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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

AMERICAN REGENT, INC., *Plaintiff*, v. LONG GROVE PHARMACEUTICALS, LLC, *Defendant*.	Civil Action No. 24-7804 *Document Electronically Filed*

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff American Regent, Inc. ("ARI" or "Plaintiff"), by its undersigned attorneys, for its Complaint against Defendant Long Grove Pharmaceuticals, LLC ("Long Grove" 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 Long Grove's submission to the United States Food and Drug Administration ("FDA") of Abbreviated New Drug Application ("ANDA") No. 217850 ("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 a generic version of ARI's Selenious Acid products ("the ANDA Product") 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, Long Grove Pharmaceuticals, LLC is an American corporation organized and existing under the laws of the State of Delaware with its principal place of business at 9450 W. Bryn Mawr Ave., Suite 640, Rosemont, Illinois, 60018.

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 Long Grove, under the New Jersey state long arm statute and consistent with due process of law because Long Grove has extensive contacts with the State of New Jersey and regularly does business in this judicial district. Further, Long Grove plans to sell the ANDA Product in the State of New Jersey, which provides an independent basis for personal jurisdiction here.

6. This Court has personal jurisdiction over Long Grove because Long Grove 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, Long Grove 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, Long Grove 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, Long Grove 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 Long Grove because, on information and belief, Long Grove 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, Long Grove 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. This Court has personal jurisdiction over Long Grove because, *inter alia*, Long Grove 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, Long Grove will make, use, import, sell, and/or offer for

sale the ANDA Product in the United States, including in New Jersey, prior to the expiration of the ’565 patent.

10. On information and belief, this Court also has personal jurisdiction over Long Grove because it has previously availed itself of the legal protections of the State of New Jersey by affirmatively invoking this Court’s jurisdiction by filing patent litigation complaints in the District of New Jersey, including in at least *Nevakar Injectables Inc. v. InfoRLife SA et al.*, No. 22-06886, ECF No. 70 (D.N.J. June 28, 2023).

11. Venue is proper for Long Grove under 28 U.S.C. §§ 1391 and/or 1400(b). On information and belief, Long Grove has committed and will commit further acts of infringement in this judicial district. In addition, Long Grove does business in this judicial district through a permanent and continuous presence in the State of New Jersey. For example, Long Grove is registered with the State of New Jersey’s Department of Health as a drug manufacturer and wholesaler under Registration No. 5006321 and continuously sells its products in this judicial district. Upon information and belief, if Long Grove succeeds in obtaining FDA approval of the ANDA, Long Grove will sell the ANDA Product in the State of New Jersey.

BACKGROUND

12. 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.

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

14. 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.

15. 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”).

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

17. On information and belief, Long Grove was responsible for preparing the ANDA which contained a Paragraph IV Certification.

18. By letters dated June 27, 2024 (“the Notice Letter”), Long Grove notified ARI pursuant to the Federal Food, Drug, and Cosmetic Act that Long Grove 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 Product prior to the expiration of the ’565 patent.

19. On information and belief, Long Grove 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.

20. On information and belief, the ANDA Product is a generic version 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 the reference listed drug, containing the same or equivalent ingredients in the same or equivalent amounts.

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

22. On information and belief, the ANDA Product 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 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)).

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

COUNT I: INFRINGEMENT OF THE '565 PATENT

24. ARI realleges paragraphs 1–24 as if fully set forth herein.

25. Long Grove'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 '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.

26. 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 Long Grove 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 Product will occur with Long Grove's specific intent and encouragement, and will constitute conduct that Long Grove knows or should know will occur. On information and belief, Long Grove 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.

27. On information and belief, Long Grove'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, Long Grove intends that the ANDA Product be used by patients and medical professionals. Also, on information and belief, Long Grove knows that the ANDA Product is especially made or adapted for use in infringing the '565 patent, and that the ANDA Product is not suitable for substantial non-infringing use.

28. ARI will be irreparably harmed if Long Grove 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 '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.

29. Long Grove has had knowledge of the '565 patent since at least the date Long Grove 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).

30. 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 Long Grove has infringed at least one claim of the '565 patent through Long Grove'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 Long Grove's commercial manufacture, use, offer for sale, sale, and/or importation within or into the United States of the ANDA Product 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 Long Grove, 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 Product, 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 Long Grove, 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 Long Grove engages in commercial manufacture, use, offers to sell, sale, and/or importation in or into the United States of the ANDA Product 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

By: s/ Charles H. Chevalier

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