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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. _____ (Filed Electronically)

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff American Regent, Inc. ("ARI"), by its undersigned attorneys, for their Complaint against Defendants Somerset Therapeutics, LLC, Somerset Pharma, LLC, and Odin Pharmaceuticals, LLC (collectively, "Somerset"), 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 ("ANDA") No. 218824 ("the ANDA") seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of a generic version of ARI's Tralement® (trace elements injection 4*, USP) Single-Dose Vials (1 mL Fill) drug product ("the ANDA Product") prior to the expiration of United States Patent No. 11,786,548 ("the '548 patent" or "the patent-in-suit").

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 or 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 have 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 ANDA 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 places 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 places 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 generic product described in the ANDA 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, and/or sell the generic product described in the ANDA in the United States, including in New Jersey, and will derive substantial revenue from the use or consumption of the generic product described in the ANDA in the State of New Jersey. *See 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 generic product described in the ANDA would, among other things, be manufactured, marketed, distributed, offered for sale, and/or sold in 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]

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

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[1] Current Happenings, https://somersetpharma.com/first-launch-of-2023-ropivacaine-hydrochloride-injection/

[2] About Us, https://somersetpharma.com/home-2/

[3] *Id.*

[4] *Id.*

[5] https://somersetlimited.com/wp-content/uploads/2023/08/Annual-Report_2022-23_Final.pdf at page 63.

[6] *Id.*

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. On information and belief, Somerset Pharma, LLC and Somerset Therapeutics, LLC have previously been sued in this District and have not challenged personal jurisdiction or venue. *See, Nexus Pharms., Inc. v. Somerset Pharma, LLC et al.*, Civil Action No. 23-1248 (ZNQ) (RLS) (D.N.J.).

BACKGROUND

25. ARI holds New Drug Application ("NDA") No. 209376 for Tralement® (trace elements injection 4*, USP), which was approved by FDA on July 2, 2020 and which ARI manufactures and sells in this judicial district and throughout the United States.

26. Tralement® is the first and only FDA-approved multi-trace element injection for patients weighing at least 10 kg. FDA has approved both 1 mL and 5 mL forms of Tralement®; ARI markets a 1 mL Tralement® product.

27. Tralement® is a combination of trace elements (zinc sulfate, cupric sulfate, manganese sulfate and selenious acid) indicated in adult and pediatric patients weighing at least 10 kg as a source of zinc, copper, manganese, and selenium for parenteral nutrition when oral or enteral nutrition is not possible, insufficient, or contraindicated.

28. Tralement® is a commercial embodiment of the '548 patent.

29. ARI is the owner of the ’548 patent, which is entitled “Trace element compositions, methods of making and use” was duly and legally issued on October 17, 2023. A copy of the ’548 patent is attached as Exhibit 1.

30. The ’548 patent has been listed in connection with Tralement® in FDA’s publication Approved Drug Products with Therapeutic Equivalence Evaluations (the “Orange Book”).

31. As indicated in the Orange Book, the patent expiration date for the ’548 patent is July 1, 2041.

32. On information and belief, both Somerset Pharma, LLC, Somerset Therapeutics, LLC, and Odin Pharmaceuticals, LLC were responsible for preparing the ANDA.

33. By letter dated January 8, 2024 (“the Notice Letter”), Somerset notified ARI pursuant to the Federal Food, Drug, and Cosmetic Act (“FDCA”) that Somerset had submitted to FDA the ANDA, seeking approval from FDA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of a generic trace element injection 4 USP (Zinc 1000 mcg, Copper 60 mcg, Manganese 3 mcg, Selenium 6 mcg) single-dose vials (1 mL fill) product prior to the expiration of the ’548 patent.

34. On information and belief, Somerset Pharma, LLC, Somerset Therapeutics, LLC, and Odin Pharmaceuticals, LLC submitted the ANDA to FDA with Somerset Therapeutics, LLC as the named applicant, which contained 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”) asserting that the ’548 patent will not be infringed by the manufacture, use, offer for sale, sale, or importation of the ANDA Product, or alternatively, that the patent is invalid.

35. The Notice Letter asserted defenses of non-infringement for certain, but not all, claims of the ’548 patent. The Notice Letter did not set forth positions of non-infringement for Claims 1-26, 34-37, 40-41, 44-46, 48, 51-52, and 55-56

36. On information and belief, the ANDA Product is a drug product that is a generic version of Tralement® (trace elements injection 4*, USP), as its reference listed drug, containing the same or equivalent ingredients in the same or equivalent amounts.

37. In the Notice Letter, Somerset disclosed that the ANDA Product is comprised of 3 mg of zinc, 0.3 mg of copper, 55 mcg of manganese, and 60 mcg of selenium in single-dose vials with 1 ml of fill.

38. On information and belief, the ANDA Product contains zinc, copper, manganese, and selenium in the same or equivalent amounts as Tralement®.

39. On information and belief, the ANDA Product will feature the same or equivalent chemical properties as Tralement®.

COUNT I: INFRINGEMENT OF THE ’548 PATENT

40. ARI realleges paragraphs 1-39 as if fully set forth herein.

41. Somerset’s submission of the ANDA 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 ’548 patent, constitutes direct and indirect infringement of the ’548 patent pursuant to 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents.

42. On information and belief, the ANDA Product, if approved by 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 '548 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 Somerset's specific intent and encouragement, and will be 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 '548 patent.

43. On information and belief, Somerset's manufacturing, use, offer for sale, sale, and/or importation of the ANDA Product, once the ANDA is approved by FDA, would constitute direct infringement under 35 U.S.C. § 271(a), induced infringement under 35 U.S.C. § 271(b), and contributory infringement under 35 U.S.C. § 271(c) of one or more claims of the '548 patent, either literally or under the doctrine of equivalents. On information and belief, Somerset intends that the ANDA Product be used by patients and medical professionals. Also, on information and belief, Somerset knows that the ANDA Product is especially made or adapted for use in infringing the '548 patent, and that the ANDA Product is not suitable for substantial non-infringing use.

44. ARI will be irreparably harmed if Somerset 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 '548 patent, or any later expiration of exclusivity for the '548 patent to which ARI is or becomes entitled, and an injunction against such infringement. ARI does not have an adequate remedy at law.

45. Somerset has had knowledge of the ’548 patent since at least the date Somerset submitted the ANDA and was aware that submission of the ANDA constituted an act of infringement under 35 U.S.C. § 271(e)(2).

46. 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 ’548 patent through Somerset’s submission of the ANDA to 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 ’548 patent;

(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 ANDA Product before the expiration of the ’548 patent will infringe, actively induce infringement, and/or contribute to the infringement of at least one claim of the ’548 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 ’548 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 Somerset, 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 ’548 patent, or inducing or contributing to the infringement of the ’548 patent until after the expiration date of the ’548

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 Somerset, 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 ’548 patent, 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 ANDA Product prior to the expiration of the ’548 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.

Dated: February 22, 2024

By: s/ Charles H. Chevalier

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