IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

AMERICAN REGENT, INC., Plaintiff, v. LONG GROVE PHARMACEUTICALS, LLC, Defendant.	Civil Action No. _____

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 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, 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. This Court has personal jurisdiction over Long Grove because, on information and belief, Long Grove is a limited liability company organized and existing under the laws of Delaware, is qualified to do business in Delaware, and has appointed a registered agent for service of process in Delaware. Therefore, Long Grove has purposefully availed itself to the privileges of conducting business in Delaware and consented to general jurisdiction in Delaware. This Court has personal jurisdiction over Long Grove because Long Grove derives substantial revenue from selling generic pharmaceutical products and/or active pharmaceutical ingredient(s) used in generic pharmaceutical products sold throughout the United States, including in this Judicial District.

6. This Court has personal jurisdiction over Long Grove because, *inter alia*, Long Grove either directly or through its subsidiaries, agents, and/or affiliates, has purposefully availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being hauled into court here. On information and belief, Long Grove either directly or through its subsidiaries, agents, and/or affiliates, develops, manufactures, imports, markets, offers to sell, sells, and/or distributes a broad range of generic pharmaceutical products throughout the United States, including in Delaware, and therefore transacts business within Delaware relating to

Plaintiffs' claims, and/or has engaged in systematic and continuous business contacts within Delaware.

7. Upon information and belief, Long Grove is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical drugs, either directly or through various operating subsidiaries, agents, and/or affiliates throughout the United States, including in Delaware.

8. In addition, this Court has personal jurisdiction over Long Grove because, among other things, on information and belief: (1) Long Grove developed the ANDA Products that are the subject of the ANDA and filed the ANDA for the purpose of seeking approval to engage in, either directly or through subsidiaries, agents, affiliates, and/or alter egos, the commercial manufacture, use, sale or offer for sale of the ANDA Products in the United States, including in Delaware; (2) upon approval of the ANDA, Long Grove intends to, either directly or through subsidiaries, agents, affiliates, and/or alter egos, market, distribute, offer for sale, sell, and/or import the ANDA Products in the United States, including in Delaware, and will derive substantial revenue from the use or consumption of the ANDA Products in Delaware; and (3) also upon approval of the ANDA, the ANDA Products will, among other things, be marketed, distributed, offered for sale, sold, and/or imported in Delaware; prescribed by physicians practicing in Delaware; dispensed by pharmacies located within Delaware; and/or used by patients in Delaware, all of which would have substantial effects on Delaware. By filing the ANDA, Long Grove has made clear that it intends to use its distribution channel to direct sales of the ANDA Products into Delaware.

9. Venue is proper in this Judicial District under 28 U.S.C. §§ 1391(b) and 1391(c), and § 1400(b).

10. Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b), at least because, upon information and belief, Long Grove is organized under the laws of the State of Delaware.

11. On information and belief, Long Grove filed the ANDA for the purpose of seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the ANDA Products in the United States, including in Delaware.

12. On information and belief, if Long Grove receives approval for the ANDA, Long Grove will market, distribute, offer for sale, and/or sell the ANDA Products in the United States, including in Delaware, and will derive substantial revenue from the use or consumption of the ANDA Products in the State of Delaware. *See Acorda Therapeutics Inc. v. Mylan Pharm. Inc.*, 817 F.3d 755, 763 (Fed. Cir. 2016).

13. On information and belief, if the ANDA is approved, the ANDA Products would, among other things, be manufactured, marketed, distributed, offered for sale, and/or sold in Delaware, prescribed by physicians practicing in Delaware, dispensed by pharmacies located within Delaware, and/or used by patients in Delaware, all of which would have a substantial effect on Delaware.

14. On information and belief, Long Grove derives substantial revenue from the marketing, manufacture, and/or sale of generic pharmaceutical products in the United States and Delaware.

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, 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 patent expiration date for the '565 patent is July 1, 2041.

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

21. 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 Products prior to the expiration of the '565 patent.

22. 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.

23. On information and belief, the ANDA Products are 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.

24. 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).

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 1–26 as if fully set forth herein.

28. 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 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 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 Products 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.

30. 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 Products be used by patients and medical professionals. Also, on information and belief, Long Grove 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 Long Grove 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. 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).

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 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 Products 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 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 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 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), 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: July 16, 2024

GIBBONS P.C.

By: */s/ Christopher Viceconte*

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