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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

AMERICAN REGENT, INC., *Plaintiff,* v. ACCORD HEALTHCARE INC. *Defendant.*	Civil Action No. 24-cv-111108 (Filed Electronically)

COMPLAINT FOR PATENT INFRINGEMENT TO ACCORD

Plaintiff American Regent, Inc. ("ARI" or "Plaintiff"), by its undersigned attorneys, for its Amended Complaint against Defendant Accord Healthcare Inc. ("Accord" or "Defendant") alleges as follows:

NATURE OF THIS 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. 218655 ("the ANDA") which contains 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 Selenious Acid products ("the ANDA Products") prior to the expiration of United States Patent No. 12,150,957 ("the '957 patent" or the "Asserted Patent"). As discussed below, this case involves the same ANDA No. 218655 and thus is a related case to *American Regent, Inc. v. Accord Healthcare, Inc.*, C.A. No. 24-7791 (D.N.J.) (the "Related Action").

THE PARTIES

2. 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.

3. 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 1009 Slater Road, Suite 210-B, Durham, North Carolina 27703.

JURISDICTION AND VENUE

4. 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.

5. 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 the ANDA Products in the State of New Jersey, which provides an independent basis for personal jurisdiction here.

6. 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.

7. 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.

8. 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.

9. 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.

10. On information and belief, this judicial district will be a destination for the ANDA Products.

11. 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.

12. 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 Asserted Patent.

13. 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. *See, e.g.*, *Theravance Biopharma R&D IP, LLC et al v. Eugia Pharma Specialities Limited et al.*, 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. 22-06341, Dkt. No. 1 (D.N.J. Oct. 28, 2022); *Janssen Pharmaceuticals, Inc. et al. v. Accord Healthcare Inc. et al.*, 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).

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

15. 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.

16. In an email correspondence dated July 10, 2024, Accord consented to personal jurisdiction and venue in the District of New Jersey for purposes of the Related Action.

BACKGROUND

17. ARI holds New Drug Application ("NDA") No. 209379 for Selenious Acid ((1) eq. 600 mcg Selenium/10 mL (eq. 60 mcg Selenium/mL), (2) eq. 60 mcg Selenium/mL (eq. 60 mcg Selenium/mL), and (3) eq. 12 mcg Selenium/2 mL (eq. 6 mcg Selenium/mL)), which was originally approved by the FDA on April 30, 2019, which ARI manufactures and sells in this judicial district and throughout the United States.

18. The use of ARI's Selenious Acid products is covered by one or more claims of the Asserted Patent.

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

20. The ’957 patent has been listed in connection with ARI’s Selenious Acid products in the FDA’s publication Approved Drug Products with Therapeutic Equivalence Evaluations (the “Orange Book”).

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

22. On information and belief, Accord was responsible for preparing the ANDA which contained a Paragraph IV Certification.

23. By letter dated June 11, 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 U.S. Patent No. 11,998,565 (“the ’565 patent”), which is at issue in the Related Action.

24. On information and belief, Accord submitted the ANDA to the FDA, which contained a Paragraph IV Certification asserting that the ’565 patent will not be infringed by the manufacture, use, offer for sale, sale, or importation of the ANDA Products, or alternatively, that the ’565 patent is invalid.

25. Since ARI received the Notice Letter and filed its complaint against Accord in the Related Action, the ’957 patent has been listed in connection with ARI’s Selenious Acid products in the Orange Book.

26. On information and belief, the ANDA Products are generic versions of ARI’s Selenious Acid Products ((1) eq. 600 mcg Selenium/10 mL (eq. 60 mcg Selenium/mL) and (2) eq. 60 mcg Selenium/mL (eq. 60 mcg Selenium/mL)), as their reference listed drug, containing the same or equivalent ingredients in the same or equivalent amounts.

27. In the Notice Letter, Accord disclosed that the ANDA Products are: Selenious Acid Injection USP, 60 mcg base/mL single-dose vials and 600 mcg base/10 mL (60 mcg base/mL) Pharmacy Bulk Package.

28. On information and belief, the ANDA Products contain the same or equivalent ingredients in the same or equivalent amounts as ARI's Selenious Acid products ((1) eq. 600 mcg Selenium/10 mL (eq. 60 mcg Selenium/mL) and (2) eq. 60 mcg Selenium/mL (eq. 60 mcg Selenium/mL)),).

29. On information and belief, the ANDA Products will feature the same or equivalent chemical and therapeutic properties as ARI's Selenious Acid products.

COUNT I: INFRINGEMENT OF THE '957 PATENT

30. ARI realleges paragraphs 1–29 as if fully set forth herein.

31. 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.

32. 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 constitute 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.

33. On information and belief, Accord's 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 '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.

34. 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.

35. Accord has had knowledge of the '957 patent since at least October 11, 2024, when ARI emailed all defendants in the Related Action to inform them that the '957 patent would issue in due course.

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

PRAYER FOR RELIEF

WHEREFORE, ARI prays that this Court grant the following relief:

(a) A judgment under 35 U.S.C. § 271(e)(2)(A) that Accord has infringed at least one claim of the Asserted Patent through Accord's submission of the ANDA with a Paragraph IV Certification to the FDA seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States the ANDA Products before the expiration of the Asserted Patent;

(b) A judgment under 35 U.S.C. §§ 271(a), (b), and/or (c) that Accord's commercial manufacture, use, offer for sale, sale, and/or importation within or into the United States of the ANDA Products before the expiration of the Asserted Patent will infringe, actively induce infringement, and/or contribute to the infringement of at least one claim of the Asserted Patent;

(c) An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of the ANDA, shall not be earlier than the latest expiration date of the Asserted Patent, including any extensions and/or additional periods of exclusivity to which ARI is or becomes entitled;

(d) The entry of a permanent and/or preliminary injunction enjoining Accord, and its affiliates and subsidiaries, and each of its officers, agents, servants, and employees, from making, having made, using, offering to sell, selling, marketing, distributing, and importing in or into the United States the ANDA Products, or any product that infringes the Asserted Patent, or inducing or contributing to the infringement of the Asserted Patent until after the expiration date of the Asserted Patent, including any extension and/or additional periods of exclusivity to which

ARI is or becomes entitled, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

(e) The entry of a permanent and/or preliminary injunction enjoining Accord, and its affiliates and subsidiaries, and each of its officers, agents, servants, and employees, from seeking, obtaining, or maintaining approval of the ANDA until the expiration of the Asserted Patent, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

(f) Damages or other monetary relief to ARI if Accord engage in commercial manufacture, use, offers to sell, sale, and/or importation in or into the United States of the ANDA Products prior to the expiration of the Asserted Patent, including any extensions and/or additional periods of exclusivity to which ARI is or becomes entitled;

(g) A finding that this is an exceptional case pursuant to 35 U.S.C. § 285 and awarding ARI its attorney's fees incurred in this action; and

(h) Such further relief as this Court deems proper and just.

JURY DEMAND

Pursuant to Federal Rule of Civil Procedure 38(b), ARI hereby demands a trial by jury on all issues triable to a jury. Specifically, ARI demands a jury trial in the event that there is a launch at risk and damages are in issue.

Dated: December 13, 2024

By: s/ Charles H. Chevalier

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