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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

AMERICAN REGENT, INC., *Plaintiff*, v. DR. REDDY'S LABORATORIES, INC. and DR. REDDY'S LABORATORIES, LTD., *Defendants.*	Civil Action No. 24-7799 *Document Electronically Filed*

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff American Regent, Inc. ("ARI"), by its undersigned attorneys, for its Complaint against Defendants Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd. (collectively, "DRL" or "Defendants") 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 DRL's submission to the United States Food and Drug Administration ("FDA") of Abbreviated New Drug Application No. 218639 ("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 a generic version 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, Dr. Reddy's Laboratories, Ltd., is a corporation organized and existing under the laws of India with its principal place of business at Door No. 8-2-337, Road No. 3, Banjara Hills, Hyderabad 500 034, Telangana, Republic of India.

4. On information and belief, Dr. Reddy's Laboratories, Ltd itself, and through its subsidiary and agent DRL Inc., develops, manufactures, and/or distributes generic drug products for marketing, sale, and/or use throughout the United States, including in this judicial district.

5. On information and belief, Dr. Reddy's Laboratories, Inc., is a corporation organized and existing under the laws of New Jersey with its principal place of business at 107 College Road East, Princeton, New Jersey 08540.

6. On information and belief, Dr. Reddy's Laboratories, Inc. is a wholly owned subsidiary of Dr. Reddy's Laboratories Ltd. and is controlled and/or dominated by Dr. Reddy's Laboratories, Inc.

7. On information and belief, Dr. Reddy's Laboratories Ltd. established Dr. Reddy's Laboratories Inc. for the purposes of developing, manufacturing, and distributing its generic drug products throughout the United States, including in this judicial district.

8. On information and belief, Dr. Reddy's Laboratories, Inc. develops, manufactures, and/or distributes generic drug products for marketing, sale, and/or use throughout the United States, including in this judicial district.

JURISDICTION AND VENUE

9. 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.

10. On information and belief, this Court has personal jurisdiction over Dr. Reddy's Laboratories, Inc., under the New Jersey state long arm statute and consistent with due process of law, because Dr. Reddy's Laboratories, Inc. maintains its principal place of business in New Jersey.

11. On information and belief, this Court has personal jurisdiction over Dr. Reddy's Laboratories Ltd., under the New Jersey state long arm statute and consistent with due process of law because Dr. Reddy's Laboratories Ltd. has extensive contacts with the State of New Jersey, including through its subsidiary Dr. Reddy's Laboratories, Inc., and regularly does business in this judicial district, including through its subsidiary Dr. Reddy's Laboratories, Inc. Further, Dr. Reddy's Laboratories Ltd. plans to sell the ANDA Products in the State of New Jersey, which provides an independent basis for personal jurisdiction here.

12. This Court has personal jurisdiction over DRL because DRL 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, Dr. Reddy's Laboratories, Inc. is

registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey under Business Id. No. 0100518911, and Dr. Reddy's Laboratories, Inc. is also licensed to do business with the New Jersey Department of Health as a "Manufacturer and Wholesale[r]" of pharmaceuticals in the State of New Jersey under Registration Number 5002312. On information and belief, DRL 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, DRL 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.

13. This Court has personal jurisdiction over DRL because, on information and belief, DRL 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.

14. Dr. Reddy's Laboratories Ltd. has previously availed itself of the legal protections of the State of New Jersey by, among other things, selecting the State of New Jersey as the place of incorporation and principal place of business for Dr. Reddy's Laboratories, Inc., not contesting personal jurisdiction in this judicial district, and asserting counterclaims in this judicial district, in the related litigation, *Intra-Cellular Therapies, Inc. v. Dr. Reddy's Lab'ys, Inc. et al.*, C.A. No. 24-4314 (D.N.J.).

15. Dr. Reddy's Laboratories Ltd has also not contested personal jurisdiction in this judicial district, and asserted counterclaims in other cases in this judicial district, including at least *Novo Nordisk Inc. et al. v. Dr. Reddy's Lab'ys, Ltd. et al.*, C.A. No. 23-22112 (D.N.J.); *Bausch & Lomb Inc. et al., v. Dr. Reddy's Lab'ys, Ltd. et al.*, C.A. No. 23-03463 (D.N.J.); *Eisai R&D Mgmt.*

Co., Ltd. et al. v. Dr. Reddy's Lab'ys, Inc. et al., C.A. No. 22-05950 (D.N.J.); *Celgene Corp. v. Dr. Reddy's Lab'ys, Ltd. et al.*, C.A. No. 21-02111 (D.N.J.); *Merck Sharp & Dohme BV et al. v. Dr. Reddy's Lab'ys, Inc. et al.*, C.A. No. 20-02909 (D.N.J.); *Mitsubishi Tanabe Pharma Corp. et al. v. Dr. Reddy's Lab'ys, Inc.* et al., C.A. No. 19-18764 (D.N.J.); *AstraZeneca LP et al. v. Dr. Reddy's Lab'ys, Ltd. et al.*, C.A. No. 19-15739 (D.N.J.); *Supernus Pharm., Inc. v. Dr. Reddy's Lab'ys, Ltd. et al.*, C.A. No. 22-04705 (D.N.J.); *Bausch & Lomb Inc. et al. v. Slayback Pharma LLC et al.*, C.A. No. 21-16766 (D.N.J.).

16. This Court has personal jurisdiction over DRL because, *inter alia*, DRL 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, DRL 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.

17. In the alternative, this Court has personal jurisdiction over Dr. Reddy's Laboratories, Ltd. 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) Dr. Reddy's Laboratories, Ltd. is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) Dr. Reddy's Laboratories, Ltd. has sufficient contacts with the United States as a whole, including, but not limited to, preparing and submitting an 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 Dr. Reddy's Laboratories, Ltd. satisfies due process.

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

19. On information and belief, venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b) at least because Dr. Reddy's Laboratories, Inc. is organized under the laws of the State of New Jersey and therefore "resides" in this judicial district, and has committed acts of infringement in New Jersey and has a regular and established place of business in New Jersey. Dr. Reddy's Laboratories Ltd. 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).

20. On information and belief, DRL has committed acts of infringement under the meaning of 28 U.S.C. § 1400(b) by submitting the ANDA to the FDA, by taking steps indicating its intent to market the ANDA Products in New Jersey, and by the acts that it non-speculatively intends to take in New Jersey if the ANDA receives final FDA approval.

21. On information and belief, Dr. Reddy's Laboratories, Inc. has a regular and established place of business in New Jersey under the meaning of 28 U.S.C. § 1400(b) because, *inter alia*, its principal place of business is in New Jersey. As set forth above, on information and belief, Dr. Reddy's Laboratories, Inc. maintains regular and established places of business in New Jersey, including its headquarters, offices, laboratories, and/or facilities at 107 College Road East, Princeton, New Jersey, 08540.

22. On information and belief, Dr. Reddy's Laboratories Ltd. and Dr. Reddy's Laboratories, Inc. have taken steps in New Jersey, including preparing the ANDA and communicating with the FDA regarding the ANDA, that indicate their intent to market the ANDA Product. As set forth above, on information and belief, if the ANDA is approved, DRL intends to commit acts of patent infringement in New Jersey, including marketing, distributing, offering for sale, and/or selling the ANDA Product.

BACKGROUND

23. ARI holds New Drug Application ("NDA") No. 209379 for Selenious Acid (eq 12 mcg selenium/2 mL ((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)selenium/2 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.

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

25. 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.

26. 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").

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

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

29. By the letter dated June 10, 2024 ("the Notice Letter"), DRL notified ARI that, pursuant to the Federal Food, Drug, and Cosmetic Act, DRL 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.

30. On information and belief, DRL 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 Product, or alternatively, that the ’565 patent is invalid.

31. The Notice Letter did not assert defenses of non-infringement for claims 1-2, 4-11, 13-17, 19-20, 22-26, 28-29 of the ’565 patent.

32. 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/mL) and (2) eq. 60 mcg selenium/mL (eq. 60 mcg/mL), as their reference listed drug, containing the same or equivalent ingredients in the same or equivalent amounts.

33. In the Notice Letter, DRL disclosed that the ANDA Products are: selenious acid, intravenous solution, EQ 600 mcg Selenium/10 mL and EQ 60 mcg Selenium/mL.

34. On information and belief, the ANDA Products contains 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/mL) and (2) eq. 60 mcg selenium/mL (eq. 60 mcg/mL)).

35. 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

36. ARI realleges paragraphs 1–35 as if fully set forth herein.

37. DRL’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 ’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.

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

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

40. ARI will be irreparably harmed if DRL 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.

41. DRL has had knowledge of the '565 patent since at least the date DRL 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).

42. 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 DRL has infringed at least one claim of the '565 patent through DRL'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 Product before the expiration of the '565 patent;

(b) A judgment under 35 U.S.C. §§ 271(a), (b), and/or (c) that DRL'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 DRL, 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 Product, or any products 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 DRL, 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 ’565 patent, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

(f) Damages or other monetary relief to ARI if DRL 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 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), 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

By: s/ Charles H. Chevalier

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