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Somerset Pharma, LLC and Odin Pharmaceuticals, LLC

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

AMERICAN REGENT, INC.,	:	Honorable Brian R. Martinotti, U.S.D.J.
Plaintiff,	:	Civil Action No. 24 CV 1030 (BRM)(CLW)
v.	:	
SOMERSET THERAPEUTICS, LLC, SOMERSET PHARMA, LLC, and ODIN PHARMACEUTICALS, LLC,	:	**DEFENDANTS SOMERSET THERAPEUTICS, LLC, SOMERSET PHARMA, LLC, AND ODIN PHARMACEUTICALS, LLC'S ANSWER, SEPARATE DEFENSES, AND COUNTERCLAIMS**
Defendants.	:	

Defendants Somerset Therapeutics, LLC, Somerset Pharma, LLC, and Odin Pharmaceuticals, LLC (collectively "Somerset" or "Defendant"), by and through its undersigned counsel, provide the following answers, separate defenses, and counterclaims to the Complaint of patent infringement ("Complaint") (D.I. 1) of Plaintiff American Regent, Inc. ("ARI" or "Plaintiff"). This pleading is based upon Somerset's knowledge as to its own activities, and upon information and belief as to other matters. Pursuant to Fed. R. Civ. P. 8(b)(3), Somerset denies all allegations in Plaintiff's Complaint except those admitted specifically below.

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").

ANSWER: Somerset admits that Somerset Therapeutics, LLC submitted ANDA No. 218823 ("Somerset's ANDA") to the FDA seeking approval to commercially market a generic version of Multrys® injection 4, USP ("Somerset's Proposed Product") prior to the expiration of the '548 patent. Somerset further admits that Plaintiff's Complaint purports to bring an action for patent infringement under the patent laws of the United States, 35 U.S.C. § 100 et seq., but denies that Plaintiff is entitled to any relief. Somerset denies the remaining allegations this paragraph.

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: Somerset lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of this paragraph, and therefore denies the same.

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.

ANSWER: Somerset admits Somerset Therapeutics, LLC is a limited liability company organized and existing under the laws of Delaware, having a place of business at 300 Franklin Square Drive, Somerset, New Jersey. Somerset denies the remaining allegations of this paragraph.

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.

ANSWER: Somerset admits Somerset Pharma, LLC is a limited liability company organized and existing under the laws of Delaware, having a place of business at 300 Franklin

Square Drive, Somerset, New Jersey 08873. Somerset denies the remaining allegations of this paragraph.

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.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Somerset admits that it markets and sells generic pharmaceutical products throughout the United States. Somerset denies the remaining allegations of this paragraph.

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

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Somerset admits that 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.

ANSWER: Somerset admits Odin Pharmaceuticals, LLC is a limited liability company organized and existing under the laws of Delaware, having a place of business at 300 Franklin Square Drive, Somerset, New Jersey 08873. Somerset denies the remaining allegations of this paragraph.

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.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Somerset admits that Somerset Therapeutics, LLC submitted ANDA No. 218823 to FDA. Somerset denies the remaining allegations of this paragraph.

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.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Somerset does not contest jurisdiction for the purposes of this action only, and expressly reserves the right to contest jurisdiction in any other case as to any party. Somerset otherwise denies the remaining allegations of Paragraph 9.

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 their 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.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Somerset does not contest venue for the purposes of this action only, and expressly reserves the right to contest venue in any other case as to any party. Somerset otherwise denies the remaining allegations of Paragraph 10.

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.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Somerset does not contest personal jurisdiction for the purposes of this action only, and expressly reserves the right to contest personal jurisdiction in any other case as to any party. Somerset otherwise denies the remaining allegations of Paragraph 11.

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.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Somerset does not contest personal jurisdiction for the purposes

of this action only, and expressly reserves the right to contest personal jurisdiction in any other case as to any party. Somerset admits Somerset Pharma, LLC is 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 otherwise denies the remaining allegations of Paragraph 12.

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

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Somerset admits that Somerset Pharma, LLC is a subsidiary of Somerset Therapeutics, LLC. Somerset otherwise denies the remaining allegations of Paragraph 13.

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.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Somerset does not contest personal jurisdiction for the purposes of this action only, and expressly reserves the right to contest personal jurisdiction in any other case as to any party. Somerset admits Somerset Therapeutics, LLC is 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 otherwise denies the remaining allegations of Paragraph 14.

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.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To

the extent a response is required, Somerset does not contest personal jurisdiction for the purposes of this action only, and expressly reserves the right to contest personal jurisdiction in any other case as to any party. Somerset otherwise denies the allegations of Paragraph 15.

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.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Somerset does not contest personal jurisdiction for the purposes of this action only, and expressly reserves the right to contest personal jurisdiction in any other case as to any party. Somerset admits Odin Pharmaceuticals, LLC is 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. Somerset otherwise denies the remaining allegations of Paragraph 16.

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.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Somerset does not contest personal jurisdiction for the purposes of this action only, and expressly reserves the right to contest personal jurisdiction in any other case as to any party. Somerset further admits that Somerset Therapeutics, LLC submitted ANDA No. 218823 to FDA. Somerset otherwise denies the remaining allegations of Paragraph 17.

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).

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Somerset does not contest personal jurisdiction for the purposes of this action only, and expressly reserves the right to contest personal jurisdiction in any other case as to any party. Somerset otherwise denies the remaining allegations of Paragraph 18.

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.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Somerset does not contest personal jurisdiction for the purposes of this action only, and expressly reserves the right to contest personal jurisdiction in any other case as to any party. Somerset otherwise denies the remaining allegations of Paragraph 19.

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," wherein the Somerset Therapeutics, LLC name is placed on product labels, Somerset Pharma, LLC is the entity that develops and commercializes the products in the US, and Odin Pharmaceuticals, LLC "operates as a research and development facility that supports all R&D efforts undertaken by Somerset Pharma."

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Somerset does not contest personal jurisdiction for the purposes of this action only, and expressly reserves the right to contest personal jurisdiction in any other case as to any party. Somerset otherwise denies the remaining allegations of Paragraph 20.

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

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Somerset does not contest personal jurisdiction for the purposes of this action only, and expressly reserves the right to contest personal jurisdiction in any other

case as to any party. Somerset otherwise denies the remaining allegations of Paragraph 21.

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.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Somerset does not contest personal jurisdiction for the purposes of this action only, and expressly reserves the right to contest personal jurisdiction in any other case as to any party. Somerset otherwise denies the remaining allegations of Paragraph 22.

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.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Somerset does not contest personal jurisdiction for the purposes of this action only, and expressly reserves the right to contest personal jurisdiction in any other case as to any party. Somerset otherwise denies the remaining allegations of Paragraph 23.

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.).

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Somerset admits that Somerset was a party to the lawsuits identified in Paragraph 24. Somerset does not contest personal jurisdiction for the purposes of this action only, and expressly reserves the right to contest personal jurisdiction in any other case as to any party. Somerset otherwise denies the remaining allegations of Paragraph 24.

BACKGROUND

25. 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.

ANSWER: Somerset admits that the FDA's website indicates that ARI is the holder of New Drug Application ("NDA") No. 209376 for Multrys® (trace elements injection 4*, USP). Somerset lacks information or knowledge sufficient to form a belief as to the truth or falsity of the remaining allegations of this paragraph, and therefore denies the same.

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

ANSWER: Somerset admits that Multrys® is an FDA-approved multi-trace element injection product. Somerset lacks information or knowledge sufficient to form a belief as to the truth or falsity of the remaining allegations of this paragraph, and therefore denies the same.

27. 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.

ANSWER: Somerset admits that Multrys® is a multi-trace element product and that its prescribing information states that Multrys® is 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. Somerset lacks information or knowledge sufficient to form a belief as to the truth or falsity of the remaining allegations of this paragraph, and therefore denies the same.

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

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Somerset lacks information or knowledge sufficient to form a belief as to the truth or falsity of the allegations of this paragraph, and therefore denies the same.

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.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Somerset admits that on its face, the '548 patent was issued on October 17, 2023, and is entitled "Trace element compositions, methods of making and use." Somerset admits that a purported copy of the '548 patent is attached to the Complaint as Exhibit 1. Somerset specifically denies that the '548 patent was duly and lawfully issued. Somerset lacks information or knowledge sufficient to form a belief as to the truth or falsity of the remaining allegations of this paragraph, and therefore denies the same.

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

ANSWER: Somerset admits that the '548 patent is listed in the FDA's Orange Book in connection with Multrys®. Somerset denies the remaining allegations of this paragraph.

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

ANSWER: Somerset admits that the '548 patent is listed in the Orange Book with an expiration date of July 1, 2041. Somerset denies the remaining allegations of this paragraph.

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

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Somerset admits that Somerset Therapeutics, LLC filed ANDA No. 218823 seeking approval to engage in the commercial manufacture, use, or sale of Somerset's Proposed Product. Somerset otherwise denies the remaining allegations of Paragraph 32.

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 and/or sale 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.

ANSWER: Somerset admits that on January 8, 2024, Somerset Therapeutics, LLC sent

Somerset's Notice Letter. Somerset further admits that Somerset's Notice informed Plaintiff that Somerset filed ANDA No. 218823 seeking approval to engage in the commercial manufacture, use, or sale of Somerset's Proposed Product before the expiration of the '548 patent. Somerset denies the remaining allegations of Paragraph 33.

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.

ANSWER: Somerset admits that Somerset Therapeutics, LLC submitted ANDA No. 218823 to FDA. Somerset further admits that ANDA No. 218823 includes a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that the claims of the '548 patent are invalid, unenforceable, and/or will not be infringed by the activities described in Somerset's ANDA. Somerset denies the remaining allegations of Paragraph 34.

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

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Somerset admits that Somerset's Notice Letter contains non-infringement positions for certain claims the '548 Patent. Somerset otherwise denies the allegations of this paragraph.

36. 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.

ANSWER: Somerset admits that Somerset Therapeutics, LLC submitted ANDA No. 218823 to the FDA seeking approval to commercially market a generic version of Multrys® injection 4, USP. Somerset otherwise denies the allegations of this paragraph.

37. 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.

ANSWER: Somerset admits that its Notice Letter indicates that its ANDA Product contains 1000 mg of zinc, 60 mcg of copper, 3 mcg of manganese and 6 mcg of selenium in a single-dose vial. Somerset otherwise denies the allegations of this paragraph.

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

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Somerset admits that according to its prescribing information, each mL of Multrys® provides zinc 1,000 mcg, copper 60 mcg, manganese 3 mcg, and selenium 6 mcg. Somerset otherwise denies the allegations of this paragraph.

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

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Somerset lacks information or knowledge sufficient to form a belief as to the truth or falsity of the allegations of this paragraph, and therefore denies the same.

COUNT I: INFRINGEMENT OF THE '548 PATENT

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

ANSWER: To the extent an answer to Paragraph 40 is required, Somerset incorporates by reference its answers to the foregoing paragraphs 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.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Somerset denies the allegations of Paragraph 41.

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.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Somerset denies the allegations of Paragraph 42.

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.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Somerset denies the allegations of Paragraph 43.

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.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Somerset denies the allegations of Paragraph 44.

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).

ANSWER: This paragraph contains legal conclusions to which no answer is required. To

the extent a response is required, Somerset denies the allegations of Paragraph 45.

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

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Somerset denies the allegations of Paragraph 46.

PRAYER FOR RELIEF

The remainder of Plaintiff's Complaint recites a prayer for relief for which no response is required. To the extent a response is required, Somerset denies that Plaintiff is entitled to any remedy or relief.

SEPARATE DEFENSES

Somerset asserts the following defenses without prejudice to the denials in this Answer, and without admitting any allegations of the Complaint not otherwise admitted. Somerset does not assume the burden of proof on any such defenses, except as required by applicable law with respect to the particular defense asserted. Somerset reserves the right to assert other defenses and/or to otherwise supplement this Answer upon discovery of facts or evidence rendering such action appropriate.

FIRST DEFENSE

Each purported claim in the Complaint, in whole or in part, is barred for failure to state a claim upon which relief can be granted.

SECOND DEFENSE

The claims of the '548 patent are invalid for failure to comply with the statutory provisions of Title 35 of the United States Code, including without limitation sections 101, 102, 103, and/or 112, or other judicially created bases for invalidity.

THIRD DEFENSE

Somerset does not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '548 patent. If the products that are the subject of ANDA No. 218823 were marketed, Somerset would not infringe any valid and enforceable claim of the '548 patent.

FOURTH DEFENSE

Somerset has not, does not, and will not induce the infringement of, or contribute to the infringement of, any valid and enforceable claim of the '548 patent. If the products that are the subject of ANDA No. 218823 were marketed, Somerset would not induce the infringement of, or contribute to the infringement of, any valid and enforceable claim of the '548 patent.

FIFTH DEFENSE

The claims of the '548 patent are barred in whole or in part by the doctrine of prosecution history estoppel, judicial estoppel, and/or other equitable doctrines.

SIXTH DEFENSE

Somerset's actions in defending this case do not give rise to an exceptional case under 35 U.S.C. § 285.

SEVENTH DEFENSE

Any additional defenses or counterclaims that discovery may reveal.

COUNTERCLAIMS

For its Counterclaims against American Regent, Inc., ("ARI" or "Counterclaim Defendant/Plaintiff"), Counterclaim Plaintiffs/Defendants Somerset Therapeutics, LLC, Somerset Pharma, LLC, and Odin Pharmaceuticals, LLC (together "Somerset" or "Counterclaim Plaintiffs/Defendants"), states as follows:

THE PARTIES

1. On information and belief, American Regent, Inc. 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.

2. On information and belief, Somerset Therapeutics, LLC is a limited liability corporation organized under the laws of the State of Delaware, having a place of business at 300 Franklin Square Drive, Somerset, New Jersey 08873.

3. On information and belief, Somerset Pharma, LLC is a limited liability corporation organized under the laws of the State of Delaware, having a place of business at 300 Franklin Square Drive, Somerset, New Jersey 08873.

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

JURISDICTION AND VENUE

5. These counterclaims arise under the patent laws of the United States and the Declaratory Judgment Act. This Court has subject matter jurisdiction over these counterclaims pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

6. This Court has personal jurisdiction over Counterclaim Defendants/Plaintiffs on the basis of, *inter alia*, their contacts with New Jersey relating to the subject matter of this action, including having filed suit.

7. Venue is proper under 28 U.S.C. §§ 1391 and 1400.

BACKGROUND

8. On information and belief, ARI holds approved New Drug Application ("NDA") No. 209376 for Multyrs® brand trace elements injection 4, USP.

9. An NDA must include, among other things, the number of any patent that claims

the "drug" or a "method of using [the] drug" for which the NDA was submitted and for which a claim of patent infringement could reasonably be asserted against an authorized party. *See* 21 U.S.C. § 355(b)(1), (c)(2); 21 C.F.R. § 314.53(b), (c)(2).

10. Upon approval of the NDA, the U.S. Food and Drug Administration ("FDA") publishes patent information for the approved drug in the "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly known as the "Orange Book." *See* 21 U.S.C. § 355(j)(7)(A)(iii).

11. U.S. Patent 11,786,548 ("the '548 patent"), titled "Trace Element Compositions, Methods of Making and Use," issued on October 17, 2023.

12. On information and belief, American Regent, Inc. is the assignee of the '548 patent.

13. Upon information and belief, Counterclaim Defendant/Plaintiff caused the '548, patent to be listed in the Orange Book as a patent that claims such a drug for which ARI submitted NDA No. 209376.

14. Somerset Therapeutics, LLC submitted Abbreviated New Drug Application ("ANDA") No. 218823 ("Somerset ANDA") to obtain FDA approval to market a generic version of trace elements injection 4 USP ("Somerset's ANDA Product") prior to the expiration of the '548 patent.

15. By letter dated January 8, 2024 (the "Somerset Notice Letter"), pursuant to 21 U.S.C. § 355(j)(2)(B), Somerset Therapeutics, LLC notified Counterclaim Defendant/Plaintiff that ANDA No. 218823 includes a Paragraph IV Certification with respect to the '548 patent. The Somerset Notice Letter, which is incorporated herein by reference, contained a detailed statement of the factual and legal bases for Somerset Paragraph IV Certification that the claims of the '548 patent are invalid, not infringed, and/or unenforceable.

16. On February 22, 2024, Counterclaim Defendant/Plaintiff filed this instant lawsuit alleging infringement of the ’548 patent.

COUNT I
(Declaratory Judgment of Non-Infringement of the ’548 Patent)

17. Somerset re-alleges and incorporates by reference the allegations in Paragraphs 1 through 16 of its Counterclaims as though fully set forth herein.

18. Counterclaim Defendant/Plaintiff allege ownership of the ’548 patent and have brought claims against Somerset alleging infringement of the ’548 patent.

19. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Somerset’s ANDA and/or the commercial marketing of Somerset’s ANDA Product infringe, have infringed, and/or will infringe a valid and enforceable claim of the ’548 patent.

20. Somerset has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the ’548 patent and is not liable for such infringement.

21. Somerset is entitled to a declaration that the manufacture, use, or sale of Somerset’s ANDA Product would not infringe any valid or enforceable claim of the ’548 patent.

COUNT II
(Declaratory Judgment of Invalidity or Unenforceability of the ’548 Patent)

22. Somerset re-alleges and incorporates by reference the allegations in Paragraphs 1 through 21 of its Counterclaims as though fully set forth herein.

23. Counterclaim Defendant/Plaintiff allege ownership of the ’548 patent and have brought claims against Somerset alleging infringement of the ’548 patent.

24. One or more claims of the ’548 patent are invalid under one or more provisions of

35 U.S.C. §§ 101, 102, 103, and/or 112, and/or other judicially-created bases for invalidity.

25. The '548 patent describes and claims an alleged invention, the making of which did not involve the inventive faculty but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

26. The alleged invention of the '548 patent does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in the '548 patent is not more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the '548 patent and would have had a reasonable expectation of success in doing so.

27. The subject matter claimed in the '548 patent fails to comply with 35 U.S.C. § 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

28. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Somerset's ANDA and/or the commercial marketing of Somerset's ANDA Product infringes, has infringed, and/or will infringe a valid and enforceable claim of the '548 patent.

29. Somerset is entitled to a declaration that all claims of the '548 patent are invalid under 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or other judicially-created bases for invalidity.

PRAYER FOR RELIEF

WHEREFORE, Somerset respectfully requests judgment in its favor and against Counterclaim Defendant/Plaintiff as follows:

a. Declaring that the filing of Somerset's ANDA No. 218823 has not infringed and does not infringe any valid and enforceable claim of the '548 patent;

b. Declaring that the manufacture, use, offer to sell, sale, and/or importation into the United States of Somerset's ANDA Product does not, and would not, if marketed, infringe any valid and enforceable claim of the '548 patent;

c. Declaring this an exceptional case in favor of Somerset and awarding its attorneys' fees pursuant to 35 U.S.C. § 285 and/or under all applicable statutes and rules in common law that would be appropriate;

d. Awarding costs and expenses under all applicable statutes and rules in common law that would be appropriate; and

e. Awarding any and all such other relief as the Court determines to be just and proper.

MIDLIGE RICHTER LLC
Attorneys for Defendants, Somerset Therapeutics, LLC, Somerset Pharma, LLC and Odin Pharmaceuticals, LLC

By: s/ James S. Richter
James S. Richter
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Dated: April 1, 2024

OF COUNSEL:

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LOCAL CIVIL RULE 11.2 CERTIFICATION

Pursuant to Local Civil Rule 11.2 , I hereby certify, to the best of my knowledge, the same drug and patents are at issue in the following actions currently pending in this District:

- American Regent, Inc. v. Somerset Therapeutics, LLC, et al., Civil Action No. 24 CV 1022 (BRM)(CLW)
- American Regent, Inc. v. RK Pharma, Inc., et al., Civil Action No. 24 CV 1169 (BRM)(CLW)
- American Regent, Inc. v. Apotex, Inc. et al., Civil Action No. 24 CV 2268 (BRM)(CLW)

Somerset is not aware of any other action pending in any court or any pending arbitration or administrative proceeding related to this matter.

s/ James S. Richter
James S. Richter

Dated: April 1, 2024

LOCAL CIVIL RULE 201.1 CERTIFICATION

I hereby certify that the above-captioned matter is not subject to compulsory arbitration in that the parties seek, *inter alia*, declaratory relief in their respective pleadings.

I hereby certify under penalty of perjury that the foregoing is true and correct.

s/ James S. Richter
James S. Richter

Dated: April 1, 2024

CERTIFICATE OF SERVICE

The undersigned attorney certifies that a copy of Somerset's foregoing Answer, Separate Defenses, and Counterclaims was filed via ECF and served on all counsel of record by electronic mail on April 1, 2024.

s/ James S. Richter
James S. Richter

Dated: April 1, 2024