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**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

AMERICAN REGENT, INC.,

Plaintiff,

v.

RK PHARMA, INC.,

Defendant.

Civil Action No. 24-7805

Document Electronically Filed

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff American Regent, Inc. (“ARI” or “Plaintiff”), by its undersigned attorneys, for its Complaint against Defendant RK Pharma, Inc. (“RK Pharma” 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 RK Pharma’s submission to the United States Food and Drug

Administration (“FDA”) of Abbreviated New Drug Application No. 218536 (“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. 11,998,565 (“the ’565 patent”).

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, Defendant RK Pharma, Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 401 N. Middletown Road, Building 215/215A, Pearl River, New York 10965, a regular and established place of business at 23 Orchard Road, Suite 180, Skillman, New Jersey 08558 through its operations with its affiliate VGYAAN Pharmaceuticals LLC (“VGYAAN”), a regular and established place of business at 49 Napoleon Court, Somerset, New Jersey 08873 through its operations with its affiliate Apicore US LLC (“Apicore”), and a regular and established place of business at 15 Corporate Pl S, Piscataway, New Jersey 08854 through its operations with its affiliate Archis Pharma LLC (“Archis”).

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 RK Pharma, under the New Jersey state long arm statute and consistent with due process of law, because RK

Pharma has extensive contacts with the State of New Jersey and regularly does business in this judicial district, including by maintaining a regular and established place of business in New Jersey. Further, RK Pharma 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 RK Pharma because RK Pharma 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, RK Pharma Inc. is registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey under Entity Identification No. 0101052900. On information and belief, RK Pharma 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, RK Pharma 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.

7. This Court has personal jurisdiction over RK Pharma because, on information and belief, RK Pharma 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, RK Pharma 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. RK Pharma has previously availed itself of the legal protections of the State of New Jersey by, among other things, not contesting jurisdiction in this judicial district, and asserting

counterclaims in this judicial district in the related litigation, *American Regent, Inc. v. RK Pharma, Inc. et al.*, No. 24-cv-1169, ECF No. 37 (D.N.J. May 9, 2024) (later consolidated into No. 24-cv-1022) where ARI has also asserted the '565 patent. *See American Regent, Inc. v. RK Pharma, Inc.*, No. 24-cv-1022, ECF No. 43 (D.N.J. June 20, 2024).

10. This Court has personal jurisdiction over RK Pharma because, *inter alia*, RK Pharma 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, RK Pharma 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 '565 patent.

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

12. On information and belief, venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b) at least because, on information and belief, RK Pharma submitted the ANDA with a Paragraph IV Certification from its affiliate VGYAAN's Skillman, New Jersey place of business and therefore RK Pharma has committed acts of infringement and has a regular and established place of business in New Jersey for the purposes of venue.

13. On information and belief, RK Pharma has taken steps in New Jersey, including preparing the ANDA and communicating with the FDA regarding the ANDA, that indicate its intent to market the ANDA Products. As set forth above, on information and belief, if the ANDA is approved, RK Pharma intends to commit acts of patent infringement in New Jersey, including marketing, distributing, offering for sale, and/or selling the ANDA Products.

14. In an email correspondence dated July 9, 2024, RK Pharma consented to personal jurisdiction and venue in the District of New Jersey for purposes of this case.

BACKGROUND

15. 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 and which ARI manufactures and sells in this judicial district and throughout the United States.

16. ARI’s Selenious Acid products are covered by one or more claims of the ’565 patent.

17. ARI is the owner of the ’565 patent, entitled “Trace element compositions, methods of making and use,” which was duly and legally issued on June 4, 2024. A copy of the ’565 patent is attached as Exhibit 1.

18. The ’565 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”).

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

20. On information and belief, RK Pharma was responsible for preparing the ANDA which contained a Paragraph IV Certification.

21. By letter dated June 10, 2024, (“the Notice Letter”), RK Pharma notified ARI that, pursuant to the Federal Food, Drug, and Cosmetic Act, RK Pharma had submitted the ANDA with a Paragraph IV Certification to the FDA 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 '565 patent.

22. On information and belief, RK Pharma 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.

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), (2) eq. 60 mcg Selenium/mL (eq. 60 mcg Selenium/mL), and (3) eq. 12 mcg Selenium/2 mL (eq. 6 mcg Selenium/mL)), as their reference listed drugs, containing the same or equivalent ingredients in the same or equivalent amounts.

24. In the Notice Letter, RK Pharma disclosed that the ANDA Products are: (1) Selenious Acid (eq. 12 mcg Selenium/2mL (eq. 6 mcg Selenium/mL)); (2) Selenious Acid (eq. 60 mcg Selenium/mL (eq. 60 mcg Selenium/mL)); and (3) Selenious Acid (eq. 600 mcg Selenium/10 mL (eq. 60 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), (2) eq. 60 mcg Selenium/mL (eq. 60 mcg Selenium/mL), and (3) eq. 12 mcg Selenium/2 mL (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 '565 PATENT

27. ARI realleges paragraphs 1–25 as if fully set forth herein.

28. RK Pharma'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.

29. 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 RK Pharma 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 RK Pharma's specific intent and encouragement, and will constitute conduct that RK Pharma knows or should know will occur. On information and belief, RK Pharma 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.

30. On information and belief, RK Pharma'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 '565 patent, either literally or under the doctrine of equivalents. On information and belief, RK Pharma intends that the ANDA Products be used by patients and medical professionals. Also, on information and belief, RK Pharma 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.

31. ARI will be irreparably harmed if RK Pharma 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.

32. RK Pharma has had knowledge of the '565 patent since at least the date RK Pharma 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).

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 RK Pharma has infringed at least one claim of the '565 patent through RK Pharma’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 '565 patent;

(b) A judgment under 35 U.S.C. §§ 271(a), (b), and/or (c) that RK Pharma’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 '565 patent will infringe, actively induce infringement, and/or contribute to the infringement of at least one claim of the '565 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 '565 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 RK Pharma, and its affiliates and subsidiaries, and each of their 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 '565 patent, or inducing or contributing to the infringement of the '565 patent until after the expiration date of the '565 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 RK Pharma, and its affiliates and subsidiaries, and each of their officers, agents, servants, and employees, from seeking, obtaining, or maintaining approval of the ANDA until the expiration of the '565 patent, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

(f) Damages or other monetary relief to ARI if RK Pharma 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 '565 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 attorneys' 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), Plaintiff hereby demands a trial by jury on all issues triable to a jury. Specifically, Plaintiff demands a jury trial in the event that there is a launch at risk and damages are in issue.

Dated: July 16, 2024
Newark, New Jersey

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