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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

AMERICAN REGENT, INC., *Plaintiff*, v. SOMERSET THERAPEUTICS, LLC, SOMERSET PHARMA, LLC, and ODIN PHARMACEUTICALS, LLC *Defendants.*	Civil Action No. 24-11138 (Filed Electronically)

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff American Regent, Inc. ("ARI" or "Plaintiff"), by its undersigned attorneys, for its Complaint against Defendants Somerset Therapeutics, LLC, Somerset Pharma, LLC, and Odin Pharmaceuticals, LLC (collectively, "Somerset" 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 Somerset's submission to the United States Food and Drug Administration ("FDA") of Abbreviated New Drug Application No. 218780 ("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 Product") prior to the expiration of United States Patent No. 11,998,565 ("the '565 patent") and 12,150,957 ("the '957 patent") (collectively, the "Asserted Patents"). As discussed below, this case involves the same ANDA No. 218780 and thus is a related case to *American Regent, Inc. v. Somerset Therapeutics, LLC*, C.A. No. 24-7807 (D.N.J.).

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, Somerset Therapeutics, LLC is a limited liability corporation organized under the laws of the State of Delaware, having a principle place of business at 6100 Hollywood Blvd., Hollywood, Florida, and an established and regular place of business at 300 Franklin Square Drive, Somerset, New Jersey.

4. On information and belief, Somerset Pharma, LLC is a limited liability corporation organized under the laws of the State of Delaware, having a principle place of business at 300 Franklin Square Drive, Somerset, New Jersey.

5. On information and belief, Somerset Therapeutics, LLC is privately owned pharmaceutical company that manufactures and holds the intellectual property rights and marketing authorizations for generic injectable and ophthalmic drugs.

6. On information and belief, Somerset Pharma, LLC is a wholly-owned subsidiary of Somerset Therapeutics, LLC.

7. On information and belief, Defendant Odin Pharmaceuticals, LLC, is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 300 Franklin Square Drive, Somerset, New Jersey 08873-4187.

8. On information and belief, Somerset Therapeutics, LLC, Somerset Pharma, LLC, and Odin Pharmaceuticals, LLC, acted in concert to prepare and submit the ANDA to the FDA.

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. Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b), at least because, on information and belief, Somerset submitted the ANDA from its Somerset, New Jersey place of business and therefore Somerset has committed acts of infringement and has a regular and established place of business in New Jersey for the purposes of venue.

11. Based on the facts and causes alleged herein, including infringement under 35 U.S.C. § 271(e)(2) by the submission of the ANDA to the FDA and for additional reasons to be further developed through discovery if necessary, this Court has personal jurisdiction over Somerset.

12. On information and belief, Somerset Pharma, LLC has its principal place of business in the State of New Jersey and has registered to do business with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey under Business ID No. 0450400310. Somerset Pharma, LLC has thus consented to personal jurisdiction in New Jersey.

13. On information and belief, Somerset Pharma, LLC and Somerset Therapeutics, LLC are affiliates that operate within the same corporate family.

14. On information and belief, Somerset Therapeutics, LLC has registered to do business with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey under Business ID No. 0451084958. Somerset Pharma, LLC has thus consented to personal jurisdiction in New Jersey.

15. On information and belief, Somerset Therapeutics, LLC and Somerset Pharma, LLC act, operate, and/or hold themselves out to the public as a single integrated business such that Somerset Therapeutics, LLC has an established and regular place of business in the State of New Jersey at least through activities performed in conjunction with Somerset Pharma, LLC.

16. On information and belief, Odin Pharmaceuticals, LLC has its principal place of business in the State of New Jersey and has registered to do business with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey under Business ID No. 0450315269. Odin Pharmaceuticals, LLC has thus consented to personal jurisdiction in New Jersey.

17. On information and belief, Somerset Therapeutics, LLC, with the aid of Somerset Pharma, LLC and Odin Pharmaceuticals, LLC, 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 Product in the United States, including in New Jersey.

18. On information and belief, actions related to the submission of the ANDA occurred in the State of New Jersey, and if Somerset receives approval for the ANDA, Somerset will market, distribute, offer for sale, sell, and/or import the ANDA Product in the United States, including in New Jersey, and will derive substantial revenue from the use or consumption of the ANDA Product

in the State of New Jersey. *See, e.g., Acorda Therapeutics Inc. v. Mylan Pharm. Inc.*, 817 F.3d 755, 763 (Fed. Cir. 2016).

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

20. On information and belief, and as confirmed by Somerset Pharma, LLC's website, Somerset Pharma, LLC, Somerset Therapeutics, LLC, and Odin Pharmaceuticals, LLC operate publicly as "Team Somerset Pharma,"[1] wherein the Somerset Therapeutics, LLC name is placed on product labels,[2] Somerset Pharma, LLC is the entity that develops and commercializes the products in the US,[3] and Odin Pharmaceuticals, LLC "operates as a research and development facility that supports all R&D efforts undertaken by Somerset Pharma."[4]

21. On information and belief, Somerset Therapeutics, LLC, Somerset Pharma, LLC, and Odin Pharmaceuticals, LLC operate under common management by Key Managerial Persons ("KMP").[5] Somerset Therapeutics, LLC, Somerset Pharma, LLC, and Odin Pharmaceuticals, LLC are all "Enterprise[s] over which KMP [has] significant influence."[6]

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[1] Current Happenings, https://somersetpharma.com/first-launch-of-2023-ropivacainehydrochloride-injection/ (last visited on June 20, 2024).

[2] About Us, https://somersetpharma.com/home-2/ (last visited on June 20, 2024).

[3] *Id.*

[4] *Id.*

[5] https://somersetlimited.com/wp-content/uploads/2023/08/Annual-Report_2022-23_Final.pdf at page 63 (last visited on June 20, 2024).

[6] *Id.*

22. On information and belief, following any FDA approval of the ANDA, Somerset Therapeutics, LLC, Somerset Pharma, LLC, and Odin Pharmaceuticals, LLC will work in concert with one another to make, use, offer to sell, and/or sell the ANDA Product throughout the United States, and/or import such generic drug products into the United States, including in this judicial district.

23. On information and belief, Somerset derives substantial revenue from the marketing, manufacture, and/or sale of generic pharmaceutical products in the United States and New Jersey.

24. Somerset 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. Somerset Therapeutics, LLC.*, C.A. No. 24-cv-1022, ECF No. 12 (D.N.J. April 1, 2024).

BACKGROUND

25. 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.

26. ARI's Selenious Acid products or the use of ARI's Selenious Acid products are covered by one or more claims of the Asserted Patents.

27. 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 A.

28. 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”).

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

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

31. By letter dated June 10, 2024 (“the First Notice Letter”), Somerset notified ARI that, pursuant to the Federal Food, Drug, and Cosmetic Act, Somerset 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 a generic version of ARI’s Selenious Acid product (eq. 600 mcg Selenium/10 mL (eq. 60 mcg Selenium/mL)) (“the Original ANDA Product”), prior to the expiration of the ’565 patent.

32. On July 16, 2024, ARI subsequently sued Somerset regarding the ANDA and the Original ANDA product. *See American Regent, Inc. v. Somerset Therapeutics, LLC*, C.A. No. 24-7807, ECF No. 1 (D.N.J. July 16, 2024).

33. By letter dated November 20, 2024 (“the Second Notice Letter”), Somerset notified ARI that Somerset had filed an amendment to the ANDA (“the Amended ANDA”) to additionally seek approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of a generic version of ARI’s Selenious Acid product (eq. 12 mcg Selenium/2 mL (eq. 6 mcg Selenium/mL)) (“the Amended ANDA Product”), prior to the expiration of the ’565 patent.

34. On information and belief, Somerset submitted the Amended 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 Amended ANDA Product, or alternatively, that the ’565 patent is invalid.

35. The Second Notice Letter contained no non-infringement defenses for claims 1, 2-10, 12-19, 21-25, and 27-29 of the ’565 patent.

36. Since ARI received the Second Notice Letter, the ’957 patent has been listed in connection with ARI’s Selenious Acid products in the Orange Book.

37. ARI is the owner of the ’957 patent, entitled “Trace element compositions, methods of making and use,” which was duly and legally issued on November 26, 2024. A copy of the ’957 patent is attached as Exhibit B.

38. As indicated in the Orange Book, the patent expiration date for the ’957 patent is July 1, 2041.

39. On information and belief, as indicated in the Second Notice Letter, the Amended ANDA Product is a generic version of ARI’s Selenious Acid product (eq. 12 mcg Selenium/2 mL (eq. 6 mcg Selenium/mL)), as its reference listed drug, containing the same or equivalent ingredients in the same or equivalent amounts.

40. In the Second Notice Letter, Somerset disclosed that the Amended ANDA Product is Selenious Acid Injection, USP, (12 mcg Selenium/2 mL (6 mcg Selenium/mL)).

41. On information and belief, the Amended ANDA Product contains the same or equivalent ingredients in the same or equivalent amounts as ARI’s Selenious Acid product (eq. 12 mcg Selenium/2 mL (eq. 6 mcg Selenium/mL)).

42. On information and belief, the Amended 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

43. ARI realleges paragraphs 1–42 as if fully set forth herein.

44. Somerset's submission of the Amended 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 Amended 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.

45. On information and belief, the Amended 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 Somerset 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 Amended ANDA Product will occur with Somerset's specific intent and encouragement, and will constitute conduct that Somerset knows or should know will occur. On information and belief, Somerset 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.

46. On information and belief, Somerset's manufacture, use, offer for sale, sale, and/or importation of the Amended ANDA Product, once the Amended 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, Somerset intends that the Amended ANDA Product be used by patients and medical professionals. Also, on information and belief, Somerset knows that

the Amended ANDA Product is especially made or adapted for use in infringing the ’565 patent, and that the Amended ANDA Product is not suitable for substantial non-infringing use.

47. ARI will be irreparably harmed if Somerset is permitted to make, use, sell, offer to sell, and/or import the Amended 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 Amended 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.

48. Somerset has had knowledge of the ’565 patent since at least the date Somerset submitted the Amended ANDA with a Paragraph IV Certification and was aware that submission of the Amended ANDA with a Paragraph IV Certification constituted an act of infringement under 35 U.S.C. § 271(e)(2).

49. This case is “exceptional,” and ARI is entitled to an award of reasonable attorneys’ fees under 35 U.S.C. § 285.

COUNT II: INFRINGEMENT OF THE ’957 PATENT

50. ARI realleges paragraphs 1–49 as if fully set forth herein.

51. Somerset’s submission of the Amended 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 Amended ANDA Product in or into the United States, prior to the expiration of the ’957 patent, constitutes direct and indirect infringement of the ’957 patent pursuant to 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents.

52. On information and belief, the Amended 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

Somerset 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 ’957 patent, under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents. On information and belief, the administration of the Amended ANDA Product will occur with Somerset’s specific intent and encouragement, and will constitute conduct that Somerset knows or should know will occur. On information and belief, Somerset 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 ’957 patent.

53. On information and belief, Somerset’s manufacture, use, offer for sale, sale, and/or importation of the Amended ANDA Product, once the Amended 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 ’957 patent, either literally or under the doctrine of equivalents. On information and belief, Somerset intends that the Amended ANDA Product be used by patients and medical professionals. Also, on information and belief, Somerset knows that the Amended ANDA Product is especially made or adapted for use in infringing the ’957 patent, and that the Amended ANDA Product is not suitable for substantial non-infringing use.

54. ARI will be irreparably harmed if Somerset is permitted to make, use, sell, offer to sell, and/or import the Amended 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 Amended ANDA be a date that is not earlier than the expiration date of the ’957 patent, or any later expiration of exclusivity for the

’957 patent to which ARI is or becomes entitled, and an injunction against such infringement. ARI does not have an adequate remedy at law.

55. Somerset has had knowledge of the ’957 patent since at least October 11, 2024, , when ARI emailed all defendants in the Related Action to inform them that the ’957 patent would issue in due course.

56. 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 Somerset has infringed at least one claim of the Asserted Patents through Somerset’s submission of the Amended 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 Amended ANDA Product before the expiration of the Asserted Patents;

(b) A judgment under 35 U.S.C. §§ 271(a), (b), and/or (c) that Somerset’s commercial manufacture, use, offer for sale, sale, and/or importation within or into the United States of the Amended ANDA Product before the expiration of the Asserted Patents will infringe, actively induce infringement, and/or contribute to the infringement of at least one claim of the Asserted Patents;

(c) An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of the Amended ANDA, shall not be earlier than the latest expiration date of the Asserted Patents, 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 Somerset,

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 Amended ANDA Product, or any product that infringes the Asserted Patents, or inducing or contributing to the infringement of the Asserted Patents until after the expiration date of the Asserted Patents, 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 Somerset, and its affiliates and subsidiaries, and each of its officers, agents, servants, and employees, from seeking, obtaining, or maintaining approval of the Amended ANDA until the expiration of the Asserted Patents, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

(f) Damages or other monetary relief to ARI if Somerset engages in commercial manufacture, use, offers to sell, sale, and/or importation in or into the United States of the Amended ANDA Product prior to the expiration of the Asserted Patents, 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), 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: December 13, 2024 By: s/ Charles H. Chevalier

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