IN THE UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

AMERICAN REGENT, INC., *Plaintiff,* v. LONG GROVE PHARMACEUTICALS, LLC., *Defendant.*	C.A. No. 2:24-cv-07804 **JURY TRIAL DEMANDED**

DEFENDANT LONG GROVE PHARMACEUTICALS, LLC'S ANSWER AND DEFENSES TO COMPLAINT FOR PATENT INFRINGEMENT

Defendant Long Grove Pharmaceuticals, LLC ("Defendant" or "Long Grove"), through the undersigned counsel, hereby answer the Complaint for Plaintiff American Regent, Inc. ("ARI" or "Plaintiff") as follows:

NATURE OF THE 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")

ANSWER:

Defendant Long Grove admits that Plaintiff's Complaint purports to bring this action for the alleged infringement of U.S. Patent No. 11,998,565 ("the '565 patent"). Long Grove admits that it submitted ANDA No. 217850 to FDA to obtain approval to engage in the commercial importation, manufacture, use, and sale of selenious acid solution, intravenous 600 mcg/10 mL

("Long Grove's Proposed ANDA Product") in or into the United States and that ANDA No. 217850 includes a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '565 patent. Long Grove denies any remaining averments of this Paragraph of the Complaint.

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.

ANSWER:

Defendant Long Grove is without knowledge or information sufficient to form a belief as to the truth or falsity of the averments contained in this Paragraph of the Complaint, and on that basis denies such averments.

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.

ANSWER:

Defendant Long Grove admits only that Long Grove is a Delaware limited liability company with a principal place of business at 9450 W. Bryn Mawr Ave., Rosemont, IL 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.

ANSWER:

This Paragraph of the Complaint states a legal conclusion with respect to Plaintiff's alleged statutory basis for asserting jurisdiction in this action, which does not require an answer.

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.

ANSWER:

This Paragraph of the Complaint states a legal conclusion with respect to Plaintiff's alleged statutory basis for asserting jurisdiction in this action, which does not require an answer. To the extent an answer is required, solely for the purposes of this action, Defendant Long Grove does not contest personal jurisdiction in this District. Additionally, Defendant Long Grove has not determined when or where Long Grove's Proposed ANDA Product will be launched, and therefore Long Grove is without knowledge or information sufficient to form a belief as to such averments of this Paragraph and on that basis denies such averments.

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.

ANSWER:

This Paragraph of the Complaint is a legal conclusion and does not require an answer. To the extent an answer is required, solely for the purposes of this action, Defendant Long Grove does not contest personal jurisdiction in this District. Additionally, Defendant Long Grove admits only that Long Grove participates in bringing to market pharmaceutical products and that some products have been distributed in the United States and may have entered the District of New Jersey. Defendant Long Grove denies any remaining averments of this Paragraph of the Complaint.

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.

ANSWER:

This Paragraph of the Complaint is a legal conclusion and does not require an answer. To the extent an answer is required, solely for the purposes of this action, Defendant Long Grove does not contest personal jurisdiction in this District. Additionally, Defendant Long Grove admits only that Long Grove participates in bringing to market pharmaceutical products and that some products have been distributed in the United States and may have entered the District of New Jersey. Defendant Long Grove denies any remaining averments of this Paragraph of the Complaint.

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.

ANSWER:

Defendant Long Grove admits only that Long Grove participates in bringing to market pharmaceutical products and that some products have been distributed in the United States and may have entered the District of New Jersey. Defendant Long Grove denies any remaining averments of this Paragraph of the Complaint.

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.

ANSWER:

This Paragraph of the Complaint is a legal conclusion and does not require an answer. To the extent an answer is required, Defendant Long Grove denies that it has committed an act of infringement under 35 U.S.C. §271(e)(2) or that it intends a future course of conduct that includes acts of patent infringement in New Jersey. Defendant Long Grove further denies that any of its acts have led or will lead to foreseeable harm and injury to Plaintiff in New Jersey. Defendant Long Grove has not determined when or where Long Grove's vasopressin injection product will be launched, and therefore Long Grove is without knowledge or information sufficient to form a belief as to the averments of this Paragraph of the Complaint and on that basis denies the remaining averments of this Paragraph

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).

ANSWER:

This Paragraph of the Complaint is a legal conclusion and does not require an answer. To the extent an answer is required, solely for the purposes of this action, Defendant Long Grove does not contest personal jurisdiction in this District.

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.

ANSWER:

This Paragraph of the Complaint is a legal conclusion and does not require an answer. To the extent an answer is required, solely for the purposes of this action, Defendant Long Grove does contest venue in this District.

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.

ANSWER:

Defendant Long Grove admits only that the FDA website for NDA No. 209379 states that it is for Selenious Acid 600 mcg Selenium/10 mL (eq. 60 mcg Selenium/mL), 60 mcg Selenium/mL (eq. 60 mcg Selenium/mL), and 12 mcg Selenium/2 mL (eq. 6 mcg Selenium/mL) and that it was approved on April 30, 2019. Defendant Long Grove is without knowledge or information sufficient to form a belief as to the truth or falsity of the remaining averments contained in this Paragraph of the Complaint, and on that basis denies such averments.

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

ANSWER:

This Paragraph of the Complaint is a legal conclusion and does not require an answer. To the extent an answer is required, Long Grove is without knowledge or information sufficient to form a belief as to the averments of this Paragraph of the Complaint and on that basis denies the averments of this Paragraph.

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.

ANSWER:

Defendant Long Grove admits that the ’565 patent, entitled “Trace element compositions, methods of making and use,” was issued by the USPTO on June 4, 2024 but denies that it was duly and legally issued. Defendant Long Grove admits that American Regent, Inc. is named as the assignee on the face of the ’565 patent and that the ’565 patent appears to be attached to the Complaint at Exhibit 1. Long Grove denies the remaining averments of this Paragraph of the Complaint.

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”).

ANSWER:

Defendant Long Grove admits that the ’565 patent, is currently listed in the Patent and Exclusivity Information Addendum of FDA’s publication, *Approved Drug Products with Therapeutic Equivalence Evaluations*, commonly known as the Orange Book (“Orange Book”)in connection with NDA No. 209379. Long Grove denies any remaining averments of this Paragraph of the Complaint.

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

ANSWER:

Defendant Long Grove admits that according to the information published in FDA’s Orange Book the ’565 patent will expire on July 1, 2041. Long Grove denies any remaining averments of this Paragraph of the Complaint.

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

ANSWER:

Defendant Long Grove admits only that it is the named applicant for ANDA No. 217850 Long Grove denies any remaining averments of this Paragraph of the Complaint.

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.

ANSWER:

Long Grove admits only that it provided a paragraph IV notice letter, dated June 27, 2024, that stated among other things that the '565 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer to sell, sale, and/or importation of the products described in ANDA No. 217850. Long Grove denies any remaining averments of this Paragraph of the Complaint.

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.

ANSWER:

Long Grove admits that it submitted a Paragraph IV Certification to FDA asserting that the '565 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer to sell, sale, and/or importation of the products described in ANDA No. 217850. Long Grove denies any remaining averments of this Paragraph of the Complaint.

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.

ANSWER:

Long Grove admits only that the established name of the drug product that is the subject of ANDA No. 217850 is Selenious Acid Injection USP, 600 mcg/10mL (60 mcg base/mL) pharmacy bulk package and that ANDA No. 217850 references NDA No. 209379. Long Grove denies the remaining averments of this Paragraph of the Complaint.

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).

ANSWER:

Long Grove admits only that its Notice Letter disclosed that the established name of the drug product that is the subject of ANDA No. 217850 is Selenious Acid Injection USP, 600 mcg/10mL (60 mcg base/mL) pharmacy bulk package. Long Grove denies the remaining averments of this Paragraph of the Complaint.

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)).

ANSWER:

This Paragraph of the Complaint is a legal conclusion and does not require an answer. To the extent an answer is required, Long Grove admits only that its Proposed ANDA Product is Selenious Acid Injection USP, 600 mcg/10mL (60 mcg base/mL) pharmacy bulk package. Long Grove denies the remaining averments of this Paragraph of the Complaint.

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

ANSWER:

This Paragraph of the Complaint is a legal conclusion and does not require an answer. To the extent an answer is required, Long Grove admits that ANDA No. 217850 references NDA

No. 209379, and that ANDA No. 217850 complies with applicable law. Long Grove denies all other averments in this Paragraph.

COUNT I: [alleged] INFRINGEMENT OF THE '565 PATENT

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

ANSWER:

Long Grove repeats and re-alleges all responses to the foregoing Paragraphs 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.

ANSWER:

Denied.

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.

ANSWER:

Denied.

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.

ANSWER:

Denied.

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.

ANSWER:

Denied.

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).

ANSWER:

This Paragraph of the Complaint contains legal conclusions and does not require an answer. To the extent an answer is required, Long Grove admits that it has been aware of the '565 patent since at least the date on which Long Grove submitted its Paragraph IV Certification. Long Grove denies the remaining averments of this Paragraph..

30. This case is "exceptional," and ARI is entitled to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

ANSWER:

Denied.

GENERAL DENIAL AND RESPONSE TO PLAINTIFF'S PRAYER FOR RELIEF

Any allegations in Plaintiff's Complaint not expressly admitted by Long Grove are hereby denied. Having answered Plaintiff's Complaint, Long Grove denies that Plaintiff is entitled to the relief requested in Plaintiff's Prayer for Relief or any relief whatsoever.

ADDITIONAL DEFENSES

Without prejudice to denials set forth in this Answer, and without admitting any allegations of the Complaint not otherwise admitted, Defendant Long Grove asserts the following additional defenses to the Complaint without assuming the burden of proof of any such defense that would otherwise rest on the Plaintiff.

FIRST ADDITIONAL DEFENSE: FAILURE TO STATE A CLAIM

Plaintiff has failed to state a claim upon which relief can be granted, including for the reasons set forth in Long Grove's Additional Defense that follow.

SECOND ADDITIONAL DEFENSE: NON-INFRINGEMENT OF THE '565 PATENT

The manufacture, use, sale, offer for sale or importation into the United States of the product that is the subject of ANDA No. 217850 has not infringed, does not infringe, directly or indirectly, and would not, if marketed, infringe, directly or indirectly, any valid and enforceable claim of the '565 patent (the "Patent-in-Suit"), either literally or under the doctrine of equivalents.

THIRD ADDITIONAL DEFENSE: INVALIDITY OF THE '565 PATENT

The claims of the '565 patent are invalid for failure to satisfy one or more of the conditions for patentability contained in 35 U.S.C. §§ 101, 102, 103, and/or 112, double patenting or other judicially created bases for invalidation.

FOURTH ADDITIONAL DEFENSE: NO ENTITLEMENT TO INJUNCTIVE RELIEF

Plaintiff's claims for injunctive relief are barred at least because Plaintiff has not suffered irreparable injury, Plaintiff has an adequate remedy at law, and because Plaintiff cannot satisfy the other requirements applicable to its request for injunctive relief.

FIFTH ADDITIONAL DEFENSE: UNCLEAN HANDS, ESTOPPEL AND PATENT MISUSE

Plaintiff's claims are barred, in whole or in part, by the equitable doctrines of unclean hands, estoppel, and/or patent misuse.

SIXTH ADDITIONAL DEFENSE: 35 U.S.C. §288

Plaintiff is barred by 35 U.S.C. §288 from recovering any costs associated with this Action.

SEVENTH ADDITIONAL DEFENSE: FAILURE TO STATE A CLAIM OF WILLFULNESS

Plaintiff fails to state a proper claim for willful infringement or exceptional case under 35 U.S.C. §§271(e)(4) and 285, or otherwise.

RESERVATION OF DEFENSES

Defendant Long Grove reserves all affirmative defenses under the Federal Rules of Civil Procedure, defenses under the Patent Laws of the United States, and any other defenses at law or in equity, that may now exist or in the future be available.

PRAYER FOR RELIEF

WHEREFORE, Long Grove respectfully requests the following relief:

a. Entering judgment in Long Grove's favor and dismissing the Complaint with prejudice and denying each request for relief made by Plaintiff;

b. Adjudging the claims of the '565 patent are invalid, unenforceable, and/or not infringed;

c. Adjudging that this is an exceptional case under 35 U.S.C. §285 and awarding Long Grove its attorneys' fees, costs, and expenses in this action; and

d. Awarding Long Grove such other and further relief that the Court deems just and proper under the circumstances.

DEMAND FOR JURY TRIAL

Long Grove Pharmaceuticals, LLC. demands a trial by jury with respect to all issues that are triable to a jury as a matter of right.

LOCAL CIVIL RULE 11.2 CERTIFICATION

Under Local Civil Rule 11.2, the undersigned counsel for the Long Grove hereby certifies that this matter is not the subject of any other action in any other court, or of any pending arbitration or administrative proceeding.

Dated: August 23, 2024

FLASTER/GREENBERG P.C.

/s/ Jeffrey A. Cohen

Jeffrey A. Cohen, Esq.
1810 Chapel Avenue West
Cherry Hill, NJ 08002
(856) 661-1900 (telephone)
(856) 661-1919 (facsimile)
Jeff.Cohen@flastergreenberg.com

Sherry L. Rollo (*Pro Hac Vice*)
Steven E. Feldman (*Pro Hac Vice*)
HAHN LOESER & PARKS LLP
200 W. Madison St., Suite 2700
Chicago, IL 60606
(312) 637-3000 (telephone)
(312) 637-3001 (facsimile)

Attorneys for Defendant Long Grove Pharmaceuticals, LLC