IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

AMERICAN REGENT, INC., Plaintiff, v. SOMERSET THERAPEUTICS, LLC, SOMERSET PHARMA, LLC, and ODIN PHARMACEUTICALS, LLC Defendants.	Civil Action No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff American Regent, Inc. ("ARI"), by its undersigned attorneys, for its 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. 218823 ("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 Multrys® (trace elements injection 4*, USP) 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.

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. This Court has personal jurisdiction over Somerset Therapeutics, LLC because, on information and belief, Somerset Therapeutics, LLC 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, Somerset Therapeutics, LLC 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 Somerset Therapeutics, LLC because Somerset Therapeutics, LLC 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.

11. This Court has personal jurisdiction over Somerset Therapeutics, LLC because, *inter alia*, Somerset Therapeutics, LLC 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, Somerset Therapeutics, LLC 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.

12. Upon information and belief, Somerset Therapeutics, LLC 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.

13. In addition, this Court has personal jurisdiction over Somerset Therapeutics, LLC because, among other things, on information and belief: (1) Somerset Therapeutics, LLC, with assistance from Somerset Pharma, LLC and Odin Pharmaceuticals, LLC, developed the ANDA Product that is 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 Product in the United States, including in Delaware; (2) upon approval of the ANDA, Somerset Therapeutics, LLC intends to, either directly or through subsidiaries, agents, affiliates, and/or alter egos, market, distribute, offer for sale, sell, and/or import the ANDA Product in the United States, including in Delaware, and will derive substantial revenue from the use or consumption of the ANDA Product in Delaware; and (3) also upon approval of the ANDA, the ANDA Product 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, Somerset Therapeutics, LLC has made clear that it intends to use its distribution channel to direct sales of the ANDA Product into Delaware.

14. This Court has personal jurisdiction over Somerset Pharma, LLC because, on information and belief, Somerset Pharma, LLC 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, Somerset Pharma, LLC 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 Somerset Pharma, LLC because Somerset Pharma, LLC 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.

15. This Court has personal jurisdiction over Somerset Pharma, LLC because, *inter alia*, Somerset Pharma, LLC 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, Somerset Pharma, LLC 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.

16. Upon information and belief, Somerset Pharma, LLC 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.

17. In addition, this Court has personal jurisdiction over Somerset Pharma, LLC because, among other things, on information and belief: (1) Somerset Pharma, LLC, assisted in development of the ANDA Product that is the subject of the ANDA and assisted in filing 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 Product in the United States, including in Delaware; (2) upon approval of the ANDA, Somerset Pharma, LLC intends to, either directly or through subsidiaries, agents, affiliates, and/or alter egos, market, distribute, offer for sale, sell, and/or import the ANDA Product in the United States, including in Delaware, and will derive substantial revenue from the use or consumption of the ANDA Product in Delaware; and (3) also upon approval of the ANDA, the ANDA Product 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.

18. This Court has personal jurisdiction over Odin Pharmaceuticals, LLC because, on information and belief, Odin Pharmaceuticals, LLC 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, Odin Pharmaceuticals, LLC 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 Odin Pharmaceuticals, LLC because Odin Pharmaceuticals, LLC 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.

19. This Court has personal jurisdiction over Odin Pharmaceuticals, LLC because, *inter alia*, Odin Pharmaceuticals, LLC 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, Odin Pharmaceuticals, LLC 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.

20. Upon information and belief, Odin Pharmaceuticals, LLC 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.

21. In addition, this Court has personal jurisdiction over Odin Pharmaceuticals, LLC because, among other things, on information and belief: (1) Odin Pharmaceuticals, LLC, assisted in development of the ANDA Product that is the subject of the ANDA and assisted in filing 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 Product in the United States, including in Delaware; (2) upon approval of the ANDA, Odin Pharmaceuticals, LLC intends to, either directly or through subsidiaries, agents, affiliates, and/or alter egos, market, distribute, offer for sale, sell, and/or import the ANDA Product in the United States, including in Delaware, and will derive substantial revenue from the use or consumption of the ANDA Product in Delaware; and (3) also upon approval of the ANDA, the ANDA Product 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.

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

23. Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b), at least because, upon information and belief, Somerset Therapeutics LLC, Somerset Pharma LLC, and Odin Pharmaceuticals, LLC are organized under the laws of the State of Delaware.

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

25. 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 Delaware.

26. On information and belief, 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 Delaware, and will derive substantial revenue from the use or consumption of the generic product described in the ANDA in the State of Delaware. *See Acorda Therapeutics Inc. v. Mylan Pharm. Inc.*, 817 F.3d 755, 763 (Fed. Cir. 2016).

27. 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 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.

28. 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

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

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

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]

29. 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]

30. 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.

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

BACKGROUND

32. ARI holds New Drug Application ("NDA") No. 209376 for Multrys® (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.

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[3] *Id.*

[4] *Id.*

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

[6] *Id.*

33. Multrys® is the first and only FDA-approved multi-trace element injection for neonatal and pediatric patients weighing less than 10 kg.

34. Multrys® is a combination of trace elements (zinc sulfate, cupric sulfate, manganese sulfate, and selenious acid) indicated in neonatal and pediatric patients weighing less than 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.

35. Multrys® is a commercial embodiment of the '548 patent.

36. 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.

37. The '548 patent has been listed in connection with Multrys® in FDA's publication Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book").

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

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

40. 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 ("the ANDA Product") prior to the expiration of the '548 patent.

41. 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.

42. 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 26-33, 38-39, 42-43, 47, 49-50, 53-54, and 57-58.

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

44. In the Notice Letter, Somerset disclosed that the ANDA Product is comprised of 1000 mcg of zinc, 60 mcg of copper, 3 mcg of manganese, and 6 mcg of selenium in single-dose vials with 1 ml of fill.

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

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

COUNT I: INFRINGEMENT OF THE '548 PATENT

47. ARI realleges paragraphs 1-46 as if fully set forth herein.

48. 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.

49. 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.

50. 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.

51. 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.

52. 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).

53. 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 23, 2024

GIBBONS P.C.

By: */s/ Christopher Viceconte*

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