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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

AMERICAN REGENT, INC., *Plaintiff*, v. ACCORD HEALTHCARE INC., *Defendant.*	Civil Action No. 2:24-cv-09600-BRM-CLW

DEFENDANT ACCORD HEALTHCARE INC.'S ANSWER TO PLAINTIFF'S AMENDED COMPLAINT FOR PATENT INFRINGEMENT WITH AFFIRMATIVE DEFENSES AND COUNTERCLAIMS

Defendant Accord Healthcare Inc. ("Accord"), through its attorneys, hereby answers the Amended Complaint of Plaintiff American Regent, Inc. ("American Regent" or "Plaintiff") and asserts affirmative defenses and counterclaims 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. § 100 *et. seq.*, arising from Accord's submission to the United States Food and Drug Administration ("FDA") of Abbreviated New Drug Application No. 218656 ("the ANDA") which contained a certification of the type described in Section 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act ("Paragraph IV Certification") seeking approval to engage in the commercial manufacture, use, sale, and/or importation of generic versions of ARI's Tralement® (trace elements injection 4*, USP) in 1 mL and 5 mL vials and Multrys® (trace elements injection

4*, USP) in 1 mL single-dose vials drug products (the "ANDA Products") prior to the expiration of United States Patent Nos. 11,786,548 ("the '548 patent"), 11,975,022 ("the '022 patent"), 11,998,565 ("the '565 patent"), 12,150,956 ("the '956 patent"), and 12,150,957 ("the '957 patent") (collectively, the "Patents-in-Suit").

ANSWER: Accord admits that Plaintiff's Amended Complaint purports to set forth an action for patent infringement under the patent laws of the United States, Title 35 U.S.C. § 100 *et seq*. Accord admits that it submitted ANDA No. 218656 to FDA seeking approval to engage in the commercial manufacture, use, sale, and/or importation of cupric sulfate, manganese sulfate, selenious acid, and zinc sulfate intravenous solution (1mL, 60mcg/mL; 3mcg base/mL; 6mcg; 1000mcg base/mL) (1mL, 0.3mg/mL; 55mcg base/mL; 60mcg/mL; 3mg base/mL) and (5mL, 0.3mg/mL; 55mcg base/mL; 60mg/mL; 3mg base/mL) ("Proposed ANDA Products"). Accord admits that ANDA No. 218656 contains an Amended Paragraph IV Certification as to United States Patent Nos. 11,786,548 ("the '548 patent"), 11,975,022 ("the '022 patent"), 11,998,565 ("the '565 patent"), 12,150,956 ("the '956 patent"), and 12,150,957 ("the '957 patent") (collectively, the "Patents-in-Suit"). Accord denies any remaining allegations in Paragraph 1.

2. By email correspondence dated January 9, 2025, Accord consented to the filing of this Amended Complaint.

ANSWER: Admitted.

THE PARTIES

3. ARI is a corporation organized and existing under the laws of the State of New York, with a principal place of business at 5 Ramsey Road, Shirley, New York 11967.

ANSWER: Accord lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 3, and therefore denies them.

4. On information and belief, Accord is an American corporation organized and existing under the laws of North Carolina with its principal place of business at 8041 Arco Corporate Drive, Suite 200, Raleigh, North Carolina 27617.

ANSWER: Admitted.

JURISDICTION AND VENUE

5. This is a civil action for patent infringement arising under the patent laws of the United States, 35 U.S.C. § 100 *et. seq.*, and jurisdiction is proper under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

ANSWER: Paragraph 5 contains legal conclusions to which no response is required. To the extent a response is required, Accord admits that Plaintiff's Amended Complaint purports to set forth an action for patent infringement under 35 U.S.C. § § 100 *et. seq*. Accord admits that this Court has subject matter jurisdiction over this action under 28 U.S.C. §§ 1331, 1338(a) for claims under 35 U.S.C. § 271(e) relating to ANDA No. 218656 only. Accord denies any remaining allegations in Paragraph 5.

6. On information and belief, this Court has personal jurisdiction over Accord under the New Jersey state long arm statute and consistent with due process of law because Accord has extensive contacts with the State of New Jersey and regularly does business in this judicial district. Further, Accord plans to sell its ANDA Products in the State of New Jersey, which provides an independent basis for personal jurisdiction here.

ANSWER: Paragraph 6 contains legal conclusions to which no response is required. To the extent a response is required, denied. Accord does not contest personal jurisdiction for the purposes of this action only.

7. This Court has personal jurisdiction over Accord because Accord has purposefully availed itself of the rights and benefits of New Jersey law by engaging in systematic and continuous contact with the State of New Jersey. On information and belief, Accord regularly and continuously transacts business within New Jersey, including by making pharmaceutical products for sale in New Jersey and selling pharmaceutical products in New Jersey. On information and belief, Accord derives substantial revenue from the sale of those products in New Jersey and has availed itself of the privilege of conducting business within New Jersey. On information and belief, Accord derives substantial revenue from selling generic pharmaceutical products and/or pharmaceutical ingredient(s) used in generic pharmaceutical products sold throughout the United States, including in this judicial district.

ANSWER: Paragraph 7 contains legal conclusions to which no response is required. To the extent a response is required, denied. Accord does not contest personal jurisdiction for the purposes of this action only.

8. This Court has personal jurisdiction over Accord because, on information and belief, Accord derives substantial revenue from directly or indirectly selling generic pharmaceutical products and/or pharmaceutical ingredient(s) used in generic pharmaceutical products sold throughout the United States, including in this judicial district.

ANSWER: Paragraph 8 contains legal conclusions to which no response is required. To the extent a response is required, denied. Accord does not contest personal jurisdiction for the purposes of this action only.

9. On information and belief, Accord is in the business of, among other things, manufacturing, marketing, importing, offering for sale, and selling pharmaceutical products, including generic drug products, throughout the United States, including in this judicial district.

ANSWER: Accord admits that it is in the business of marketing, offering for sale and selling pharmaceutical products in the United States. Accord denies any remaining allegations in Paragraph 9. Accord does not contest personal jurisdiction for the purposes of this action only.

10. On information and belief, Accord intends to benefit directly if the ANDA is approved by participating in the manufacture, importation, distribution, and/or sale of the ANDA Products.

ANSWER: Accord admits that Accord's ANDA No. 218656 seeks approval to engage in the manufacture, importation, distribution, and/or sale of the Proposed ANDA Products. Accord lacks information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 10, and therefore denies them. Accord does not contest personal jurisdiction for the purposes of this action only.

11. On information and belief, this judicial district will be a destination for the generic drug products described in the ANDA.

ANSWER: Accord lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 11, and therefore denies them. Accord does not contest personal jurisdiction for the purposes of this action only.

12. On information and belief, Accord regularly and continuously transacts business within New Jersey, including by making pharmaceutical products for sale in New Jersey and selling pharmaceutical products in New Jersey.

ANSWER: Accord admits that Accord Healthcare Inc. has sought approval for the marketing and sale of certain drug products in the United States. Accord denies any remaining allegations in Paragraph 12. Accord does not contest personal jurisdiction for the purposes of this action only.

13. This Court has personal jurisdiction over Accord because, *inter alia*, Accord has committed an act of patent infringement under 35 U.S.C. § 271(e)(2) and intends a future course of conduct that includes acts of patent infringement in New Jersey. These acts have led and will lead to foreseeable harm and injury to ARI in New Jersey. Further, on information and belief, following approval of the ANDA, Accord will make, use, import, sell, and/or offer for sale the ANDA Products in the United States, including in New Jersey, prior to the expiration of the Patents-in-Suit.

ANSWER: Paragraph 13 contains legal conclusions to which no response is required. To the extent a response is required, denied. Accord does not contest personal jurisdiction for the purposes of this action only.

14. On information and belief, Accord has previously been sued in this Judicial District and has not challenged personal jurisdiction. Accord has also availed itself of New Jersey courts through the assertion of counterclaims in suits brought in New Jersey, including in: *American Regent, Inc. v. Accord Healthcare, Inc.*, C.A. No. 24-07791, Dkt. No. 9 (D.N.J. Aug. 15, 2024); *see also, e.g., Theravance Biopharma R&D IP, LLC et al. v. Eugia Pharma Specialties Limited*, C.A. No. 23-00926, Dkt. No. 48 (D.N.J. May 17, 2023); *Fresenius Kabi USA, LLC v. Accord Healthcare Inc.*, C.A. No. 22-00856, Dkt. No. 5 (D.N.J. Feb. 18, 2022); *Janssen Pharmaceuticals, Inc. v. Accord Healthcare Inc.*, C.A. No. 22-00856, Dkt. No. 5 (D.N.J. Feb. 18, 2022); *Eagle Pharmaceuticals, Inc. et al. v. Accord Healthcare Inc.*, C.A. No. 19-09031, Dkt. No. 11 (D.N.J. Apr. 15, 2019).

ANSWER: Paragraph 14 contains legal conclusions to which no response is required. To the extent a response is required, Accord admits that it is a party to the cases identified in Paragraph 14 and asserted counterclaims in some of the cases identified in Paragraph 14. Accord denies any remaining allegations in Paragraph 14. Accord does not contest personal jurisdiction for the purposes of this action only.

15. Venue is further proper in this Court under 28 U.S.C. §§ 1391 and/or 1400(b).

ANSWER: Paragraph 15 contains legal conclusions to which no response is required. Accord does not contest venue for the purposes of this action only.

16. Venue is proper for Accord under 28 U.S.C. §§ 1391 and/or 1400(b). On information and belief, Accord has committed and will commit further acts of infringement in this judicial district. In addition, Accord does business in this judicial district through a permanent and continuous presence in the State of New Jersey. For example, Accord is registered with the State of New Jersey's Department of Health as a drug manufacturer under Registration No. 5003815 and continuously sells its products in this judicial district. Upon information and belief, Accord employs a sales force that includes personnel that regularly and continuously work in this judicial district and, if Accord succeeds in obtaining FDA approval of the ANDA, Accord will use its salesforce to sell the ANDA Products in the State of New Jersey.

ANSWER: Paragraph 16 contains legal conclusions to which no response is required. To the extent a response is required, Accord admits that it is registered with the State of New Jersey's Department of Health as a drug manufacturer under Registration No. 5003815. Accord admits that it continuously sells its products in this judicial district. Accord admits that it employs a sales force that includes personnel that call on accounts located in this judicial district. Accord denies the remaining allegations in Paragraph 16. Accord does not contest venue for the purposes of this action only.

17. In an email correspondence dated October 2, 2024, Accord consented to personal jurisdiction and venue in the District of New Jersey for purposes of this case.

ANSWER: Admitted.

BACKGROUND

18. ARI holds New Drug Application ("NDA") No. 209376 for Tralement® (trace elements injection 4*, USP) and Multrys® (trace elements injection 4*, USP), the first of which was approved by the FDA on July 2, 2020 and which ARI manufactures and sells in this judicial district and throughout the United States.

ANSWER: Accord admits that the Orange Book states that American Regent is the holder of NDA No. 209376. Accord admits that the Orange Book states that Tralement® (trace elements injection 4*, USP) was approved by the FDA on July 2, 2020. Accord lacks information sufficient

to form a belief as to the truth of the remaining allegations in Paragraph 18, and therefore denies them.

19. Tralement® is the first and only FDA-approved multi-trace element injection product for patients weighing at least 10 kg. The FDA has approved both 1 mL and 5 mL forms of Tralement®; ARI markets a 1 mL Tralement® product.

ANSWER: Accord admits that the FDA has approved both 1 mL and 5 mL forms of Tralement®. Accord lacks information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 19, and therefore denies them.

20. Tralement® is a combination of trace elements (zinc sulfate, cupric sulfate, manganese sulfate, and selenious acid) indicated in adult and pediatric patients weighing at least 10 kg as a source of zinc, copper, manganese, and selenium for parenteral nutrition when oral or enteral nutrition is not possible, insufficient, or contraindicated.

ANSWER: Accord admits that the Tralement® full prescribing instructions states that "Tralement is a combination of trace elements (zinc sulfate, cupric sulfate, manganese sulfate and selenious acid) indicated in adult and pediatric patients weighing at least 10 kg as a source of zinc, copper, manganese, and selenium for parenteral nutrition when oral or enteral nutrition is not possible, insufficient, or contraindicated." Accord denies any remaining allegations in Paragraph 20.

21. Multrys® is the first and only FDA-approved multi-trace element injection product for neonatal and pediatric patients weighing less than 10 kg.

ANSWER: Accord lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 21, and therefore denies them.

22. Multrys® is a combination of trace elements (zinc sulfate, cupric sulfate, manganese sulfate, and selenious acid) indicated in neonatal and pediatric patients weighing less than 10 kg as a source of zinc, copper, manganese, and selenium for parenteral nutrition when oral or enteral nutrition is not possible, insufficient, or contraindicated.

ANSWER: Accord admits that the Multrys® full prescribing instructions states "Multrys is a combination of trace elements (zinc sulfate, cupric sulfate, manganese sulfate, and selenious

acid) indicated in neonatal and pediatric patients weighing less than 10 kg as a source of zinc, copper, manganese, and selenium for parenteral nutrition when oral or enteral nutrition is not possible, insufficient, or contraindicated." Accord denies any remaining allegations in Paragraph 22.

23. Tralement® and Multrys®, as well as the use of Tralement® and Multrys® in accordance with their labels, are covered by one or more claims of the Patents-in-Suit.

ANSWER: Accord lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 23, and therefore denies them.

24. ARI is the owner of the '548 patent, which is entitled "Trace element compositions, methods of making and use" and was duly and legally issued on October 17, 2023. A copy of the '548 patent is attached as Exhibit 1.

ANSWER: Accord admits that the '548 patent is entitled "Trace Element Compositions, Methods of Making and Use" and that it issued on October 17, 2023. Accord admits that Exhibit 1 attached to the Amended Complaint appears to be a copy of the '548 patent. Accord denies that the '548 patent was duly and legally issued. Accord admits that American Regent purports to be the owner of the '548 patent. Accord denies any remaining allegations in Paragraph 24.

25. The '548 patent has been listed in connection with Tralement® and Multrys® in the FDA's publication Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book").

ANSWER: Admitted.

26. As indicated in the Orange Book, the patent expiration date for the '548 patent is July 1, 2041.

ANSWER: Accord admits that the Orange Book indicates that the patent expiration date for the '548 patent is July 1, 2041. Accord lacks information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 26, and therefore denies them.

27. ARI is the owner of the '022 patent, which is entitled "Trace element compositions, methods of making and use" and was duly and legally issued on May 7, 2024. A copy of the '022 patent is attached as Exhibit 2.

ANSWER: Accord admits that the '022 patent is entitled "Trace Element Compositions, Methods of Making and Use" and that it issued on May 7, 2024. Accord admits that Exhibit 2 attached to the Amended Complaint appears to be a copy of the '022 patent. Accord denies that the '022 patent was duly and legally issued. Accord admits that American Regent purports to be the owner of the '022 patent. Accord denies any remaining allegations in Paragraph 27.

28. The '022 patent has been listed in connection with Tralement® and Multrys® in the Orange Book.

ANSWER: Admitted.

29. As indicated in the Orange Book, the patent expiration date for the '022 patent is July 1, 2041.

ANSWER: Accord admits that the Orange Book indicates that the patent expiration date for the '022 patent is July 1, 2041. Accord lacks information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 29, and therefore denies them.

30. ARI is the owner of the '565 patent, which is entitled "Trace element compositions, methods of making and use" and was duly and legally issued on June 4, 2024. A copy of the '565 patents is attached as Exhibit 3.

ANSWER: Accord admits that the '565 patent is entitled "Trace Element Compositions, Methods of Making and Use" and that it issued on June 4, 2024. Accord admits that Exhibit 3 attached to the Amended Complaint appears to be a copy of the '565 patent. Accord denies that the '565 patent was duly and legally issued. Accord admits that American Regent purports to be the owner of the '565 patent. Accord denies any remaining allegations in Paragraph 30.

31. The '565 patent has been listed in connection with Tralement® and Multrys® in the Orange Book.

ANSWER: Admitted.

32. As indicated in the Orange Book, the patent expiration date for the '565 patent is July 1, 2041.

ANSWER: Accord admits that the Orange Book indicates that the patent expiration date for the '565 patent is July 1, 2041. Accord lacks information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 32, and therefore denies them.

33. By letter dated August 28, 2024 ("the Notice Letter"), Accord notified ARI pursuant to the Federal Food, Drug, and Cosmetic Act that Accord had submitted to the FDA the ANDA with a Paragraph IV Certification to seek approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the ANDA Products prior to the expiration of the Patents-in-Suit.

ANSWER: Accord admits that it sent a letter to Plaintiff on or about August 28, 2024, regarding the submission of ANDA No. 218656 and its subsequent Paragraph IV Certification to the FDA seeking approval for the Proposed ANDA Products prior to the expiration of the '548, '022, and '565 patents. Accord denies any remaining allegations in Paragraph 33.

34. On information and belief, Accord submitted the ANDA to the FDA, which contained a Paragraph IV Certification asserting that the Patents-in-Suit will not be infringed by the manufacture, use, offer for sale, sale, or importation of the ANDA Products, or alternatively, that the Patents-in-Suit are invalid.

ANSWER: Admitted.

35. The Notice Letter asserted defenses of non-infringement for certain, but not all, claims of the Patents-in-Suit. The Notice Letter did not assert defenses of non-infringement for claims 1-7, 9-10, or 12-58 of the '548 patent, for any claim of the '022 patent, or for any claim of the '565 patent.

ANSWER: Paragraph 35 contains legal conclusions to which no response is required. To the extent a response is required, denied. *See Viskase Corp. v. Am. Nat'l Can Co.*, 261 F.3d 1316, 1323 (Fed. Cir. 2001).

36. Since ARI received the Notice Letter and filed its initial Complaint against Accord (ECF No. 1), the '956 and '957 patents have been listed in connection with Tralement® and Multrys® in the Orange Book.

ANSWER: Admitted.

37. ARI is the owner of the '956 patent, which is entitled "Trace element compositions, methods of making and use" and was duly and legally issued on November 26, 2024. A copy of the '956 patent is attached as Exhibit 4.

ANSWER: Accord admits that the '956 patent is entitled "Trace Element Compositions, Methods of Making and Use" and that it issued on November 26, 2024. Accord admits that Exhibit 4 attached to the Amended Complaint appears to be a copy of the '956 patent. Accord denies that the '956 patent was duly and legally issued. Accord admits that American Regent purports to be the owner of the '956 patent. Accord denies any remaining allegations in Paragraph 37.

38. As indicated in the Orange Book, the patent expiration date for the '956 patent is July 1, 2041.

ANSWER: Accord admits that the Orange Book indicates that the patent expiration date for the '956 patent is July 1, 2041. Accord lacks information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 38, and therefore denies them.

39. ARI is the owner of the '957 patent, which is entitled "Trace element compositions, methods of making and use" and was duly and legally issued on November 26, 2024. A copy of the '957 patent is attached as Exhibit 5.

ANSWER: Accord admits that the '957 patent is entitled "Trace Element Compositions, Methods of Making and Use" and that it issued on November 26, 2024. Accord admits that Exhibit 5 attached to the Amended Complaint appears to be a copy of the '957 patent. Accord denies that the '957 patent was duly and legally issued. Accord admits that American Regent purports to be the owner of the '957 patent. Accord denies any remaining allegations in Paragraph 39.

40. As indicated in the Orange Book, the patent expiration date for the '957 patent is July 1, 2041.

ANSWER: Accord admits that the Orange Book indicates that the patent expiration date for the '957 patent is July 1, 2041. Accord lacks information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 40, and therefore denies them.

41. On information and belief, the ANDA Products are generic versions of Tralement® (trace elements injection 4*, USP) and Multrys® (trace elements injection 4*, USP), as their reference listed drugs, containing the same or equivalent ingredients in the same or equivalent amounts.

ANSWER: Accord admits that Tralement® (trace elements injection 4*, USP) and Multrys® (trace elements injection 4*, USP) are the referenced listed drugs for the Proposed ANDA Products. Accord denies any remaining allegations in Paragraph 41.

42. In the Notice Letter, Accord disclosed that the ANDA Products are (1) a single-dose, 1 mL generic version of Tralement® containing 3 mg of zinc, 0.3 mg of copper, 55 mcg of manganese, and 60 mcg of selenium; (2) a 5 mL generic version of Tralement® containing 3 mg/mL of zinc, 0.3 mg/mL of copper, 55 mcg/mL of manganese, and 60 mcg/mL of selenium; and (3) a single-dose, 1 mL generic version of Multrys® containing 1000 mcg of zinc, 60 mcg of copper, 3 mcg of manganese, and 6 mcg of selenium.

ANSWER: Accord admits that in the Notice Letter, Accord stated that the ANDA Products are cupric sulfate, manganese sulfate, selenious acid, and zinc sulfate intravenous solution (1mL, 60mcg/mL; 3mcg base/mL; 6mcg; 1000mcg base/mL) (1mL, 0.3mg/mL; 55mcg base/mL; 60mcg/mL; 3mg base/mL) and (5mL, 0.3mg/mL; 55mcg base/mL; 60mg/mL; 3mg base/mL). Accord denies any remaining allegations in Paragraph 42.

43. On information and belief, the ANDA Products contain zinc, copper, manganese, and selenium in the same or equivalent amounts as Tralement® and Multrys®, respectively.

ANSWER: Paragraph 43 contains legal conclusions to which no response is required. To the extent a response is required, Accord admits that according to its prescribing information, each mL of Multrys® contains zinc 1,000 mcg, copper 60 mcg, manganese 3 mcg, and selenium 6 mcg and that according to its prescribing information, each mL of Tralement® contains 3 mg of zinc, 0.3 mg of copper, 55 mcg of manganese, and 60 mcg of selenium. Accord denies any remaining allegations in Paragraph 43.

44. On information and belief, the ANDA Products will feature the same or equivalent chemical and therapeutic properties as Tralement® and Multrys®.

ANSWER: Paragraph 44 contains legal conclusions to which no response is required. To the extent a response is required, Accord lacks information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 44, and therefore denies them.

COUNT I: INFRINGEMENT OF THE '548 PATENT

45. ARI realleges paragraphs 1-44 as if fully set forth herein.

ANSWER: Insofar as Plaintiff incorporates the allegations of the proceeding paragraphs 1-44 of the Amended Complaint, Accord repeats and realleges its responses thereto, as if fully set forth herein.

46. Accord's submissions of the ANDA with a Paragraph IV Certification to obtain approval to engage in the commercial manufacture, use, offer for sale, sale and/or importation of the ANDA Products in or into the United States, prior to the expiration of the '548 patent, constitutes direct and indirect infringement of the '548 patent pursuant to 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents.

ANSWER: Denied.

47. On information and belief, the ANDA Products, if approved by the FDA, will be manufactured, used, offered for sale, sold, and/or imported in or into the United States by Accord or on its behalf, and will be administered by patients and/or medical practitioners in the United States according to the directions and instructions in the proposed package insert, which will constitute direct infringement by patients and/or medical practitioners of one or more claims of the '548 patent, under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents. On information and belief, the administration of the ANDA Products will occur with Accord's specific intent and encouragement, and will be conduct that Accord knows or should know will occur. On information and belief, Accord will actively induce, encourage, aid, and abet that conduct by patients and/or medical practitioners, with knowledge and specific intent that the conduct will be in contravention of ARI's rights under the '548 patent.

ANSWER: Denied.

48. On information and belief, Accord's commercial manufacture, use, offer for sale, sale, and/or importation of the ANDA Products, once the ANDA with a Paragraph IV Certification is approved by the FDA, would constitute direct infringement under 35 U.S.C. § 271(a), induced infringement under 35 U.S.C. § 271(b), and/or contributory infringement under 35 U.S.C. § 271(c) of one or more claims of the '548 patent, either literally or under the doctrine of equivalents. On information and belief, Accord intends that the ANDA Products be used by patients and medical

professionals. Also, on information and belief, Accord knows that the ANDA Products are especially made or adapted for use in infringing the '548 patent, and that the ANDA Products are not suitable for substantial non-infringing use.

ANSWER: Denied.

49. ARI will be irreparably harmed if Accord is permitted to make, use, sell, offer to sell, and/or import the ANDA Products in or into the United States, and is not enjoined from doing so. ARI is entitled to relief provided by 35 U.S.C. §§ 271(e)(4) and/or 283, including an order of this Court that the effective date of approval of the ANDA be a date that is not earlier than the expiration date of the '548 patent, or any later expiration of exclusivity for the '548 patent to which ARI is or becomes entitled, and an injunction against such infringement. ARI does not have an adequate remedy at law.

ANSWER: Denied.

50. Accord has had knowledge of the '548 patent since at least the date Accord submitted the ANDA with a Paragraph IV Certification and was aware that submission of the ANDA with a Paragraph IV Certification constituted an act of infringement under 35 U.S.C. § 271(e)(2).

ANSWER: Paragraph 50 contains legal conclusions to which no response is required. To the extent a response is required, Accord admits that it has been aware of the '548 patent since at least the date on which Accord submitted its Paragraph IV Certification. Accord denies the remaining allegations in Paragraph 50.

51. This case is "exceptional," and ARI is entitled to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

ANSWER: Denied.

COUNT II: INFRINGEMENT OF THE '022 PATENT

52. ARI realleges paragraphs 1-51 as if fully set forth herein.

ANSWER: Insofar as Plaintiff incorporates the allegations of the proceeding paragraphs 1-51 of the Amended Complaint, Accord repeats and realleges its responses thereto, as if fully set forth herein.

53. Accord's submission of the ANDA with a Paragraph IV Certification to obtain approval to engage in the commercial manufacture, use, offer for sale, sale and/or importation of the ANDA Products in or into the United States, prior to the expiration of the '022 patent,

constitutes infringement of the '022 patent pursuant to 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents.

ANSWER: Denied.

54. On information and belief, the ANDA Products, if approved by the FDA, will be manufactured, used, offered for sale, sold, and/or imported in or into the United States by Accord or on its behalf, and will be administered by patients and/or medical practitioners in the United States according to the directions and instructions in the proposed package insert, which will constitute direct infringement by patients and/or medical practitioners of one or more claims of the '022 patent, under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents. On information and belief, the administration of the ANDA Products will occur with Accord's specific intent and encouragement, and will be conduct that Accord knows or should know will occur. On information and belief, Accord will actively induce, encourage, aid, and abet that conduct by patients and/or medical practitioners, with knowledge and specific intent that the conduct will be in contravention of ARI's rights under the '022 patent.

ANSWER: Denied.

55. On information and belief, Accord's commercial manufacture, use, offer for sale, sale, and/or importation of the ANDA Products, once the ANDA with a Paragraph IV Certification is approved by the FDA, would constitute induced infringement under 35 U.S.C. § 271(b) and contributory infringement under 35 U.S.C. § 271(c) of one or more claims of the '022 patent, either literally or under the doctrine of equivalents. On information and belief, Accord intends that the ANDA Products be used by patients and medical professionals. Also, on information and belief, Accord knows that the ANDA Products are especially made or adapted for use in infringing the '022 patent, and that the ANDA Products are not suitable for substantial non-infringing use.

ANSWER: Denied.

56. ARI will be irreparably harmed if Accord is permitted to make, use, sell, offer to sell, and/or import the ANDA Products in or into the United States, and is not enjoined from doing so. ARI is entitled to relief provided by 35 U.S.C. §§271(e)(4) and/or 283, including an order of this Court that the effective date of approval of the ANDA be a date that is not earlier than the expiration date of the '022 patent, or any later expiration of exclusivity for the '022 patent to which ARI is or becomes entitled, and an injunction against such infringement. ARI does not have an adequate remedy at law.

ANSWER: Denied.

57. Accord has had knowledge of the '022 patent since at least the date Accord submitted the ANDA with a Paragraph IV Certification and was aware that the submission of the

ANDA with a Paragraph IV Certification constituted an act of infringement under 35 U.S.C. § 271(e)(2).

ANSWER: Paragraph 57 contains legal conclusions to which no response is required. To the extent a response is required, Accord admits that it has been aware of the '022 patent since at least the date on which Accord submitted its Paragraph IV Certification. Accord denies the remaining allegations in Paragraph 57.

58. This case is "exceptional," and ARI is entitled to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

ANSWER: Denied.

COUNT III: INFRINGEMENT OF THE '565 PATENT

59. ARI realleges paragraphs 1-58 as if fully set forth herein.

ANSWER: Insofar as Plaintiff incorporates the allegations of the proceeding paragraphs 1-58 of the Amended Complaint, Accord repeats and realleges its responses thereto, as if fully set forth herein.

60. Accord's submission of the ANDA with a Paragraph IV Certification to obtain approval to engage in the commercial manufacture, use, offer for sale, sale and/or importation of the ANDA Products in or into the United States, prior to the expiration of the '565 patent, constitutes direct and indirect infringement of the '565 patent pursuant to 35 U.S.C. § 271(e)(2)(a), either literally or under the doctrine of equivalents.

ANSWER: Denied.

61. On information and belief, the ANDA Products, if approved by the FDA, will be manufactured, used, offered for sale, sold, and/or imported in or into the United States by Accord or on its behalf, and will be administered by patients and/or medical practitioners in the United States according to the directions and instructions in the proposed package insert, which will constitute direct infringement by patients and/or medical practitioners of one or more claims of the '565 patent, under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents. On information and belief, the administration of the ANDA Products will occur with Accord's specific intent and encouragement, and will be conduct that Accord knows or should know will occur. On information and belief, Accord will actively induce, encourage, aid, and abet that conduct by patients and/or medical practitioners, with knowledge and specific intent that the conduct will be in contravention of ARI's rights under the '565 patent.

ANSWER: Denied.

62. On information and belief, Accord's commercial manufacture, use, offer for sale, sale, and/or importation of the ANDA Products, once the ANDA with a Paragraph IV Certification is approved by the FDA, would constitute direct infringement under 35 U.S.C. § 271(a), induced infringement under 35 U.S.C. § 271(b), and contributory infringement under 35 U.S.C. § 271(c) of one or more claims of the '565 patent, either literally or under the doctrine of equivalents. On information and belief, Accord intends that the ANDA Products be used by patients and medical professionals. Also, on information and belief, Accord knows that the ANDA Products are especially made or adapted for use in infringing the '565 patent, and that the ANDA Products are not suitable for substantial non-infringing use.

ANSWER: Denied.

63. ARI will be irreparably harmed if Accord is permitted to make, use, sell, offer to sell, and/or import the ANDA Products in or into the United States, and is not enjoined from doing so. ARI is entitled to relief provided by 35 U.S.C. §§271(e)(4) and/or 283, including an order of this Court that the effective date of approval of the ANDA be a date that is not earlier than the expiration date of the '565 patent, or any later expiration of exclusivity for the '565 patent to which ARI is or becomes entitled, and an injunction against such infringement. ARI does not have an adequate remedy at law.

ANSWER: Denied.

64. Accord has had knowledge of the '565 patent since at least the date Accord submitted the ANDA with a Paragraph IV Certification and was aware that submission of the ANDA with a Paragraph IV Certification constituted an act of infringement under 35 U.S.C. § 271(e)(2).

ANSWER: Paragraph 64 contains legal conclusions to which no response is required. To the extent a response is required, Accord admits that it has been aware of the '565 patent since at least the date on which Accord submitted its Paragraph IV Certification. Accord denies the remaining allegations in Paragraph 64.

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

ANSWER: Denied.

COUNT IV: INFRINGEMENT OF THE '956 PATENT

66. ARI realleges paragraphs 1-65 as if fully set forth herein.

ANSWER: Insofar as Plaintiff incorporates the allegations of the proceeding paragraphs 1-65 of the Amended Complaint, Accord repeats and realleges its responses thereto, as if fully set forth herein.

67. Accord's submission of the ANDA with a Paragraph IV Certification to obtain approval to engage in the commercial manufacture, use, offer for sale, sale and/or importation of the ANDA Products in or into the United States, prior to the expiration of the '956 patent, constitutes direct and indirect infringement of the '956 patent pursuant to 35 U.S.C. § 271(e)(2)(a), either literally or under the doctrine of equivalents.

ANSWER: Denied.

68. On information and belief, the ANDA Products, if approved by the FDA, will be manufactured, used, offered for sale, sold, and/or imported in or into the United States by Accord or on its behalf, and will be administered by patients and/or medical practitioners in the United States according to the directions and instructions in the proposed package insert, which will constitute direct infringement by patients and/or medical practitioners of one or more claims of the '956 patent, under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents. On information and belief, the administration of the ANDA Products will occur with Accord's specific intent and encouragement, and will be conduct that Accord knows or should know will occur. On information and belief, Accord will actively induce, encourage, aid, and abet that conduct by patients and/or medical practitioners, with knowledge and specific intent that the conduct will be in contravention of ARI's rights under the '956 patent.

ANSWER: Denied.

69. On information and belief, Accord's commercial manufacture, use, offer for sale, sale, and/or importation of the ANDA Products, once the ANDA with a Paragraph IV Certification is approved by the FDA, would constitute direct infringement under 35 U.S.C. § 271(a), induced infringement under 35 U.S.C. § 271(b), and contributory infringement under 35 U.S.C. § 271(c) of one or more claims of the '956 patent, either literally or under the doctrine of equivalents. On information and belief, Accord intends that the ANDA Products be used by patients and medical professionals. Also, on information and belief, Accord knows that the ANDA Products are especially made or adapted for use in infringing the '956 patent, and that the ANDA Products are not suitable for substantial non-infringing use.

ANSWER: Denied.

70. ARI will be irreparably harmed if Accord is permitted to make, use, sell, offer to sell, and/or import the ANDA Products in or into the United States, and is not enjoined from doing so. ARI is entitled to relief provided by 35 U.S.C. §§271(e)(4) and/or 283, including an order of

this Court that the effective date of approval of the ANDA be a date that is not earlier than the expiration date of the '956 patent, or any later expiration of exclusivity for the '956 patent to which ARI is or becomes entitled, and an injunction against such infringement. ARI does not have an adequate remedy at law.

ANSWER: Denied.

71. This case is "exceptional," and ARI is entitled to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

ANSWER: Denied.

COUNT V: INFRINGEMENT OF THE '957 PATENT

72. ARI realleges paragraphs 1-71 as if fully set forth herein.

ANSWER: Insofar as Plaintiff incorporates the allegations of the proceeding paragraphs 1-71 of the Amended Complaint, Accord repeats and realleges its responses thereto, as if fully set forth herein.

73. Accord's submission of the ANDA with a Paragraph IV Certification to obtain approval to engage in the commercial manufacture, use, offer for sale, sale and/or importation of the ANDA Products in or into the United States, prior to the expiration of the '957 patent, constitutes direct and indirect infringement of the '957 patent pursuant to 35 U.S.C. § 271(e)(2)(a), either literally or under the doctrine of equivalents.

ANSWER: Denied.

74. On information and belief, the ANDA Products, if approved by the FDA, will be manufactured, used, offered for sale, sold, and/or imported in or into the United States by Accord or on its behalf, and will be administered by patients and/or medical practitioners in the United States according to the directions and instructions in the proposed package insert, which will constitute direct infringement by patients and/or medical practitioners of one or more claims of the '957 patent, under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents. On information and belief, the administration of the ANDA Products will occur with Accord's specific intent and encouragement, and will be conduct that Accord knows or should know will occur. On information and belief, Accord will actively induce, encourage, aid, and abet that conduct by patients and/or medical practitioners, with knowledge and specific intent that the conduct will be in contravention of ARI's rights under the '957 patent.

ANSWER: Denied.

75. On information and belief, Accord's commercial manufacture, use, offer for sale, sale, and/or importation of the ANDA Products, once the ANDA with a Paragraph IV Certification is approved by the FDA, would constitute direct infringement under 35 U.S.C. § 271(a), induced

infringement under 35 U.S.C. § 271(b), and contributory infringement under 35 U.S.C. § 271(c) of one or more claims of the '957 patent, either literally or under the doctrine of equivalents. On information and belief, Accord intends that the ANDA Products be used by patients and medical professionals. Also, on information and belief, Accord knows that the ANDA Products are especially made or adapted for use in infringing the '957 patent, and that the ANDA Products are not suitable for substantial non-infringing use.

ANSWER: Denied.

76. ARI will be irreparably harmed if Accord is permitted to make, use, sell, offer to sell, and/or import the ANDA Products in or into the United States, and is not enjoined from doing so. ARI is entitled to relief provided by 35 U.S.C. §§271(e)(4) and/or 283, including an order of this Court that the effective date of approval of the ANDA be a date that is not earlier than the expiration date of the '957 patent, or any later expiration of exclusivity for the '957 patent to which ARI is or becomes entitled, and an injunction against such infringement. ARI does not have an adequate remedy at law.

ANSWER: Denied.

77. This case is "exceptional," and ARI is entitled to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

ANSWER: Denied.

PRAYER FOR RELIEF

Accord denies that Plaintiff is entitled to any of the relief requested against Accord in Paragraphs (a) through (h) of the Prayer for Relief section of the Amended Complaint.

GENERAL DENIAL

To the extent not specifically admitted above, including but not limited to every instance where Accord is without knowledge or information sufficient to form a belief about the truth of the allegations, Accord denies all allegations of the Amended Complaint, including all headings to the extent the headings may be deemed allegations.

AFFIRMATIVE AND OTHER DEFENSES

In response to Plaintiff's Amended Complaint, Accord asserts the following affirmative and other defenses. In asserting these defenses, Accord does not assume the burden of proof with respect to any issue upon which applicable law puts the burden of proof upon Plaintiff.

First Affirmative Defense
Failure to State a Claim

Plaintiff's Amended Complaint, in whole or in part, fails to state a claim upon which relief may be granted.

Second Affirmative Defense
Non-Infringement of the '548 Patent

The submission of ANDA No. 218656 to FDA did not, and the importation, manufacture, use, offer for sale, or sale of the Proposed ANDA Products will not, infringe any valid and enforceable claim of the '548 patent under any section of 35 U.S.C. § 271, either literally or under the doctrine of equivalents.

Third Affirmative Defense
Non-Infringement of the '022 Patent

The submission of ANDA No. 218656 to FDA did not, and the importation, manufacture, use, offer for sale, or sale of the Proposed ANDA Products will not, infringe any valid and enforceable claim of the '022 patent under any section of 35 U.S.C. § 271, either literally or under the doctrine of equivalents.

Fourth Affirmative Defense
Non-Infringement of the '565 Patent

The submission of ANDA No. 218656 to FDA did not, and the importation, manufacture, use, offer for sale, or sale of the Proposed ANDA Products will not, infringe any valid and enforceable claim of the '565 patent under any section of 35 U.S.C. § 271, either literally or under the doctrine of equivalents.

Fifth Affirmative Defense
Non-Infringement of the '956 Patent

The submission of ANDA No. 218656 to FDA did not, and the importation, manufacture, use, offer for sale, or sale of the Proposed ANDA Products will not, infringe any valid and

enforceable claim of the '956 patent under any section of 35 U.S.C. § 271, either literally or under the doctrine of equivalents.

Sixth Affirmative Defense
Non-Infringement of the '957 Patent

The submission of ANDA No. 218656 to FDA did not, and the importation, manufacture, use, offer for sale, or sale of the Proposed ANDA Products will not, infringe any valid and enforceable claim of the '957 patent under any section of 35 U.S.C. § 271, either literally or under the doctrine of equivalents.

Seventh Affirmative Defense
Invalidity of the '548 Patent

The claims of the '548 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
Invalidity of the '022 Patent

The claims of the '022 patent are invalid for failure to satisfy one or more of the conditions for patentability of 35 U.S.C. § 101 *et seq*.

Ninth Affirmative Defense
Invalidity of the '565 Patent

The claims of the '565 patent are invalid for failure to satisfy one or more of the conditions for patentability of 35 U.S.C. § 101 *et seq*.

Tenth Affirmative Defense
Invalidity of the '956 Patent

The claims of the '956 patent are invalid for failure to satisfy one or more of the conditions for patentability of 35 U.S.C. § 101 *et seq*.

Eleventh Affirmative Defense
Invalidity of the '957 Patent

The claims of the '957 patent are invalid for failure to satisfy one or more of the conditions for patentability of 35 U.S.C. § 101 *et seq*.

Twelfth Affirmative Defense
No Costs

Upon information and belief, Plaintiff is barred under 35 U.S.C. § 288 from recovering costs in connection with this action.

Thirteenth Affirmative Defense
Failure to State Claim of Willfulness

Plaintiff fails to state a proper claim for willful infringement or exceptional case under 35 U.S.C. §§ 271(e)(4) and 285, or otherwise.

RESERVATION OF DEFENSES

Accord reserves the right to assert additional defenses in the event that discovery or other analysis indicates that additional separate and/or affirmative defenses are appropriate, including, but not limited to, the defense of unenforceability.

COUNTERCLAIMS

For its counterclaims against American Regent, Inc. ("Counterclaim Defendant"), Accord Healthcare Inc. ("Counterclaimant Accord") states as follows:

The Parties

1. Accord Healthcare Inc. is a corporation organized and existing under the laws of North Carolina, having a principal place of business at 8041 Arco Corporate Drive, Suite 200, Raleigh, NC 27617.

2. On information and belief, based on Counterclaim Defendant's allegation, American Regent, Inc. is a corporation organized and existing under the laws of the State of New York, with its principal place of business at 5 Ramsey Road, Shirley, New York 11967.

Nature of the Action

3. These counterclaims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202 and under the patent laws of the United States, 35 U.S.C. § 1 *et seq*.

4. Counterclaimant Accord seeks a declaration that it has not infringed, is not infringing, or will not infringe, directly or indirectly, any valid and enforceable claim of United States Patent Nos. 11,786,548 ("the '548 patent"), 11,975,022 ("the '022 patent"), 11,998,565 ("the '565 patent"), 12,150,956 ("the '956 patent"), and 12,150,957 ("the '957 patent") (collectively, the "Patents-in-Suit"), literally or under the doctrine of equivalents.

5. Counterclaimant Accord also seeks a declaration that the claims of the Patents-in-Suit are invalid under one or more sections of 35 U.S.C. § 101 *et seq*.

6. As a consequence of Counterclaim Defendant's Amended Complaint against Counterclaimant Accord, and based on Accord's denials in its Answer thereto, there exists an actual, continuing, and substantial case or controversy between Counterclaim Defendant and Counterclaimant Accord having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaratory judgment regarding the alleged infringement of the Patents-in-Suit.

Jurisdiction and Venue

7. This Court has subject matter jurisdiction over these Counterclaims under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

8. Counterclaim Defendant has submitted to this Court's personal jurisdiction by suing Counterclaimant Accord in this District. On information and belief, Counterclaim Defendant sells products in this District, including the Tralement® (trace elements injection 4*, USP) and Multrys® (trace elements injection 4*, USP) products at issue in this case, and conducts substantial business in, and has regular and systemic contacts with, this District.

9. Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b).

Background

10. American Regent, Inc. is the holder of New Drug Application ("NDA") No. 209376 for Tralement® (trace elements injection 4*, USP) and Multrys® (trace elements injection 4*, USP), the first of which was approved by the FDA on July 2, 2020 and which American Regent manufactures and sells in this judicial district and throughout the United States.

11. The Patents-in-Suit are listed in the Orange Book in connection with Tralement® (trace elements injection 4*, USP) and Multrys® (trace elements injection 4*, USP).

12. The face of the '548 patent, titled "Trace Element Compositions, Methods of Making and Use," states that it issued on October 17, 2023.

13. Based on the face of the '548 patent, and on information and belief, American Regent, Inc. is the assignee of the '548 patent.

14. The face of the '022 patent, titled "Trace Element Compositions, Methods of Making and Use," states that it issued on May 7, 2024.

15. Based on the face of the '022 patent, and on information and belief, American Regent, Inc. is the assignee of the '022 patent.

16. The face of the '565 patent, titled "Trace Element Compositions, Methods of Making and Use," states that it issued on June 4, 2024.

17. Based on the face of the ’565 patent, and on information and belief, American Regent, Inc. is the assignee of the ’565 patent.

18. The face of the ’956 patent, titled “Trace Element Compositions, Methods of Making and Use,” states that it issued on November 26, 2024.

19. Based on the face of the ’956 patent, and on information and belief, American Regent, Inc. is the assignee of the ’956 patent.

20. The face of the ’957 patent, titled “Trace Element Compositions, Methods of Making and Use,” states that it issued on November 26, 2024.

21. Based on the face of the ’957 patent, and on information and belief, American Regent, Inc. is the assignee of the ’957 patent.

22. Accord Healthcare Inc. submitted ANDA No. 218656 to FDA seeking approval for cupric sulfate, manganese sulfate, selenious acid, and zinc sulfate intravenous solution (1mL, 60mcg/mL; 3mcg base/mL; 6mcg; 1000mcg base/mL) (1mL, 0.3mg/mL; 55mcg base/mL; 60mcg/mL; 3mg base/mL) and (5mL, 0.3mg/mL; 55mcg base/mL; 60mg/mL; 3mg base/mL) (“the Proposed ANDA Products”) before the expiration of the Patents-in-Suit.

23. By a letter dated August 28, 2024 (“First Notice Letter”), Counterclaimant Accord notified Counterclaim Defendant American Regent of the filing of ANDA No. 218656 and that the filing contains a certification provided for in 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that each claim of the ’548, ’022, ’565 patents is invalid, unenforceable, and/or will not be infringed by the Proposed ANDA Products.

24. In accordance with 21 U.S.C. § 355(j)(2)(B)(iv)(II), the First Notice Letter included a detailed statement of the factual and legal basis for the certification that each claim of the ’548,

’022, ’565 patents is invalid, unenforceable, and/or will not be infringed by the Proposed ANDA Products.

25. By a letter dated January 9, 2025 (“Second Notice Letter”), Counterclaimant Accord notified Counterclaim Defendant American Regent of the filing of ANDA No. 218656 and that the filing contains a certification provided for in 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that each claim of the ’956 and ’957 patents is invalid, unenforceable, and/or will not be infringed by the Proposed ANDA Products.

26. In accordance with 21 U.S.C. § 355(j)(2)(B)(iv)(II), the Second Notice Letter included a detailed statement of the factual and legal basis for the certification that each claim of the ’956 and ’957 patents is invalid, unenforceable, and/or will not be infringed by the Proposed ANDA Products.

27. Counterclaim Defendant filed suit on October 3, 2024, alleging that Counterclaimant Accord infringed the ’548, ’022, ’565 patents and filed an Amended Complaint on January 9, 2025 alleging that Counterclaimant Accord additionally infringed the ’956 and ’957 patents.

First Counterclaim
Declaratory Judgment of Non-Infringement of the ’548 Patent

28. Counterclaimant Accord realleges Paragraphs 1-27 as if fully set forth herein.

29. There is an actual, substantial, and continuing justiciable case or controversy between Counterclaimant Accord and Counterclaim Defendant regarding non-infringement of the ’548 patent.

30. Counterclaim Defendant has accused Counterclaimant Accord of infringing the ’548 patent in connection with submission of ANDA No. 218656 and in connection with the

prospective manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed ANDA Products if ANDA No. 218656 is approved.

31. The submission of ANDA No. 218656 to FDA does not infringe, directly or indirectly, any valid and enforceable claim of the '548 patent, either literally or under the doctrine of equivalents.

32. The manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed ANDA Products pursuant to ANDA No. 218656 would not infringe, directly or indirectly, any valid and enforceable claim of the '548 patent, either literally or under the doctrine of equivalents.

33. Because Counterclaimant Accord has not infringed and will not infringe any valid and enforceable claim of the '548 patent, Counterclaim Defendant is not entitled to any damages or any other relief from or against Counterclaimant Accord.

34. Counterclaimant Accord is entitled to a declaration that the submission of ANDA No. 218656 to FDA does not infringe any valid and enforceable claim of the '548 patent.

35. Further, Counterclaimant Accord is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of the Proposed ANDA Products have not infringed, do not infringe, and would not, if marketed, infringe any valid and enforceable claim of the '548 patent.

Second Counterclaim
Declaratory Judgment of Non-Infringement of the '022 Patent

36. Counterclaimant Accord realleges Paragraphs 1-35 as if fully set forth herein.

37. There is an actual, substantial, and continuing justiciable case or controversy between Counterclaimant Accord and Counterclaim Defendant regarding non-infringement of the '022 patent.

38. Counterclaim Defendant has accused Counterclaimant Accord of infringing the '022 patent in connection with submission of ANDA No. 218656 and in connection with the prospective manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed ANDA Products if ANDA No. 218656 is approved.

39. The submission of ANDA No. 218656 to FDA does not infringe, directly or indirectly, any valid and enforceable claim of the '022 patent, either literally or under the doctrine of equivalents.

40. The manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed ANDA Products pursuant to ANDA No. 218656 would not infringe, directly or indirectly, any valid and enforceable claim of the '022 patent, either literally or under the doctrine of equivalents.

41. Because Counterclaimant Accord has not infringed and will not infringe any valid and enforceable claim of the '022 patent, Counterclaim Defendant is not entitled to any damages or any other relief from or against Counterclaimant Accord.

42. Counterclaimant Accord is entitled to a declaration that the submission of ANDA No. 218656 to FDA does not infringe any valid and enforceable claim of the '022 patent.

43. Further, Counterclaimant Accord is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of the Proposed ANDA Products have not infringed, do not infringe, and would not, if marketed, infringe any valid and enforceable claim of the '022 patent.

Third Counterclaim
Declaratory Judgment of Non-Infringement of the '565 Patent

44. Counterclaimant Accord realleges Paragraphs 1-43 as if fully set forth herein.

45. There is an actual, substantial, and continuing justiciable case or controversy between Counterclaimant Accord and Counterclaim Defendant regarding non-infringement of the '565 patent.

46. Counterclaim Defendant has accused Counterclaimant Accord of infringing the '565 patent in connection with submission of ANDA No. 218656 and in connection with the prospective manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed ANDA Products if ANDA No. 218656 is approved.

47. The submission of ANDA No. 218656 to FDA does not infringe, directly or indirectly, any valid and enforceable claim of the '565 patent, either literally or under the doctrine of equivalents.

48. The manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed ANDA Products pursuant to ANDA No. 218656 would not infringe, directly or indirectly, any valid and enforceable claim of the '565 patent, either literally or under the doctrine of equivalents.

49. Because Counterclaimant Accord has not infringed and will not infringe any valid and enforceable claim of the '565 patent, Counterclaim Defendant is not entitled to any damages or any other relief from or against Counterclaimant Accord.

50. Counterclaimant Accord is entitled to a declaration that the submission of ANDA No. 218656 to FDA does not infringe any valid and enforceable claim of the '565 patent.

51. Further, Counterclaimant Accord is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of the Proposed ANDA Products have not infringed, do not infringe, and would not, if marketed, infringe any valid and enforceable claim of the '565 patent.

Fourth Counterclaim
Declaratory Judgment of Non-Infringement of the '956 Patent

52. Counterclaimant Accord realleges Paragraphs 1-51 as if fully set forth herein.

53. There is an actual, substantial, and continuing justiciable case or controversy between Counterclaimant Accord and Counterclaim Defendant regarding non-infringement of the '956 patent.

54. Counterclaim Defendant has accused Counterclaimant Accord of infringing the '956 patent in connection with submission of ANDA No. 218656 and in connection with the prospective manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed ANDA Products if ANDA No. 218656 is approved.

55. The submission of ANDA No. 218656 to FDA does not infringe, directly or indirectly, any valid and enforceable claim of the '956 patent, either literally or under the doctrine of equivalents.

56. The manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed ANDA Products pursuant to ANDA No. 218656 would not infringe, directly or indirectly, any valid and enforceable claim of the '956 patent, either literally or under the doctrine of equivalents.

57. Because Counterclaimant Accord has not infringed and will not infringe any valid and enforceable claim of the '956 patent, Counterclaim Defendant is not entitled to any damages or any other relief from or against Counterclaimant Accord.

58. Counterclaimant Accord is entitled to a declaration that the submission of ANDA No. 218656 to FDA does not infringe any valid and enforceable claim of the '956 patent.

59. Further, Counterclaimant Accord is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of the Proposed ANDA Products have

not infringed, do not infringe, and would not, if marketed, infringe any valid and enforceable claim of the ’956 patent.

Fifth Counterclaim
Declaratory Judgment of Non-Infringement of the ’957 Patent

60. Counterclaimant Accord realleges Paragraphs 1-59 as if fully set forth herein.

61. There is an actual, substantial, and continuing justiciable case or controversy between Counterclaimant Accord and Counterclaim Defendant regarding non-infringement of the ’957 patent.

62. Counterclaim Defendant has accused Counterclaimant Accord of infringing the ’957 patent in connection with submission of ANDA No. 218656 and in connection with the prospective manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed ANDA Products if ANDA No. 218656 is approved.

63. The submission of ANDA No. 218656 to FDA does not infringe, directly or indirectly, any valid and enforceable claim of the ’957 patent, either literally or under the doctrine of equivalents.

64. The manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed ANDA Products pursuant to ANDA No. 218656 would not infringe, directly or indirectly, any valid and enforceable claim of the ’957 patent, either literally or under the doctrine of equivalents.

65. Because Counterclaimant Accord has not infringed and will not infringe any valid and enforceable claim of the ’957 patent, Counterclaim Defendant is not entitled to any damages or any other relief from or against Counterclaimant Accord.

66. Counterclaimant Accord is entitled to a declaration that the submission of ANDA No. 218656 to FDA does not infringe any valid and enforceable claim of the ’957 patent.

67. Further, Counterclaimant Accord is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of the Proposed ANDA Products have not infringed, do not infringe, and would not, if marketed, infringe any valid and enforceable claim of the '957 patent.

Sixth Counterclaim
Declaratory Judgment of Invalidity of the '548 Patent

68. Counterclaimant Accord realleges Paragraphs 1-67 as if fully set forth herein.

69. There is an actual, substantial, and continuing justiciable case or controversy between Counterclaimant Accord and Counterclaim Defendant regarding invalidity of the '548 patent.

70. The '548 patent is invalid for failing to satisfy one or more of the conditions for patentability set forth in 35 U.S.C. §§ 101, *et seq.*, including without limitation, 35 U.S.C. §§ 101, 102, 103, 112, and/or 116, including for the reasons stated in Accord's First Notice Letter and Detailed Statement, and/or for obviousness type double patenting.

71. Counterclaimant Accord is entitled to a judicial declaration that the '548 patent is invalid.

Seventh Counterclaim
Declaratory Judgment of Invalidity of the '022 Patent

72. Counterclaimant Accord realleges Paragraphs 1-71 as if fully set forth herein.

73. There is an actual, substantial, and continuing justiciable case or controversy between Counterclaimant Accord and Counterclaim Defendant regarding invalidity of the '022 patent.

74. The '022 patent is invalid for failing to satisfy one or more of the conditions for patentability set forth in 35 U.S.C. §§ 101, *et seq.*, including without limitation, 35 U.S.C. §§ 101,

102, 103, 112, and/or 116, including for the reasons stated in Accord's First Notice Letter and Detailed Statement, and/or for obviousness type double patenting.

75. Counterclaimant Accord is entitled to a judicial declaration that the '022 patent is invalid.

Eighth Counterclaim
Declaratory Judgment of Invalidity of the '565 Patent

76. Counterclaimant Accord realleges Paragraphs 1-75 as if fully set forth herein.

77. There is an actual, substantial, and continuing justiciable case or controversy between Counterclaimant Accord and Counterclaim Defendant regarding invalidity of the '565 patent.

78. The '565 patent is invalid for failing to satisfy one or more of the conditions for patentability set forth in 35 U.S.C. §§ 101, *et seq.*, including without limitation, 35 U.S.C. §§ 101, 102, 103, 112, and/or 116, including for the reasons stated in Accord's First Notice Letter and Detailed Statement, and/or for obviousness type double patenting.

79. Counterclaimant Accord is entitled to a judicial declaration that the '565 patent is invalid.

Ninth Counterclaim
Declaratory Judgment of Invalidity of the '956 Patent

80. Counterclaimant Accord realleges Paragraphs 1-79 as if fully set forth herein.

81. There is an actual, substantial, and continuing justiciable case or controversy between Counterclaimant Accord and Counterclaim Defendant regarding invalidity of the '956 patent.

82. The '956 patent is invalid for failing to satisfy one or more of the conditions for patentability set forth in 35 U.S.C. §§ 101, *et seq.*, including without limitation, 35 U.S.C. §§ 101,

102, 103, 112, and/or 116, including for the reasons stated in Accord's Second Notice Letter and Detailed Statement, and/or for obviousness type double patenting.

83. Counterclaimant Accord is entitled to a judicial declaration that the '956 patent is invalid.

Tenth Counterclaim
Declaratory Judgment of Invalidity of the '957 Patent

84. Counterclaimant Accord realleges Paragraphs 1-83 as if fully set forth herein.

85. There is an actual, substantial, and continuing justiciable case or controversy between Counterclaimant Accord and Counterclaim Defendant regarding invalidity of the '957 patent.

86. The '957 patent is invalid for failing to satisfy one or more of the conditions for patentability set forth in 35 U.S.C. §§ 101, *et seq.*, including without limitation, 35 U.S.C. §§ 101, 102, 103, 112, and/or 116, including for the reasons stated in Accord's Second Notice Letter and Detailed Statement, and/or for obviousness type double patenting.

87. Counterclaimant Accord is entitled to a judicial declaration that the '957 patent is invalid.

Prayer for Relief

WHEREFORE, Counterclaimant Accord respectfully requests that the Court award the following relief:

A. A declaration that by filing ANDA No. 218656, Counterclaimant Accord has not infringed, is not infringing, and will not infringe, directly or indirectly, any valid and enforceable claim of the Patents-in-Suit, literally or under the doctrine of equivalents, and that Counterclaimant Accord has a lawful right to obtain FDA approval of its ANDA No. 218656 for the Proposed ANDA Products;

B. A declaration that Counterclaimant Accord will not directly infringe, or contribute to or induce infringement of any valid and enforceable claim of the Patents-in-Suit, literally or under the doctrine of equivalents, by the importation, manufacture, use, offer for sale, or sale of Proposed ANDA Products;

C. A declaration that the Patents-in-Suit are invalid;

D. An injunction against Counterclaim Defendant, their officers, employees, agents, representatives, attorneys, and others acting on their behalf, from threatening or initiating infringement litigation against Counterclaimant Accord or its customers, suppliers, or any prospective or present sellers, distributors, or customers of Counterclaimant Accord, or charging them either verbally or in writing with infringement of the Patents-in-Suit with respect to the Proposed ANDA Products;

E. A declaration that this is an exceptional case, and that the Counterclaimant Accord be awarded its attorneys' fees and costs pursuant to 35 U.S.C. § 285;

F. A declaration that Counterclaim Defendant is entitled to no damages, interest, costs, or other relief (including injunctive relief) from or against Counterclaimant Accord for infringement of the Patents-in-Suit;

G. An award of costs and expenses to Counterclaimant Accord; and

H. An award to Counterclaimant Accord of such further relief as this Court may deem necessary, just, and proper.

Dated: January 23, 2025

BENESCH FRIEDLANDER COPLAN & ARONOFF LLP

By: */s/ Kristen Healey Cramer*

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Attorneys for Defendant Accord Healthcare Inc.

CERTIFICATE OF SERVICE

I hereby certify that on January 23, 2025, a copy of the foregoing *Defendant Accord Healthcare Inc.'s Answer to Plaintiff's Amended Complaint with Affirmative Defenses and Counterclaims* was filed electronically. Notice of this filing will be sent by operation of the Court's electronic filing system to all parties indicated on the electronic filing receipt. Parties may access this filing through the Court's CM/ECF system.

/s/ Kristen Healey Cramer
Kristen Healey Cramer

Attorney for Defendant Accord Healthcare Inc.