IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

VELOXIS PHARMACEUTICALS, INC., Plaintiff, v. ACCORD HEALTHCARE, INC. and INTAS PHARMACEUTICALS LTD., Defendants.	C.A. No. 22-909-MN

ACCORD HEALTHCARE, INC. AND INTAS PHARMACEUTICALS LTD.'S ANSWER, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS

Defendants Accord Healthcare, Inc. ("Accord") and Intas Pharmaceuticals Ltd. (collectively, "Defendants") respond to the Complaint by Plaintiff Veloxis Pharmaceuticals, Inc. as follows.

NATURE OF THE ACTION

1. This is an action for patent infringement under the patent laws of the United States, 35 U.S.C. § 1 et seq., arising from Defendants' submission of Abbreviated New Drug Application ("ANDA") No. 217255 to the United States Food and Drug Administration ("FDA"). Defendants' ANDA seeks FDA approval to market and sell 0.75 mg, 1 mg, and 4 mg extended-release tablets of tacrolimus ("Defendants' ANDA Products") prior to the expiration of U.S. Patent Nos. 8,685,998 ("the '998 Patent"); 9,549,918 ("the '918 Patent"); 10,166,190 ("the '190 Patent"); 10,864,199 ("the '199 Patent"); 11,110,081 ("the '081 Patent"); and 11,123,331 ("the '331 Patent").

ANSWER: Defendants admit that Plaintiffs purport to bring this action for alleged infringement of the '998, '918, '190, '199, '081, and '331 patents under the patent laws of the United States, 35 U.S.C. § 1 et seq. Accord admits that it submitted ANDA No. 217255 in the name of Accord Healthcare, Inc. Defendants deny any remaining allegations in this paragraph.

2. Veloxis owns the patents-in-suit and is the holder of FDA approved New Drug Application ("NDA") No. 206406 for the brand name drug ENVARSUS XR® (tacrolimus). The patents-in-suit generally cover oral dosage forms and methods of use and administration of tacrolimus, including ENVARSUS XR®. Defendants' ANDA Products are generic versions of ENVARSUS XR®.

ANSWER: Defendants admit that Veloxis is listed as an assignee of record for the patents-in-suit. Defendants admit that ENVARSUS XR® (tacrolimus) is the subject of approved NDA No. 206406. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore deny them.

THE PARTIES

3. Plaintiff Veloxis is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 2000 Regency Parkway, Suite 500, Cary, NC 27518.

ANSWER: Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore deny them.

4. Upon information and belief, Defendant Accord Healthcare is a corporation organized and existing under the laws of North Carolina, having a principal place of business at 1009 Slater Road, Suite 210 Durham, North Carolina 27703. Upon information and belief, Accord Healthcare is in the business of, among other things, developing, manufacturing, and selling generic versions of branded pharmaceutical products, including for the United States market.

ANSWER: Defendants admit that Accord Healthcare is a corporation organized and existing under the laws of North Carolina, having a principal place of business at 1009 Slater Road, Suite 210 Durham, North Carolina 27703. Defendants admit that Accord Healthcare markets and distributes generic pharmaceutical products in the United States. Defendants deny any remaining allegations in this paragraph.

5. Upon information and belief, Defendant Intas is a corporation organized and existing under the laws of India, having a principal place of business at Corporate House, Near Sola Bridge, S. G. Highway, Thaltej, Ahmedabad – 380054, Gujarat, India. Upon information

and belief, Intas is in the business of, among other things, developing, manufacturing, and selling generic versions of branded pharmaceutical products, including for the United States market.

ANSWER: Defendants admit that Intas Pharmaceuticals Ltd. is a corporation organized and existing under the laws of India, and that Intas Pharmaceuticals Ltd. has a principal place of business at Corporate House, Near Sola Bridge, S.G. Highway, Thaltej, Ahmedabad 380054, Gujarat, India. Defendants deny any remaining allegations in this paragraph.

6. Upon information and belief, Accord Healthcare is a wholly-owned subsidiary of Intas and is controlled and/or dominated by Intas. Upon information and belief, Accord Healthcare is the commercial arm of Intas. Upon information and belief, Accord Healthcare and Intas are agents of each other and/or operate in concert as integrated parts of the same business group.

ANSWER: Defendants admit that Accord is a wholly-owned subsidiary of Intas Pharmaceuticals Limited. Defendants deny any remaining allegations in this paragraph.

JURISDICTION AND VENUE

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

ANSWER: Paragraph 7 states a legal conclusion to which no answer is required. To the extent and answer is required, Defendants admit that this Court generally has subject matter jurisdiction over a civil action properly alleging infringement of a U.S. patent under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202. Defendants deny any remaining allegations in this paragraph.

8. Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b), and this Court has personal jurisdiction over Defendants.

ANSWER: Paragraph 8 states a legal conclusion to which no answer is required. To the extent an answer is required, Defendants do not contest venue in this proceeding. Defendants also do not contest personal jurisdiction in this proceeding. Defendants deny any remaining allegations in this paragraph.

9. Accord Healthcare, through their counsel, by email dated June 23, 2022, have consented to personal jurisdiction and venue in this Court for purposes of this matter.

ANSWER: Defendants admit that Defendants agreed not to contest personal jurisdiction and venue in this Court for purposes of this case only. Defendants deny any remaining allegations in this paragraph.

10. This Court also has personal jurisdiction over Accord Healthcare because Accord Healthcare, itself and/or through its parent Intas, has purposefully availed itself of the benefits and protections of the State of Delaware and, therefore, could reasonably anticipate being sued in this Judicial District. Upon information and belief, Accord Healthcare, directly or indirectly, manufactures, imports, markets, offers to sell, sells and/or distributes generic drugs throughout the United States, including Delaware, and Delaware would be a destination of Defendants' ANDA Products. Upon information and belief, Accord Healthcare, on its own or acting in concert with Intas, prepared and filed ANDA No. 217255 with the FDA. Upon information and belief, Accord Healthcare, on its own or acting in concert with Intas, will manufacture, import, market, offer to sell, sell and/or distribute Defendants' ANDA Products in the United States, including Delaware, upon approval of ANDA No. 217255, and will derive substantial revenue from the use or consumption of Defendants' ANDA Products in Delaware.

ANSWER: Defendants do not contest personal jurisdiction in this proceeding. Defendants admit that Accord prepared and filed ANDA No. 217255 with the FDA. Defendants deny any remaining allegations in this paragraph.

11. This Court also has personal jurisdiction over Intas because Intas, itself and/or through its subsidiary Accord Healthcare, has purposefully availed itself of the benefits and protections of the State of Delaware and, therefore, could reasonably anticipate being sued in this Judicial District. Upon information and belief, Intas, directly or indirectly, manufactures, imports, markets, offers to sell, sells and/or distributes generic drugs throughout the United States, including Delaware, and Delaware would be a destination of Defendants' ANDA Products. Upon information and belief, Intas, on its own or acting in concert with Accord Healthcare, prepared and submitted ANDA No. 217255 to the FDA. Upon information and belief, Intas, on its own or acting in concert with Accord Healthcare, will manufacture, import, market, offer to sell, sell and/or distribute Defendants' ANDA Products in the United States, including in Delaware, upon approval of ANDA No. 217255, and will derive substantial revenue from the use or consumption of Defendants' ANDA Products in Delaware.

ANSWER: Defendants do not contest personal jurisdiction in this proceeding. Defendants admit that Accord prepared and filed ANDA No. 217255 with the FDA. Defendants deny any remaining allegations in this paragraph.

12. In the alternative, this Court also has personal jurisdiction over Intas pursuant to Rule 4(k)(2), Fed. R. Civ. P. This action arises from actions of Intas directed toward Delaware, and Intas has purposefully availed itself of the rights and benefits of Delaware law by engaging in systematic and continuous contacts with Delaware. Upon information and belief, Intas regularly and continuously transacts business within Delaware, including by selling pharmaceutical products in Delaware, either on its own or through affiliates. Upon information and belief, Intas derives substantial revenue from the sale of those products in Delaware and has availed itself of the privilege of conducting business in Delaware.

ANSWER: Paragraph 12 states a legal conclusion to which no answer is required. To the extent an answer is required, Defendants do not contest personal jurisdiction in this proceeding. Defendants deny any remaining allegations in this paragraph.

13. Venue is also proper in this Court with respect to Intas because, upon information and belief, Intas is a foreign corporation that may be sued in any judicial district where it is subject to the personal jurisdiction of the Court.

ANSWER: Defendants do not contest venue in this proceeding. Defendants deny any remaining allegations in this paragraph.

14. Personal jurisdiction and venue are also proper in this Judicial District because Defendants have availed themselves of the legal protections of Delaware by, among other things, admitting jurisdiction and asserting counterclaims in lawsuits filed in this Court. *See e.g.*, *Celgene Corp. et al. v. Accord Healthcare Inc.*, No. 21-1795 (D. Del. Dec. 22, 2021); *Teva Pharmaceuticals International GmbH et al v. Accord Healthcare Inc.*, No. 21-952 (D. Del. June 29, 2021); *Taiho Pharmaceutical Co., Ltd. et al v. Accord Healthcare Inc. et al*, No. 21-838 (D. Del. June 9, 2021); *Bayer Pharma AG et al v. Accord Healthcare Inc. et al*, No. 21-566 (D. Del. Apr. 22, 2021); *Purdue Pharma L.P. et al v. Accord Healthcare Inc.*, No. 20-1362 (D. Del. Oct. 8, 2020); *Otsuka Pharmaceutical Co., Ltd. et al v. Accord Healthcare Inc.*, No. 20-1287 (D. Del. Sep. 25, 2020); *Sanofi-Aventis U.S. LLC et al v. Accord Healthcare Inc.*, No. 20-803 (D. Del. Jun. 12, 2020). *Merck Sharp & Dohme Corp. v. Accord Healthcare Inc. et al.*, No. 19-2192 (D. Del. Jan. 24, 2020); *Novartis Pharm. Co. v. Accord Healthcare Inc. et al.*, No. 18-1043 (D. Del. Aug. 8, 2018); *Amgen Inc. v. Accord Healthcare et al.*, No. 18-956 (D. Del. June 28, 2018).

ANSWER: Defendants do not contest personal jurisdiction and venue in this proceeding. Defendants deny any remaining allegations in this paragraph.

PATENTS-IN-SUIT

15. On April 1, 2014, the '998 Patent, titled "Tacrolimus for Improved Treatment of Transplant Patients," was duly and lawfully issued by the United States Patent and Trademark Office ("USPTO"). Veloxis is the assignee of the '998 Patent. A true copy of the '998 Patent is attached hereto as **Exhibit A**.

ANSWER: Defendants admit that Veloxis is an assignee of record of the '998 Patent. Defendants admit that the '998 Patent is entitled "Tacrolimus for Improved Treatment of Transplant Patients." Defendants admit that Exhibit A purports to be a copy of the '998 Patent. Defendants lack knowledge or information sufficient to form a belief about the truth of any remaining allegations in this paragraph, and therefore deny them.

16. On January 24, 2017, the '918 Patent, titled "Stabilized Tacrolimus Composition," was duly and lawfully issued by the USPTO. Veloxis is the assignee of the '918 Patent. A true copy of the '918 Patent is attached hereto as **Exhibit B**.

ANSWER: Defendants admit that Veloxis is an assignee of record of the '918 Patent. Defendants admit that the '918 Patent is entitled "Stabilized Tacrolimus Composition." Defendants admit that Exhibit B purports to be a copy of the '918 Patent. Defendants lack knowledge or information sufficient to form a belief about the truth of any remaining allegations in this paragraph, and therefore deny them.

17. On January 1, 2019, the '190 Patent, titled "Stabilized Tacrolimus Composition," was duly and lawfully issued by the USPTO. Veloxis is the assignee of the '190 Patent. A true copy of the '190 Patent is attached hereto as **Exhibit C**.

ANSWER: Defendants admit that Veloxis is an assignee of record of the '190 patent. Defendants admit that the '190 Patent is entitled "Stabilized Tacrolimus Composition." Defendants admit that Exhibit C purports to be a copy of the '190 Patent. Defendants lack

knowledge or information sufficient to form a belief about the truth of any remaining allegations in this paragraph, and therefore deny them.

18. On December 15, 2020, the '199 Patent, titled "Tacrolimus for Improved Treatment of Transplant Patients," was duly and lawfully issued by the USPTO. Veloxis is the assignee of the '199 Patent. A true copy of the '199 Patent is attached hereto as **Exhibit D**.

ANSWER: Defendants admit that Veloxis is an assignee of record of the '199 Patent. Defendants admit that the '199 Patent is entitled "Tacrolimus for Improved Treatment of Transplant Patients." Defendants admit that Exhibit D purports to be a copy of the '199 Patent. Defendants lack knowledge or information sufficient to form a belief about the truth of any remaining allegations in this paragraph, and therefore deny them.

19. On September 7, 2021, the '081 Patent, titled "Tacrolimus for Improved Treatment of Transplant Patients," was duly and lawfully issued by the USPTO. Veloxis is the assignee of the '081 Patent. A true copy of the '081 Patent is attached hereto as **Exhibit E**.

ANSWER: Defendants admit that Veloxis is an assignee of record of the '081 Patent. Defendants admit that the '081 Patent is entitled "Tacrolimus for Improved Treatment of Transplant Patients." Defendants admit that Exhibit E purports to be a copy of the '081 Patent. Defendants lack knowledge or information sufficient to form a belief about the truth of any remaining allegations in this paragraph, and therefore deny them.

20. On September 21, 2021, the '331 Patent, titled "Tacrolimus for Improved Treatment of Transplant Patients," was duly and lawfully issued by the USPTO. Veloxis is the assignee of the '331 Patent. A true copy of the '331 Patent is attached hereto as **Exhibit F**.

ANSWER: Defendants admit that Veloxis is an assignee of record of the '331 Patent. Defendants admit that the '331 Patent is entitled "Tacrolimus for Improved Treatment of Transplant Patients." Defendants admit that Exhibit F purports to be a copy of the '331 Patent. Defendants lack knowledge or information sufficient to form a belief about the truth of any remaining allegations in this paragraph, and therefore deny them.

VELOXIS' ENVARSUS XR®

21. Veloxis holds approved NDA No. 206406 for extended-release tablets containing the active ingredient tacrolimus. Veloxis markets and sells tacrolimus extended-release tablets under the trade name ENVARSUS XR®.

ANSWER: Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore deny them.

22. ENVARSUS XR® is a calcineurin-inhibitor immunosuppressant indicated for: (1) the prophylaxis of organ rejection in de novo kidney transplant patients in combination with other immunosuppressants and (2) the prophylaxis of organ rejection in kidney transplant patients converted from tacrolimus immediate-release formulations in combination with other immunosuppressants. A copy of the complete prescribing information for ENVARSUS XR® is attached hereto as **Exhibit G**.

ANSWER: Defendants admit that Exhibit G purports to be the prescribing information for ENVARSUS XR®. Defendants lack knowledge or information sufficient to form a belief about the truth of any remaining allegations in this paragraph, and therefore deny them.

23. Pursuant to 21 U.S.C. § 355(b)(1) and related FDA regulations, Veloxis listed the '998, '918, '190, '199, '081, and '331 patents in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to ENVARSUS XR®. The prescribing information for ENVARSUS XR® instructs and encourages physicians, other healthcare workers and patients to administer ENVARSUS XR® tablets according to one or more of the methods claimed in the patents-in-suit.

ANSWER: Defendants admit that the '998, '918, '190, '199, '081, and '331 patents are listed in the Orange book in connection with ENVARSUS XR®. Defendants lack knowledge or information sufficient to form a belief about the truth of any remaining allegations in this paragraph, and therefore deny them.

ACTS GIVING RISE TO THIS ACTION

24. By letter dated May 23, 2022 ("Notice Letter"), Accord Healthcare notified Veloxis that Accord Healthcare had submitted ANDA No. 217255 to the FDA under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)). Veloxis received the Notice Letter no earlier than May 26, 2022.

ANSWER: Defendants admit that Accord Healthcare, Inc. sent a letter dated May 23, 2022 to Plaintiff providing a Notice of Paragraph IV Certification with respect to Accord's ANDA and the'998, '918, '190, '199, and '331 patents. Defendants lack knowledge or information sufficient to form a belief about the truth of any remaining allegations in this paragraph, and therefore deny them.

25. The Notice Letter states that Accord Healthcare seeks approval from the FDA to engage in the commercial manufacture, use, sale, offer to sell, and/or importation in the United States of Defendants' ANDA Products before expiration of the '998, '918, '190, '199, '081, and '331 patents. Upon information and belief, Defendants intend to, directly or indirectly, engage in the commercial manufacture, use, sale, offer for sale, and/or importation of Defendants' ANDA Products promptly upon receiving FDA approval.

ANSWER: Defendants admit that Accord filed ANDA No. 217255. Defendants admit that the Notice Letter provides a Notice of Paragraph IV Certification with respect to Accord's ANDA and the'998, '918, '190, '199, and '331 patents. Defendants deny any remaining allegations of this paragraph.

26. By filing ANDA No. 217255, Defendants have necessarily represented to the FDA that Defendants' ANDA Products have the same active ingredient, the same dosage form, the same route of administration, and the same strengths as ENVARSUS XR®. By submitting ANDA No. 217255, Defendants also have necessarily represented to the FDA that Defendants' ANDA Products are bioequivalent to ENVARSUS XR®. Upon information and belief, Defendants are seeking approval to market and sell their ANDA Products for the same approved indications as ENVARSUS XR®.

ANSWER: Defendants admit that Accord filed ANDA No. 217255. Defendants deny any remaining allegations of this paragraph.

27. In the Notice Letter, Accord Healthcare states that Defendants' ANDA contains a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certification") asserting that the claims of the '998 patent are invalid under 35 U.S.C. §§ 102 and/or 103. The Notice Letter does not contest that the claims of the '998 patent are enforceable and will be infringed by the commercial manufacture, use, offer to sell, sale, and/or importation of Defendants' ANDA Products.

ANSWER: Defendants admit that Accord filed ANDA No. 217255 with a Paragraph IV certification with respect to the '998 patent. Defendants deny any remaining allegations in this paragraph.

28. In the Notice Letter, Accord Healthcare states that its ANDA contains a Paragraph IV Certification asserting that the claims of the '918 patent are not infringed. The Notice Letter does not contest that the claims of the '918 patent are valid and enforceable.

ANSWER: Defendants admit that Accord filed ANDA No. 217255 with a Paragraph IV certification with respect to the '918 patent. Defendants deny any remaining allegations in this paragraph.

29. In the Notice Letter, Accord Healthcare states that its ANDA contains a Paragraph IV Certification asserting that the claims of the '190 patent are not infringed. The Notice Letter does not contest that the claims of the '190 patent are valid and enforceable.

ANSWER: Defendants admit that Accord filed ANDA No. 217255 with a Paragraph IV certification with respect to the '190 patent. Defendants deny any remaining allegations in this paragraph.

30. In the Notice Letter, Accord Healthcare states that its ANDA contains a Paragraph IV Certification asserting that the claims of the '199 patent are invalid under 35 U.S.C. § 103. In the Notice Letter, Accord Healthcare also states that its Paragraph IV Certification against the '199 asserts that claims 1-13 and 17-19 of the '199 patent are not infringed. The Notice Letter does not contest that claims 14-16 of the '199 patent are enforceable and will be infringed by the commercial manufacture, use, offer to sell, sale, and/or importation of Defendants' ANDA Products.

ANSWER: Defendants admit that Accord filed ANDA No. 217255 with a Paragraph IV certification with respect to the '199 patent. Defendants deny any remaining allegations in this paragraph.

31. In the Notice Letter, Accord Healthcare does not address the '081 Patent, even though it is listed in the Orange Book. The Notice Letter does not contest that the claims of the '081 patent are valid, enforceable and will be infringed by the commercial manufacture, use, offer to sell, sale, and/or importation of Defendants' ANDA Products.

ANSWER: Pursuant to 21 U.S.C. § 355(j)(2)(A)(viii), Accord has certified to the FDA that Accord is not seeking approval for the method of use claimed in the '081 patent. Defendants deny any remaining allegations in this paragraph.

32. In the Notice Letter, Accord Healthcare states that its ANDA contains a Paragraph IV Certification asserting that the claims of the '331 patent are invalid under 35 U.S.C. §§ 112. The Notice Letter does not contest that the claims of the '331 patent are enforceable and will be infringed by the commercial manufacture, use, offer to sell, sale, and/or importation of Defendants' ANDA Products. The Notice Letter also does contest the validity of the claims of the '331 patent under 35 U.S.C. §§ 102 or 103.

ANSWER: Defendants admit that Accord filed ANDA No. 217255 with a Paragraph IV certification with respect to the '331 patent. Defendants deny any remaining allegations in this paragraph.

COUNT I
INFRINGEMENT OF THE '998 PATENT

33. Veloxis repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

ANSWER: Defendants incorporate their answers to each of the prior paragraphs.

34. Defendants' submission of their ANDA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Defendants' ANDA Products, prior to the expiration of the '998 patent, constitutes infringement of one or more claims of that patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents, including at least claim 1.

ANSWER: Denied.

35. Upon information and belief, Defendants' ANDA Products and/or their use in accordance with the product label satisfies each and every element of at least claim 1 of the '998 Patent.

ANSWER: Denied.

36. There is a justiciable controversy between the parties hereto as to the infringement and/or validity of the '998 patent.

ANSWER: Denied.

37. Unless enjoined by this Court, upon FDA approval of Defendants' ANDA, Defendants will infringe one or more claims of the '998 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Defendants' ANDA Products in the United States.

ANSWER: Denied.

38. Unless enjoined by this Court, upon FDA approval of Defendants' ANDA Products, Defendants will induce infringement of one or more claims of the '998 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Defendants' ANDA Products in the United States. Upon information and belief, upon FDA approval of Defendants' ANDA Products, Defendants will intentionally encourage acts of direct infringement with knowledge of the '998 patent and knowledge that their acts are encouraging infringement, with specific intent to induce infringement of the '998 patent.

ANSWER: Denied.

39. Unless enjoined by this Court, upon FDA approval of Defendants' ANDA Products, Defendants will contributorily infringe one or more claims of the '998 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Defendants' ANDA Products in the United States. Upon information and belief, Defendants have had and continue to have knowledge that Defendants' ANDA Products are especially adapted for a use that infringes one or more claims of the '998 patent and that there is no substantial non-infringing use for Defendants' ANDA Products.

ANSWER: Denied.

40. Veloxis will be substantially and irreparably damaged and harmed if Defendants' infringement of the '998 patent is not enjoined.

ANSWER: Denied.

41. Veloxis does not have an adequate remedy at law.

ANSWER: Denied.

42. Upon information and belief, Defendants had knowledge of the '998 patent prior to filing their ANDA with the FDA.

ANSWER: Denied.

43. This case is an exceptional one, and Veloxis is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

ANSWER: Denied.

COUNT II
INFRINGEMENT OF THE '918 PATENT

44. Veloxis repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

ANSWER: Defendants incorporate their answers to each of the prior paragraphs.

45. Defendants' submission of their ANDA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Defendants' ANDA Products, prior to the expiration of the '918 patent, constitutes infringement of one or more claims of that patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents, including at least claim 1.

ANSWER: Denied.

46. Upon information and belief, Defendants' ANDA Products and/or their use in accordance with the product label satisfies each and every element of at least claim 1 of the '918 Patent.

ANSWER: Denied.

47. There is a justiciable controversy between the parties hereto as to the infringement and/or validity of the '918 patent.

ANSWER: Denied.

48. Unless enjoined by this Court, upon FDA approval of Defendants' ANDA, Defendants will infringe one or more claims of the '918 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Defendants' ANDA Products in the United States.

ANSWER: Denied.

49. Unless enjoined by this Court, upon FDA approval of Defendants' ANDA Products, Defendants will induce infringement of one or more claims of the '918 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Defendants' ANDA Products in the United States. Upon information and belief, upon FDA approval of Defendants' ANDA Products, Defendants will intentionally encourage acts of direct infringement with knowledge of the '918 patent and knowledge that their acts are encouraging infringement, with specific intent to induce infringement of the '918 patent.

ANSWER: Denied.

50. Unless enjoined by this Court, upon FDA approval of Defendants' ANDA Products, Defendants will contributorily infringe one or more claims of the '918 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Defendants' ANDA Products in the United States. Upon information and belief, Defendants have had and continue to have knowledge that Defendants' ANDA Products are especially adapted for a use that infringes one or more claims of the '918 patent and that there is no substantial non-infringing use for Defendants' ANDA Products.

ANSWER: Denied.

51. Veloxis will be substantially and irreparably damaged and harmed if Defendants' infringement of the '918 patent is not enjoined.

ANSWER: Denied.

52. Veloxis does not have an adequate remedy at law.

ANSWER: Denied.

53. Upon information and belief, Defendants had knowledge of the '918 patent prior to filing their ANDA with the FDA.

ANSWER: Denied.

54. This case is an exceptional one, and Veloxis is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

ANSWER: Denied.

COUNT III
INFRINGEMENT OF THE '190 PATENT

55. Veloxis repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

ANSWER: Defendants incorporate their answers to each of the prior paragraphs.

56. Defendants' submission of their ANDA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Defendants' ANDA Products, prior to the expiration of the '190 patent, constitutes infringement of one or more claims of that patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents, including at least claim 1.

ANSWER: Denied.

57. Upon information and belief, Defendants' ANDA Products and/or their use in accordance with the product label satisfies each and every element of at least claim 1 of the '190 Patent.

ANSWER: Denied.

58. There is a justiciable controversy between the parties hereto as to the infringement and/or validity of the '190 patent.

ANSWER: Denied.

59. Unless enjoined by this Court, upon FDA approval of Defendants' ANDA, Defendants will infringe one or more claims of the '190 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Defendants' ANDA Products in the United States.

ANSWER: Denied.

60. Unless enjoined by this Court, upon FDA approval of Defendants' ANDA Products, Defendants will induce infringement of one or more claims of the '190 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Defendants' ANDA Products in the United States. Upon information and belief, upon FDA approval of Defendants' ANDA Products, Defendants will intentionally encourage acts of direct infringement with knowledge of the '190 patent and knowledge that their acts are encouraging infringement, with specific intent to induce infringement of the '190 patent.

ANSWER: Denied.

61. Unless enjoined by this Court, upon FDA approval of Defendants' ANDA Products, Defendants will contributorily infringe one or more claims of the '190 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Defendants' ANDA Products in the United States. Upon information and belief, Defendants have had and continue to have knowledge that Defendants' ANDA Products are especially adapted for a use that infringes one or more claims of the '190 patent and that there is no substantial non-infringing use for Defendants' ANDA Products.

ANSWER: Denied.

62. Veloxis will be substantially and irreparably damaged and harmed if Defendants' infringement of the '190 patent is not enjoined.

ANSWER: Denied.

63. Veloxis does not have an adequate remedy at law.

ANSWER: Denied.

64. Upon information and belief, Defendants had knowledge of the '190 patent prior to filing their ANDA with the FDA.

ANSWER: Denied.

65. This case is an exceptional one, and Veloxis is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

ANSWER: Denied.

COUNT IV
INFRINGEMENT OF THE '199 PATENT

66. Veloxis repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

ANSWER: Defendants incorporate their answers to each of the prior paragraphs.

67. Defendants' submission of their ANDA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Defendants' ANDA Products, prior to the expiration of the '199 patent, constitutes infringement of one or more claims of that patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents, including at least claim 14.

ANSWER: Denied.

68. Upon information and belief, Defendants' ANDA Products and/or their use in accordance with the product label satisfies each and every element of at least claim 14 of the '199 Patent.

ANSWER: Denied.

69. There is a justiciable controversy between the parties hereto as to the infringement and/or validity of the '199 patent.

ANSWER: Denied.

70. Unless enjoined by this Court, upon FDA approval of Defendants' ANDA Products, Defendants will induce infringement of one or more claims of the '199 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Defendants' ANDA Products in the United States. Upon information and belief, upon FDA approval of Defendants' ANDA Products, Defendants will intentionally encourage acts of direct infringement with knowledge of the '199 patent and knowledge that their acts are encouraging infringement, with specific intent to induce infringement of the '199 patent.

ANSWER: Denied.

71. Unless enjoined by this Court, upon FDA approval of Defendants' ANDA Products, Defendants will contributorily infringe one or more claims of the '199 patent under 35 U.S.C. § 271€ by making, using, offering to sell, selling, and/or importing Defendants' ANDA Products in the United States. Upon information and belief, Defendants have had and continue to have knowledge that Defendants' ANDA Products are especially adapted for a use that infringes one or more claims of the '199 patent and that there is no substantial non-infringing use for Defendants' ANDA Products.

ANSWER: Denied.

72. Veloxis will be substantially and irreparably damaged and harmed if Defendants' infringement of the '199 patent is not enjoined.

ANSWER: Denied.

73. Veloxis does not have an adequate remedy at law.

ANSWER: Denied.

74. Upon information and belief, Defendants had knowledge of the '199 patent prior to filing their ANDA with the FDA.

ANSWER: Denied.

75. This case is an exceptional one, and Veloxis is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

ANSWER: Denied.

COUNT V
INFRINGEMENT OF THE '081 PATENT

76. Veloxis repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

ANSWER: Defendants incorporate their answers to each of the prior paragraphs.

77. Defendants' submission of their ANDA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Defendants' ANDA Products, prior to the expiration of the '081 patent, constitutes infringement of one or more claims of that patent under 35 U.S.C. § 271€(2)(A), either literally or under the doctrine of equivalents, including at least claim 1.

ANSWER: Denied.

78. Upon information and belief, Defendants' ANDA Products and/or their use in accordance with the product label satisfies each and every element of at least claim 1 of the '081 Patent.

ANSWER: Denied.

79. There is a justiciable controversy between the parties hereto as to the infringement and/or validity of the '081 patent.

ANSWER: Denied.

80. Unless enjoined by this Court, upon FDA approval of Defendants' ANDA Products, Defendants will induce infringement of one or more claims of the '081 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Defendants' ANDA Products in the United States. Upon information and belief, upon FDA approval of Defendants' ANDA Products, Defendants will intentionally encourage acts of direct infringement with knowledge of the '081 patent and knowledge that their acts are encouraging infringement, with specific intent to induce infringement of the '081 patent.

ANSWER: Denied.

81. Unless enjoined by this Court, upon FDA approval of Defendants' ANDA Products, Defendants will contributorily infringe one or more claims of the '081 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Defendants' ANDA Products in the United States. Upon information and belief, Defendants have had and continue to have knowledge that Defendants' ANDA Products are especially adapted for a use that infringes one or more claims of the '081 patent and that there is no substantial non-infringing use for Defendants' ANDA Products.

ANSWER: Denied.

82. Veloxis will be substantially and irreparably damaged and harmed if Defendants' infringement of the '081 patent is not enjoined.

ANSWER: Denied.

83. Veloxis does not have an adequate remedy at law.

ANSWER: Denied.

84. Upon information and belief, Defendants had knowledge of the '081 patent prior to filing their ANDA with the FDA.

ANSWER: Denied.

85. This case is an exceptional one, and Veloxis is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

ANSWER: Denied.

COUNT VI
INFRINGEMENT OF THE '331 PATENT

86. Veloxis repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

ANSWER: Defendants incorporate their answers to each of the prior paragraphs.

87. Defendants' submission of their ANDA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Defendants' ANDA Products, prior to the expiration of the '331 patent, constitutes infringement of one or more claims of that patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents, including at least claim 1.

ANSWER: Denied.

88. Upon information and belief, Defendants' ANDA Products and/or their use in accordance with the product label satisfies each and every element of at least claim 1 of the '331 Patent.

ANSWER: Denied.

89. There is a justiciable controversy between the parties hereto as to the infringement and/or validity of the '331 patent.

ANSWER: Denied.

90. Unless enjoined by this Court, upon FDA approval of Defendants' ANDA Products, Defendants will induce infringement of one or more claims of the '331 patent under 35 U.S.C. §271(b) by making, using, offering to sell, selling, and/or importing Defendants' ANDA Products in the United States. Upon information and belief, upon FDA approval of Defendants' ANDA Products, Defendants will intentionally encourage acts of direct infringement with knowledge of the '331 patent and knowledge that their acts are encouraging infringement, with specific intent to induce infringement of the '331 patent.

ANSWER: Denied.

91. Unless enjoined by this Court, upon FDA approval of Defendants' ANDA Products, Defendants will contributorily infringe one or more claims of the '331 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Defendants' ANDA Products in the United States. Upon information and belief, Defendants have had and continue to have knowledge that Defendants' ANDA Products are especially adapted for a use that infringes one or more claims of the '331 patent and that there is no substantial non-infringing use for Defendants' ANDA Products.

ANSWER: Denied.

92. Veloxis will be substantially and irreparably damaged and harmed if Defendants' infringement of the '331 patent is not enjoined.

ANSWER: Denied.

93. Veloxis does not have an adequate remedy at law.

ANSWER: Denied.

94. Upon information and belief, Defendants had knowledge of the '331 patent prior to filing their ANDA with the FDA.

ANSWER: Denied.

95. This case is an exceptional one, and Veloxis is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

ANSWER: Denied.

RESPONSE TO PRAYER FOR RELIEF

Defendants deny that Plaintiff is entitled to the requested relief or to any relief whatsoever.

AFFIRMATIVE DEFENSES

FIRST AFFIRMATIVE DEFENSE

The claims of the '998 patent are invalid for failure to satisfy one or more of the conditions for patentability of 35 U.S.C. § 101 et seq., at least for the reasons set forth in Accord's Notice Letter dated May 23, 2022.

SECOND AFFIRMATIVE DEFENSE

The manufacture, use, sale, offer for sale, or importation of Accord's ANDA Products has not infringed, does not infringe, and would not, if marketed, manufactured, used, sold, offered for sale, or imported, infringe any valid or enforceable claim of the '918 patent.

THIRD AFFIRMATIVE DEFENSE

The manufacture, use, sale, offer for sale, or importation of Accord's ANDA Products has not infringed, does not infringe, and would not, if marketed, manufactured, used, sold, offered for sale, or imported, infringe any valid or enforceable claim of the '190 patent.

FOURTH AFFIRMATIVE DEFENSE

The claims of the '199 patent are invalid for failure to satisfy one or more of the conditions for patentability of 35 U.S.C. § 101 et seq., at least for the reasons set forth in Accord's Notice Letter dated May 23, 2022.

FIFTH AFFIRMATIVE DEFENSE

The manufacture, use, sale, offer for sale, or importation of Accord's ANDA Products has not infringed, does not infringe, and would not, if marketed, manufactured, used, sold, offered for sale, or imported, infringe the claims of the '199 patent.

SIXTH AFFIRMATIVE DEFENSE

The manufacture, use, sale, offer for sale, or importation of Accord's ANDA Products has not infringed, does not infringe, and would not, if marketed, manufactured, used, sold, offered for sale, or imported, infringe any valid or enforceable claim of the '081 patent.

SEVENTH AFFIRMATIVE DEFENSE

The claims of the '081 patent are invalid for failure to satisfy one or more of the conditions for patentability of 35 U.S.C. § 101 et seq.

EIGHTH AFFIRMATIVE DEFENSE

The claims of the '331 patent are invalid for failure to satisfy one or more of the conditions for patentability of 35 U.S.C. § 101 et seq., at least for the reasons set forth in Accord's Notice Letter dated May 23, 2022.

RESERVATION OF DEFENSES

Defendants reserve the right to assert any and all additional defenses and counterclaims that discovery may reveal.

COUNTERCLAIMS

For its counterclaims against Plaintiff Veloxis Pharmaceuticals, Inc. ("Veloxis" or "Plaintiff"), Defendants Accord Healthcare, Inc. ("Accord") and Intas Pharmaceuticals Ltd. ("Intas") (collectively, "Defendants") state as follows:

THE PARTIES

1. Accord is a corporation organized under the laws of North Carolina, having a principal place of business at 1009 Slater Road, Suite 210B, Durham, NC 27703.

2. Intas Pharmaceuticals Ltd. is a corporation organized and existing under the laws of India, having a principal place of business at Corporate House, Near Sola Bridge, S.G. Highway, Thaltej, Ahmedabad 380054, Gujarat, India.

3. On information and belief, Veloxis Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 2000 Regency Parkway, Suite 500, Cary, NC 27518.

JURISDICTION AND VENUE

4. These counterclaims arise under the Patent Laws of the United States, 35 U.S.C. § 100 et seq., and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

5. The Court has original jurisdiction over the subject matter of these counterclaims pursuant to 28 U.S.C. §§ 1331 and 1338(a).

6. The Court has personal jurisdiction over Plaintiff because Plaintiff commenced and continues to maintain this action against Defendants in this judicial district.

7. Venue for these counterclaims is proper in this judicial District pursuant to 28 U.S.C. §§ 1391(b)-(c) and 1400(b).

ACTS GIVING RISE TO THESE COUNTERCLAIMS

8. On April 1, 2014, the U.S. Patent and Trademark Office ("USPTO") issued U.S. Patent No. 8,685,998 ("the '998 patent"), entitled "TACROLIMUS FOR IMPROVED TREATMENT OF TRANSPLANT PATIENTS." Veloxis claims to be the owner of the '998 patent by virtue of assignment.

9. On January 24, 2017, the U.S. Patent and Trademark Office ("USPTO") issued U.S. Patent No. 9,549,918 ("the '918 Patent"), entitled "STABILIZED TACROLIMUS COMPOSITION." Veloxis claims to be the owner of the '918 patent by virtue of assignment.

10. On January 1, 2019, the U.S. Patent and Trademark Office ("USPTO") issued U.S. Patent No. 10,166,190 ("the '190 Patent"), entitled "STABILIZED TACROLIMUS COMPOSITION." Veloxis claims to be the owner of the '190 patent by virtue of assignment.

11. On December 15, 2020, the U.S. Patent and Trademark Office ("USPTO") issued U.S. Patent No. 10,864,199 ("the '199 Patent"), entitled "TACROLIMUS FOR IMPROVED TREATMENT OF TRANSPLANT PATIENTS." Veloxis claims to be the owner of the '199 patent by virtue of assignment.

12. On September 7, 2021, the U.S. Patent and Trademark Office ("USPTO") issued U.S. Patent No. 11,110,081 ("the '081 Patent"), entitled "TACROLIMUS FOR IMPROVED TREATMENT OF TRANSPLANT PATIENTS." Veloxis claims to be the owner of the '081 patent by virtue of assignment.

13. On September 21, 2021, the U.S. Patent and Trademark Office ("USPTO") issued U.S. Patent No. 11,123,331 ("the '331 Patent"), entitled "TACROLIMUS FOR IMPROVED TREATMENT OF TRANSPLANT PATIENTS." Veloxis claims to be the owner of the '331 patent by virtue of assignment.

14. On information and belief, Veloxis Pharmaceuticals, Inc. is indicated in the records of the U.S. Food and Drug Administration ("FDA") as the holder of New Drug Application ("NDA") No. 206406 for ENVARSUS XR® (tacrolimus).

15. On information and belief, Veloxis submitted the '998, '918, '190, '199, '081, and '331 patents for listing in the electronic version of the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book") in connection with ENVARSUS XR®.

16. By letter dated May 23, 2022 ("Accord's Notice Letter"), Accord Healthcare, Inc. notified Veloxis that it had filed Abbreviated New Drug Application ("ANDA") No. 217255 with a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that each of the '998, '918, '190,

'199, and '331 patents is invalid, unenforceable, and/or will not be infringed by the products that are the subject of ANDA No. 217255 ("Accord's ANDA Products").

17. Pursuant to 21 U.S.C. § 355(j)(2)(B)(iv)(II), Accord's Notice Letter included a detailed statement of the factual and legal bases for the certification that each of the '998, '918, '190, '199, and '331 patents is invalid, unenforceable, and/or will not be infringed by Accord's ANDA Products.

18. Accord's Notice Letter also included an Offer of Confidential Access pursuant to 21 U.S.C. § 355(j)(5)(C)(i)(III).

19. Pursuant to 21 U.S.C. § 355(j)(2)(A)(viii), Accord has certified to the FDA that Accord is not seeking approval for the method of use claimed in the '081 patent.

20. On July 7, 2022, Plaintiff filed suit against Defendants, alleging infringement of the '998, '918, '190, '199, '081, and '331 patents.

FIRST CLAIM FOR RELIEF
(DECLARATORY JUDGMENT OF INVALIDITY OF THE '998 PATENT)

21. Defendants restate and reallege each of the foregoing paragraphs 1-20 as if fully set forth herein.

22. Plaintiff has accused Defendants of infringing the '998 patent.

23. Defendants deny infringement of the '998 patent and allege that the claims of the '998 patent are invalid for failure to satisfy one or more of the conditions for patentability of 35 U.S.C. § 101 *et seq.*, at least for the reasons set forth in Accord's Notice Letter.

24. A definite and concrete, real and substantial, justiciable, and continuing case or controversy exists between Defendants and Plaintiff regarding the validity of the '998 patent.

25. Defendants are entitled to a judicial declaration that the claims of the '998 patent are invalid under one or more of 35 U.S.C. § 101 *et seq*.

SECOND CLAIM FOR RELIEF
(DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE '918 PATENT)

26. Defendants restate and reallege each of the foregoing paragraphs 1-25 as if fully set forth herein.

27. Plaintiff has accused Defendants of infringing the '918 patent.

28. Defendants deny infringement of the '918 patent and allege that the manufacture, use, sale, offer for sale, or importation of Accord's ANDA Products have not infringed, do not infringe, and would not, if manufactured, used, sold, offered for sale, or imported, infringe, either directly, indirectly, or contributorily, and would not induce infringement of, any valid or enforceable claim of the '918 patent.

29. A definite and concrete, real and substantial, justiciable, and continuing case or controversy exists between Defendants and Plaintiff regarding the infringement of the '918 patent.

30. Defendants are entitled to a judicial declaration that the manufacture, use, sale, offer for sale, or importation of Accord's ANDA Products have not infringed, do not infringe, and would not, if manufactured, used, sold, offered for sale, or imported, infringe, either directly, indirectly, or contributorily, and would not induce infringement of, any valid or enforceable claim of the '918 patent.

THIRD CLAIM FOR RELIEF
(DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE '190 PATENT)

31. Defendants restate and reallege each of the foregoing paragraphs 1-30 as if fully set forth herein.

32. Plaintiff has accused Defendants of infringing the '190 patent.

33. Defendants deny infringement of the '190 patent and allege that the manufacture, use, sale, offer for sale, or importation of Accord's ANDA Products have not infringed, do not infringe, and would not, if manufactured, used, sold, offered for sale, or imported, infringe, either directly, indirectly, or contributorily, and would not induce infringement of, any valid or enforceable claim of the '190 patent.

34. A definite and concrete, real and substantial, justiciable, and continuing case or controversy exists between Defendants and Plaintiff regarding the infringement of the '190 patent.

35. Defendants are entitled to a judicial declaration that the manufacture, use, sale, offer for sale, or importation of Accord's ANDA Products have not infringed, do not infringe, and would not, if manufactured, used, sold, offered for sale, or imported, infringe, either directly, indirectly, or contributorily, and would not induce infringement of, any valid or enforceable claim of the '190 patent.

FOURTH CLAIM FOR RELIEF
(DECLARATORY JUDGMENT OF INVALIDITY OF THE '199 PATENT)

36. Defendants restate and reallege each of the foregoing paragraphs 1-35 as if fully set forth herein.

37. Plaintiff has accused Defendants of infringing the '199 patent.

38. Defendants deny infringement of the '199 patent and allege that the claims of the '199 patent are invalid for failure to satisfy one or more of the conditions for patentability of 35 U.S.C. § 101 *et seq.*, at least for the reasons set forth in Accord's Notice Letter.

39. A definite and concrete, real and substantial, justiciable, and continuing case or controversy exists between Defendants and Plaintiff regarding the validity of the '199 patent.

40. Defendants are entitled to a judicial declaration that the claims of the '199 patent are invalid under one or more of 35 U.S.C. § 101 *et seq*.

FIFTH CLAIM FOR RELIEF
(DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE '199 PATENT)

41. Defendants restate and reallege each of the foregoing paragraphs 1-40 as if fully set forth herein.

42. Plaintiff has accused Defendants of infringing the '199 patent.

43. Defendants deny infringement of the '199 patent and allege that the manufacture, use, sale, offer for sale, or importation of Accord's ANDA Products have not infringed, do not infringe, and would not, if manufactured, used, sold, offered for sale, or imported, infringe, either directly, indirectly, or contributorily, and would not induce infringement of, any valid or enforceable claim of the '199 patent.

44. A definite and concrete, real and substantial, justiciable, and continuing case or controversy exists between Defendants and Plaintiff regarding the infringement of the '199 patent.

45. Defendants are entitled to a judicial declaration that the manufacture, use, sale, offer for sale, or importation of Accord's ANDA Products have not infringed, do not infringe, and would not, if manufactured, used, sold, offered for sale, or imported, infringe, either directly, indirectly, or contributorily, and would not induce infringement of, any valid or enforceable claim of the '199 patent.

SIXTH CLAIM FOR RELIEF
(DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE '081 PATENT)

46. Defendants restate and reallege each of the foregoing paragraphs 1-45 as if fully set forth herein.

47. Plaintiff has accused Defendants of infringing the '081 patent.

48. Defendants deny infringement of the '081 patent and allege that the manufacture, use, sale, offer for sale, or importation of Accord's ANDA Products have not infringed, do not infringe, and would not, if manufactured, used, sold, offered for sale, or imported, infringe, either directly, indirectly, or contributorily, and would not induce infringement of, any valid or enforceable claim of the '081 patent.

49. A definite and concrete, real and substantial, justiciable, and continuing case or controversy exists between Defendants and Plaintiff regarding the infringement of the '081 patent.

50. Defendants are entitled to a judicial declaration that the manufacture, use, sale, offer for sale, or importation of Accord's ANDA Products have not infringed, do not infringe, and would not, if manufactured, used, sold, offered for sale, or imported, infringe, either directly, indirectly, or contributorily, and would not induce infringement of, any valid or enforceable claim of the '081 patent.

SEVENTH CLAIM FOR RELIEF
(DECLARATORY JUDGMENT OF INVALIDITY OF THE '081 PATENT)

51. Defendants restate and reallege each of the foregoing paragraphs 1-50 as if fully set forth herein.

52. Plaintiff has accused Defendants of infringing the '081 patent.

53. Defendants deny infringement of the '081 patent and allege that the claims of the '081 patent are invalid for failure to satisfy one or more of the conditions for patentability of 35 U.S.C. § 101 *et seq*.

54. A definite and concrete, real and substantial, justiciable, and continuing case or controversy exists between Defendants and Plaintiff regarding the validity of the '081 patent.

55. Defendants are entitled to a judicial declaration that the claims of the '081 patent are invalid under one or more of 35 U.S.C. § 101 *et seq*.

EIGHTH CLAIM FOR RELIEF
(DECLARATORY JUDGMENT OF INVALIDITY OF THE '331 PATENT)

56. Defendants restate and reallege each of the foregoing paragraphs 1-55 as if fully set forth herein.

57. Plaintiff has accused Defendants of infringing the '331 patent.

58. Defendants deny infringement of the '331 patent and allege that the claims of the '331 patent are invalid for failure to satisfy one or more of the conditions for patentability of 35 U.S.C. § 101 *et seq.*, at least for the reasons set forth in Accord's Notice Letter.

59. A definite and concrete, real and substantial, justiciable, and continuing case or controversy exists between Defendants and Plaintiff regarding the validity of the '331 patent.

60. Defendants are entitled to a judicial declaration that the claims of the '331 patent are invalid under one or more of 35 U.S.C. § 101 *et seq*.

PRAYER FOR RELIEF

WHEREFORE, Defendants respectfully pray for judgment in its favor and against Plaintiff:

(a) Declaring that each of the claims of the '998, '199, '081, and '331 patents is invalid under one or more of 35 U.S.C. § 101 *et seq*.;

(a) Declaring that the manufacture, use, sale, offer for sale, or importation of Accord's ANDA Products have not infringed, do not infringe, and would not infringe any valid or enforceable claim of the '918, '190, '199, and '081 patents;

(b) Declaring that the manufacture, use, sale, offer for sale, or importation of Accord's ANDA Products have not induced, do not induce, and would not induce the infringement of any valid or enforceable claim of the '918, '190, '199, and '081 patents.

(c) Declaring that the manufacture, use, sale, offer for sale, or importation of Accord's ANDA Products have not contributorily infringed, do not contributorily infringe, and would not contributorily infringe any valid or enforceable claim of the '918, '190, '199, and '081 patents;

(d) Ordering that Plaintiff's Complaint be dismissed with prejudice and judgment entered in favor of Defendants;

(e) Declaring this case exceptional and awarding Defendants their reasonable attorney's fees and costs of these Counterclaims pursuant to 35 U.S.C. § 285;

(f) Awarding Defendants such other relief as the Court may deem just and proper.

/s/ Kelly E. Farnan
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Dated: September 9, 2022