including any extensions or regulatory exclusivities;

G. The entry of a judgment declaring that Defendants' acts render this case an exceptional case and awarding Plaintiffs their attorneys' fees pursuant to 35 U.S.C. §§ 271(e)(4) and 285;

H. An award to Plaintiffs of their costs and expenses in this action; and

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

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

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