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

AMERICAN REGENT, INC., *Plaintiff,* v. ASPIRO PHARMA LTD., *Defendant.*	Civil Action No. 24-CV-11109 (Filed Electronically)

COMPLAINT FOR PATENT INFRINGEMENT TO ASPIRO

Plaintiff American Regent, Inc. ("ARI" or "Plaintiff"), by its undersigned attorneys, for its Complaint against Defendant Aspiro Pharma Ltd. ("Aspiro" 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 Aspiro's submission to the United States Food and Drug

Administration ("FDA") of Abbreviated New Drug Application No. 219633 ("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. 219633 and thus is a related case to *American Regent, Inc. v. Aspiro Pharma Ltd.*, C.A. No. 24-7794 (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, Aspiro is a corporation organized and existing under the laws of India with its principal place of business at House No. 8-3-166/7/1, 3rd Floor, Erragadda Hyderabad, Telangana, 500018 India.

4. By the letter dated June 11, 2024 (the "Notice Letter"), Aspiro identified Somaraju Indukuri, Ph.D., U.S. Agent for Aspiro Pharama Ltd., whose office is at 121 New England Avenue Piscataway, New Jersey 08854, as the person authorized to accept service of process for any patent infringement complaint.

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.

6. On information and belief, this Court has personal jurisdiction over Aspiro, under the New Jersey state long arm statute and consistent with due process of law because Aspiro has

extensive contacts with the State of New Jersey and regularly does business in this judicial district. For example, by the letter dated June 11, 2024 (the "Notice Letter"), Aspiro identified Somaraju Indukuri, Ph.D., U.S. Agent for Aspiro Pharama Ltd., whose office is at 121 New England Avenue Piscataway, New Jersey 08854, as the person authorized to accept service of process for any patent infringement complaint. Further, Aspiro plans to sell the ANDA Products in the State of New Jersey, which provides an independent basis for personal jurisdiction here.

7. This Court has personal jurisdiction over Aspiro because Aspiro 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, Aspiro 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, Aspiro 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, Aspiro 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.

8. This Court has personal jurisdiction over Aspiro because, on information and belief, Aspiro 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.

9. On information and belief, Aspiro 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.

10. This Court has personal jurisdiction over Aspiro because, *inter alia*, it has purposefully availed itself of the privilege of doing business in New Jersey, including directly or indirectly through its agent, Somaraju Indukuri, Ph.D., whose office located in Piscataway, New Jersey and designated by Aspiro as U.S. Agent for service in the Notice Letter.

11. This Court has personal jurisdiction over Aspiro because, *inter alia*, Aspiro 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, Aspiro 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.

12. In the alternative, this Court has personal jurisdiction over Aspiro because the requirements of Federal Rule of Civil Procedure 4(k)(2)(A) are met as (a) ARI's claims arise under federal law; (b) Asprio is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) Aspiro has sufficient contacts with the United States as a whole, including, but not limited to, preparing and submitting the ANDA to the FDA and/or manufacturing and/or selling pharmaceutical products distributed throughout the United States, such that this Court's exercise of jurisdiction over Aspiro satisfies due process.

13. Venue is further proper in this Court under 28 U.S.C. §§ 1391 and/or 1400(b) at least because, on information and belief, Aspiro is a foreign company not residing in any United States judicial district and may be sued in any judicial district. 28 U.S.C. § 1391(c)(3).

BACKGROUND

14. 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.

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

16. 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.

17. 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").

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

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

20. By the letter dated June 11, 2024 ("the Notice Letter"), Aspiro notified ARI that, pursuant to the Federal Food, Drug, and Cosmetic Act, Aspiro had submitted the ANDA with a Paragraph IV Certification to the FDA seeking 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 U.S. Patent No. 11,998,565 ("the '565 patent"), which is at issue in the Related Action.

21. On information and belief, Aspiro 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.

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

23. 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. 12 mcg/2mL (eq. 6 mcg selenium/mL)), as their reference listed drug, containing the same or equivalent ingredients in the same or equivalent amounts.

24. In the Notice Letter, Aspiro disclosed that the ANDA Products are: Selenious Acid Injection USP, eq. 600 mcg Selenium/10 mL (eq. 60 mcg Selenium/mL) and eq. 12 mcg Selenium/2 mL (eq. 6 mcg Selenium/mL).

25. 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. 12 mcg/2mL (eq. 6 mcg selenium/mL)).

26. 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

27. ARI realleges paragraphs 1–26 as if fully set forth herein.

28. Aspiro’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 Product 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.

29. On information and belief, the ANDA Product, if approved by the FDA, will be manufactured, used, offered for sale, sold, and/or imported in or into the United States by Aspiro 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 Product will occur with Aspiro's specific intent and encouragement, and will constitute conduct that Aspiro knows or should know will occur. On information and belief, Aspiro 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.

30. On information and belief, Aspiro's manufacture, use, offer for sale, sale, and/or importation of the ANDA Product, 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, Aspiro intends that the ANDA Product be used by patients and medical professionals. Also, on information and belief, Aspiro knows that the ANDA Product is especially made or adapted for use in infringing the '957 patent, and that the ANDA Product is not suitable for substantial non-infringing use.

31. ARI will be irreparably harmed if Aspiro is permitted to make, use, sell, offer to sell, and/or import the ANDA Product 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.

32. Aspiro 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.

33. 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 Aspiro has infringed at least one claim of the Asserted Patent through Aspiro'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 Aspiro'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 Aspiro, 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 Aspiro, 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 Aspiro engages 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), Plaintiffs hereby demand a trial by jury on all issues triable to a jury. Specifically, Plaintiffs demand 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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