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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 2268 (BRM)(CLW)
v.	
APOTEX, INC. and APOTEX CORP.,	**DEFENDANTS' ANSWER, SEPARATE DEFENSES AND COUNTERCLAIMS TO COMPLAINT FOR PATENT INFRINGEMENT**
Defendants.	

Defendants Apotex Inc. and Apotex Corp. (collectively, "Apotex"), by and through their counsel, hereby answer and respond to each of the allegations of the Complaint of Plaintiff American Regent, Inc. ("Plaintiff" or "ARI") (ECF No. 1), and assert their separate defenses and counterclaims as follows:

GENERAL DENIAL

Pursuant to Rule 8(b)(3) of the Federal Rule of Civil Procedure, Apotex denies all allegations in Plaintiff's Complaint except those specifically admitted below. To the extent that any of the Complaint's headings constitute factual allegations, Apotex specifically denies each and every such allegation.

NATURE OF THE ACTION

1. This is an action for patent infringement under the patent laws of the United States, 35 U.S.C. § 100 *et. seq.*, arising from Apotex's submission to the United States Food and Drug Administration ("FDA") of Abbreviated New Drug Application No. 218576 ("ANDA") 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") seeking approval to engage in the commercial manufacture, use, or sale of generic versions of ARI's Tralement® (trace elements injection 4*, USP) in 1 mL single-dose vials and Multrys® (trace elements injection 4*, USP) in 1 mL single-dose vials drug products ("the ANDA Products") prior to the expiration of United States Patent No. 11,786,548 ("the '548 patent" or "the patent-in-suit").

ANSWER: This Paragraph states a legal conclusion that does not require an answer. To the extent that an answer is required, Apotex admits that Plaintiff's Complaint purports to be a civil action against Apotex alleging infringement of United States Patent No. 11,786,548 ("the '548 patent") arising under the United States patent laws, title 35, United States Code, § 100, *et seq*. Apotex further admits that Plaintiff purports to attach the '548 patent as an exhibit to the Complaint. Apotex further admits that it submitted ANDA No. 218576 to FDA seeking approval for the same. Apotex denies the remaining allegations of 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: Apotex lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 2 and, therefore, denies those allegations.

3. On information and belief, Apotex, Inc. is a Canadian corporation with its principal place of business at 150 Signet Drive, Toronto, Ontario M9L 1T9, Canada.

ANSWER: Admitted.

4. On information and belief, Apotex, Corp. is a Delaware corporation with a principal place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326.

ANSWER: Admitted.

5. On information and belief, Apotex Corp. is a wholly owned subsidiary of Apotex, Inc.

ANSWER: This Paragraph states a legal conclusion that does not require an answer. To the extent that an answer is required, denied.

6. On information and belief, Apotex, Corp. is the designated U.S. agent for Apotex, Inc. in accordance with 21 C.F.R. § 314.50(a) in connection with the ANDA.

ANSWER: Admitted.

7. On information and belief, Apotex Corp. is a generic pharmaceutical company that sells, offers for sale, markets, distributes and/or imports generic pharmaceutical products in the State of New Jersey and throughout the United States that are manufactured by Apotex, Inc.

ANSWER: Apotex admits only that Apotex Corp. sells pharmaceutical products in the United States. Apotex denies the remaining allegations of this Paragraph.

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

ANSWER: Apotex admits only that some of Apotex's pharmaceutical products may be sold in the United States. Apotex 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: Apotex admits this is an action for purported patent infringement arising under the patent laws of the United States, 35 U.S.C. § 100 *et. seq.* Further, this Paragraph states a legal conclusion that does not require an answer. To the extent an answer is required, solely for the purpose of this action, Apotex is not contesting subject matter jurisdiction. Otherwise, denied.

10. This Court has personal jurisdiction over Apotex, Inc. by virtue of, inter alia, its systematic and continuous contacts with this jurisdiction, as alleged herein.

ANSWER: Apotex admits that ARI alleges that personal jurisdiction applies to Apotex Inc. Apotex does not contest person jurisdiction for purposes of this action only. Otherwise, denied.

11. On information and belief, either directly or through its subsidiaries, agents, and/or affiliates, Apotex, Inc. regularly and continuously transacts business within this District, including by manufacturing, selling, offering for sale, marketing, distributing, and/or importing generic versions of pharmaceutical products in the United States, including New Jersey.

ANSWER: Apotex admits only that some of Apotex's pharmaceutical products may be sold in the United States. Apotex does not contest personal jurisdiction for purposes of this action only. Apotex denies the remaining allegations of this Paragraph.

12. On information and belief, Apotex, Inc. makes pharmaceutical products for sale in New Jersey, and currently markets, distributes, and sells either directly or through its subsidiaries, agents, and/or affiliates, pharmaceutical products throughout the United States, including in this

District. For example, upon information and belief, Apotex, Inc. states on its website that it "export[s] to more than 115 countries and territories, and operate[s] in more than 45 countries, including a significant presence in the [sic] US, Mexico and India where we continue to invest."[1] On information and belief, Apotex, Inc. derives substantial revenue from the sale of those products in New Jersey and has availed itself of the privilege of conducting business within New Jersey.

ANSWER: Apotex admits that ARI's quotation from the referenced webpage is correct (though the "[sic]" is not). Apotex further admits, per answers above, that some of Apotex's pharmaceutical products may be sold in the United States. To the extent any further answer to this Paragraph is required, solely for the purpose of this action, Apotex is not contesting personal jurisdiction. Otherwise, denied. To the extent that the remaining allegations of this Paragraph state a legal conclusion, no answer is required.

13. This Court also has personal jurisdiction because Apotex, Inc. filed the ANDA seeking approval from FDA to market and sell the ANDA Products throughout the United States, including in New Jersey.

ANSWER: Apotex admits that it filed an "ANDA seeking approval from FDA." To the extent that the remaining allegations of this Paragraph state a legal conclusion, no answer is required. To the extent any further answer to this Paragraph is required, solely for the purpose of this action, Apotex is not contesting personal jurisdiction.

14. On information and belief, Apotex, Inc. intends to commercially manufacture, use, and sell the ANDA Products upon receiving FDA approval. On information and belief, if and when FDA approves the ANDA, the ANDA Products would, among other things, be marketed, distributed and sold in New Jersey, and/or prescribed by physicians practicing within this District

[1] https://www1.apotex.com/us/about-us/about-apotex

and/or dispensed by pharmacies located within this District, all of which would have a substantial effect on New Jersey. By filing the ANDA, Apotex, Inc. has made clear that it intends to use its distribution channels to direct sales of the ANDA Products into New Jersey.

ANSWER: This Paragraph states a legal conclusion that does not require an answer. To the extent an answer is required, solely for the purpose of this action, Apotex is not contesting personal jurisdiction. Apotex denies the remaining allegations of this Paragraph.

15. This Court has personal jurisdiction over Apotex, Inc. because Apotex, Inc. has previously been sued in this district and has not challenged personal jurisdiction, and Apotex, Inc. has affirmatively availed itself of this Court's jurisdiction by filing counterclaims in this district. *See, e.g., Amgen Inc. v. Apotex Inc.*, No. 22-cv-03827 (D.N.J.); *Supernus Pharms., Inc. v. Apotex Inc.*, No. 22-cv-00322 (D.N.J.); *Takeda Pharms. Am., Inc., v. Apotex, Inc.*, No. 21-12998 (D.N.J.); *Celgene Corp. v. Apotex Inc.*, No. 19-05806 (D.N.J.); *Celgene Corp. v. Apotex Inc.*, No. 18-16395 (D.N.J.); *Celgene Corp. v. Hetero Labs Ltd.*, No. 17-03387 (D.N.J.); *Mitsubishi Tanabe Pharma Corp. v. Apotex Inc.*, No. 17-05278 (D.N.J.); *AstraZeneca AB v. Apotex Corp.*, No. 15-08492 (D.N.J.); *Bausch & Lomb Inc. v. Apotex Inc.*, No. 15-03879 (D.N.J.); *Novartis Pharm. Corp. v. Apotex Inc.*, No. 15-03634 (D.N.J.); *Merck Sharp & Dohme Corp. v. Apotex Inc.*, No. 15-02384 (D.N.J.); *Patheon Softgels Inc. v. Apotex Inc.*, No. 17-13819 (D.N.J.); *Dexcel Pharma Techs. Ltd. v. Apotex Corp.*, No. 17-02423 (D.N.J.); *Boehringer Ingelheim Pharms., Inc. v. Apotex Inc.*, No. 18-11350 (D.N.J.). Upon information and belief, Apotex, Inc. has also availed itself of the legal protections of the State of New Jersey by having filed suit in this jurisdiction. *See, e.g., Apotex Inc. v. Shire LLC*, No. 08-03598 (D.N.J.); *Apotex Inc. v. Pharm. Res., Inc.*, No. 06-01153 (D.N.J.).

ANSWER: Apotex admits that Apotex Inc. has been a party to the actions listed in this Paragraph. To the extent a further answer is required, solely for the purpose of this

action, Apotex is not contesting personal jurisdiction. Apotex denies the remaining allegations, to the extent that legal conclusions are required, of this Paragraph.

16. Alternatively, this Court may exercise personal jurisdiction over Apotex, Inc. pursuant to Federal Rule of Civil Procedure 4(k)(2) because ARI's claims arise under federal law; Apotex, Inc. is a foreign company not subject to general personal jurisdiction in the courts of any state; and Apotex, Inc. has sufficient contacts with the United States as a whole, including but not limited to preparing and submitting an ANDA to FDA, and/or marketing and/or selling generic pharmaceutical products that are distributed and sold throughout the United States, such that this Court's exercise of jurisdiction over Apotex, Inc. satisfies due process.

ANSWER: This Paragraph states a legal conclusion that does not require an answer. To the extent an answer is required, solely for the purpose of this action, Apotex is not contesting personal jurisdiction. Apotex denies the remaining allegations of this Paragraph.

17. This Court has personal jurisdiction over Apotex, Corp. by virtue of, inter alia, its systematic and continuous contacts with this jurisdiction, as alleged herein.

ANSWER: This Paragraph states a legal conclusion that does not require an answer. To the extent an answer is required, solely for the purpose of this action, Apotex is not contesting personal jurisdiction. Apotex denies the remaining allegations of this Paragraph.

18. On information and belief, either directly or through its subsidiaries, agents, and/or affiliates, Apotex, Corp. regularly and continuously transacts business within this District, including by selling, offering for sale, marketing, distributing, and/or importing generic versions of pharmaceutical products in the United States, including New Jersey.

ANSWER: This Paragraph states a legal conclusion that does not require an answer. To the extent an answer is required, Apotex admits that Apotex Corp. sells pharmaceutical

products in the United States. Further, solely for the purpose of this action, Apotex is not contesting personal jurisdiction. Apotex denies the remaining allegations of this Paragraph.

19. On information and belief, Apotex, Corp. makes available pharmaceutical products for sale in New Jersey, and currently markets, distributes, and sells either directly or through its subsidiaries, agents, and/or affiliates, pharmaceutical products throughout the United States, including in this District. On information and belief, Apotex, Corp. derives substantial revenue from the sale of those products in New Jersey and has availed itself of the privilege of conducting business within New Jersey.

ANSWER: This Paragraph states a legal conclusion that does not require an answer. To the extent an answer is required, Apotex admits that Apotex Corp. sells pharmaceutical products in the United States. Further, solely for the purpose of this action, Apotex is not contesting personal jurisdiction. Apotex denies the remaining allegations of this Paragraph.

20. This Court also has personal jurisdiction because Apotex, Corp. filed the ANDA seeking approval from FDA to market and sell the ANDA Products throughout the United States, including in New Jersey.

ANSWER: Apotex admits that it filed the "ANDA seeking approval from FDA." To the extent that this Paragraph states a legal conclusion, it does not require an answer. To the extent that an answer is required, solely for the purpose of this action, Apotex is not contesting personal jurisdiction. Apotex denies the remaining allegations of this Paragraph.

21. On information and belief, Apotex, Corp. intends to commercially sell and distribute the ANDA Products upon receiving FDA approval. On information and belief, if and when FDA approves the ANDA, the ANDA Products would, among other things, be marketed, distributed and sold in New Jersey, and/or prescribed by physicians practicing within this District

and/or dispensed by pharmacies located within this District, all of which would have a substantial effect on New Jersey. By filing the ANDA, Apotex, Corp. has made clear that it intends to use its distribution channels to direct sales of the ANDA Products into New Jersey.

ANSWER: This Paragraph states a legal conclusion that does not require an answer. To the extent an answer is required, solely for the purpose of this action, Apotex is not contesting personal jurisdiction. Apotex denies the remaining allegations of this Paragraph.

22. This Court has personal jurisdiction over Apotex, Corp. because Apotex, Corp. has previously been sued in this district and has not challenged personal jurisdiction, and Apotex, Corp. has affirmatively availed itself of this Court's jurisdiction by filing counterclaims in this district. *See, e.g., Patheon Softgels Inc., et al. v. Apotex Inc., et al., C*ivil Action No. 17-13819 (MAS)(LHG) (D.N.J.); *Dexcel Pharma Technologies Ltd., et al. v. Apotex Corp., et al*., Civil Action No. 17-02423 (SDW)(LDW) (D.N.J.); *Supernus Pharms. Inc. v. Apotex Inc., et al*., C.A. No. 20-7870 (FLW) (TJB)*; Boehringer Ingelheim Pharmaceuticals, Inc., et al. v. Apotex Inc., et al.,* Civil Action No. 18-11350 (MAS)(LHG) (D.N.J.); *Mitsubishi Tanabe Pharma Corp., et al. v. Apotex Inc., et al.,* Civil Action No. 17-05278 (RMB)(JS) (D.N.J.); *AstraZeneca AB, et al. v. Apotex Corp., et al.,* Civil Action No. 15-08492 (FLW)(DEA) (D.N.J.); *Apotex Inc. v. Shire LLC, Civil Action No. 08-03598 (SRC)(MAS) (D.N.J.).* Upon information and belief, Apotex, Corp. has also availed itself of the legal protections of the State of New Jersey by having filed suit in this jurisdiction. *See, e.g., Apotex Inc., et al. v. Pharmaceutical Resources, Inc., et al.,* Civil Action No. 06-01153 (JLL)(MF) (D.N.J.).

ANSWER: Apotex admits that Apotex Corp. has been a party to the actions listed in this Paragraph. To the extent a further answer is required, solely for the purpose of this

action, Apotex is not contesting personal jurisdiction. Apotex denies the remaining allegations, to the extent that legal conclusions are required, of this Paragraph.

23. On information and belief, Apotex Corp. is a subsidiary of Apotex Inc. and is controlled and dominated by Apotex Inc. On information and belief, Apotex Inc. and Apotex Corp. operate as part of a single, integrated generic pharmaceutical manufacturer with Apotex Inc. as the ultimate parent. Apotex, Inc.'s website states that Apotex is a "global pharmaceutical company that produces high-quality, affordable medicines (both generic and innovative pharmaceuticals) for patients around the world," that it "employ[s] more than 8,000 people worldwide in manufacturing, R&D and commercial operations," and "[t]hrough vertical integration, Apotex is comprised of multiple divisions and affiliates," including "Apotex Inc., focused on generics."[2]

ANSWER: Apotex admits ARI's quotation from the referenced webpage is correct except for the inclusion of "(both generic and innovative pharmaceuticals)." Otherwise, denied. To the extent that the remaining allegations of this Paragraph state a legal conclusion, no answer is required.

24. Upon information and belief, Apotex Corp. is registered as a wholesale drug distributor in the State of New Jersey under the Registration No. 5003192. Apotex Corp. has, therefore, purposefully availed itself of the rights, benefits, and privileges of New Jersey's laws.

ANSWER: Apotex admits that Apotex Corp. is a registered wholesale drug distributor. This Paragraph otherwise states a legal conclusion that does not require an answer. To the extent an answer is required, solely for the purpose of this action, Apotex is not contesting personal jurisdiction. Apotex denies the remaining allegations of this Paragraph.

[2] https://www1.apotex.com/us/about-us/about-apotex

25. On information and belief, Apotex Corp. and Apotex Inc. have been, and continue to be, joint and prime actors in the drafting, submission, approval, and maintenance of the ANDA.

ANSWER: This Paragraph states a legal conclusion that does not require an answer. Otherwise, denied.

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

ANSWER: This Paragraph states a legal conclusion that does not require an answer. To the extent an answer is required, solely for the purpose of this action, Apotex is not contesting venue.

27. Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b) because Apotex, Inc. is a foreign corporation organized and existing under the laws of Canada and may be sued in any judicial district in the United States in which it is subject to the court's personal jurisdiction, including in this District[.]

ANSWER: This Paragraph states a legal conclusion that does not require an answer. To the extent an answer is required, solely for the purpose of this action, Apotex is not contesting venue. Apotex denies the remaining allegations of this Paragraph.

28. Venue is proper for Apotex Corp. under 28 U.S.C. §§ 1391 and/or 1400(b). As set forth above, Apotex Corp. has committed and will commit further acts of infringement in this Judicial District. In addition, Apotex Corp. does business in this Judicial District through a permanent and continuous presence in the State of New Jersey. For example, Apotex Corp. is registered with the State of New Jersey's Department of Health as a drug wholesaler under Registration No. 5003192 and continuously sells its products in this Judicial District. Upon information and belief, Apotex Corp. employs a salesforce that includes personnel that regularly

and continuously work in this Judicial District and, if Apotex Corp. succeeds in obtaining FDA approval, Apotex Corp. will use its salesforce to sell the Apotex ANDA Product in the State of New Jersey.

ANSWER: This Paragraph states a legal conclusion that does not require an answer. To the extent an answer is required, solely for the purpose of this action, Apotex is not contesting venue. Apotex denies the remaining allegations of this Paragraph.

BACKGROUND

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

ANSWER: Apotex lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this Paragraph and, therefore, denies those allegations.

30. 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.

ANSWER: Apotex lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this Paragraph and, therefore, denies those allegations.

31. 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.

ANSWER: Apotex lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this Paragraph and, therefore, denies those allegations.

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

ANSWER: Apotex lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this Paragraph and, therefore, denies those allegations.

33. 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: Apotex lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this Paragraph and, therefore, denies those allegations.

34. Both Tralement® and Multrys® are commercial embodiments of the '548 patent.

ANSWER: Apotex lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this Paragraph and, therefore, denies those allegations.

35. 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: Apotex admits only that the '548 patent is entitled "Trace Element Compositions, Methods of Making and Use," issued on October 17, 2023, and a purported copy thereof was attached as Exhibit 1 to the Complaint. Apotex lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of this Paragraph and, therefore, denies those allegations.

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

ANSWER: Admitted.

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

ANSWER: Apotex admits that the Orange Book lists the patent expiration date for the ’548 patent as July 1, 2041 but otherwise denies any legal conclusions that may be implied from this Paragraph.

38. On information and belief, both Apotex, Inc. and Apotex Corp. were responsible for preparing the ANDA which contained a Paragraph IV Certification.

ANSWER: This Paragraph states a legal conclusion that does not require an answer. Apotex admits that its ANDA contained a Paragraph IV Certification. Otherwise, denied.

39. By letter dated January 25, 2024 (“the Notice Letter”), Apotex notified ARI pursuant to the Federal Food, Drug, and Cosmetic Act that Apotex had submitted to the FDA the ANDA with a Paragraph IV Certification to FDA to seek approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the ANDA Products prior to the expiration of the ’548 patent.

ANSWER: Admitted.

40. On information and belief, Apotex submitted the ANDA to FDA, which contained a 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 Products, or alternatively, that the ’548 patent is invalid.

ANSWER: Apotex admits that Apotex submitted an ANDA to FDA which asserted that the claims of the '548 patent were invalid and would not be infringed by Apotex's proposed products related to the ANDA. To the extent that the remainder of this paragraph requires a legal conclusion, no answer is required. Apotex denies the remaining allegations of this Paragraph.

41. The Notice Letter asserted defenses of non-infringement for certain, but not all, claims of the '548 patent. Importantly, the Notice Letter did not identify the specific claims allegedly not infringed, merely stating that "Apotex's proposed products contain varying amounts of active ingredients, depending on whether the product will be indicated for adult or pediatric use. Accordingly, each of Apotex's proposed products cannot infringe each claim of the '548 patent . . . ."

ANSWER: Apotex admits that this Paragraph's quotation was included in the "Notice Letter." Otherwise, denied.

42. On information and belief, the ANDA Products are generic versions of Tralement® (trace elements injection 4*, USP) and Multrys® (trace elements injection 4*, USP), as their reference listed drugs, containing the same or equivalent ingredients in the same or equivalent amounts.

ANSWER: Apotex admits that the identified products are the reference listed drugs for Apotex's ANDA. This Paragraph otherwise seeks a legal conclusion that does not require an answer. To the extent that an answer is required, denied.

43. In the Notice Letter, Apotex disclosed that the ANDA Products are (1) a single-dose, 1 mL generic version of Tralement® containing 3 mg of zinc, 0.3 mg of copper, 55 mcg of

manganese, and 60 mcg of selenium; and (2) a single-dose, 1 mL generic version of Multrys® containing 1000 mcg of zinc, 60 mcg of copper, 3 mcg of manganese, and 6 mcg of selenium.

ANSWER: Denied.

44. On information and belief, the ANDA Products contain zinc, copper, manganese, and selenium in the same or equivalent amounts as Tralement® and Multrys®, respectively.

ANSWER: Apotex avers that the product that is the subject of the Apotex ANDA does not infringe any independent claims of the patent in suit and, therefore, admits that its Notice Letter stated the same. Apotex further admits that its proposed ANDA products contain varying amounts of the recited ingredients. Apotex denies the remaining allegations of this Paragraph.

45. On information and belief, the ANDA Products will feature the same or equivalent chemical properties as Tralement® and Multrys®.

ANSWER: Apotex avers that the product that is the subject of the Apotex ANDA does not infringe any independent claims of the patent in suit and, therefore, admits that its Notice Letter stated the same. Apotex denies the remaining allegations of this Paragraph.

COUNT I: INFRINGEMENT OF THE '548 PATENT

46. ARI realleges paragraphs 1-45 as if fully set forth herein.

ANSWER: Apotex repeats and re-alleges each of the responses to Paragraphs 1–45 as if fully set forth herein.

47. Apotex's submission of the ANDA with a Paragraph IV Certification to obtain approval to engage in the commercial manufacture, use, offer for sale, sale and/or importation of the ANDA Products 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: Denied.

48. On information and belief, the ANDA Products, if approved by FDA, will be manufactured, used, offered for sale, sold, and/or imported in or into the United States by Apotex 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 Products will occur with Apotex's specific intent and encouragement, and will be conduct that Apotex knows or should know will occur. On information and belief, Apotex 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: Denied.

49. On information and belief, Apotex's manufacturing, use, offer for sale, sale, and/or importation of the ANDA Products, once the ANDA with a Paragraph IV Certification 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/or 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, Apotex intends that the ANDA Products be used by patients and medical professionals. Also, on information and belief, Apotex knows that the ANDA Products are especially made or adapted for use in infringing the '548 patent, and that the ANDA Products are not suitable for substantial non-infringing use.

ANSWER: Denied.

50. ARI will be irreparably harmed if Apotex is permitted to make, use, sell, offer to sell, and/or import the ANDA Products 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: Denied.

51. Apotex has had knowledge of the '548 patent since at least the date Apotex submitted the ANDA with a Paragraph IV Certification and was aware that submission of the ANDA with a Paragraph IV Certification constituted an act of infringement under 35 U.S.C. § 271(e)(2).

ANSWER: Denied.

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

ANSWER: Denied.

PRAYER FOR RELIEF

All remaining allegations not specifically admitted herein are denied. It is further denied that Plaintiff is entitled to the relief requested in the Complaint or to any relief whatsoever.

SEPARATE DEFENSES

Without prejudice to the denials set forth in its Answer, and without admitting any allegations of the Complaint not expressly admitted, Apotex asserts the following separate

defenses to the Complaint without assuming the burden of proof on any such defense that would otherwise rest with Plaintiff.

FIRST SEPARATE DEFENSE

Plaintiff has failed to state a claim upon which relief can be granted.

SECOND SEPARATE DEFENSE

The claims of the '548 patent are invalid for failure to satisfy one or more of the conditions for patentability contained in 35 U.S.C. §§ 101, 102, 103, 112, and/or double patenting.

THIRD SEPARATE DEFENSE

Apotex has not directly or indirectly infringed any claim of the '548 patent. The manufacture, use, offer for sale, sale, and/or importation of the products that are the subject of Apotex's ANDA No. 218576 does not and will not infringe any claim of the '548 patent, either literally or under the doctrine of equivalents.

FOURTH SEPARATE DEFENSE

Plaintiff is not entitled to attorney's fees, or any other award, because Plaintiff has not sufficiently alleged, and cannot prove, that this is an exceptional case under 35 U.S.C. § 285 as it relates to Plaintiff.

FIFTH SEPARATE DEFENSE

35 U.S.C. § 288 prevents Plaintiff from recovering any costs associated with this case.

SIXTH AFFIRMATIVE DEFENSE

Apotex reserves all defenses, at law or equity, which may now exist or in the future be available on discovery and further factual investigation in this case.

COUNTERCLAIMS

Counterclaim-Plaintiffs Apotex Inc. and Apotex Corp. (collectively, "Apotex") for their Counterclaims against Plaintiff/Counterclaim Defendant American Regent, Inc. ("Counterclaim Defendant" or "ARI"), allege as follows:

1. This is a counterclaim action for declaratory judgment of noninfringement and invalidity of one or more claims of United States Patent No. 11,786,548 ("the '548 patent") pursuant to the Declaratory Judgment Act, 28 U.S.C. §§ 2201–02, and the Patent Laws of the United States, 35 U.S.C. § 100 *et seq.*, and for such other relief as the Court deems just and proper.

THE PARTIES

2. Apotex Inc. is a Canadian corporation, with its principal place of business at 150 Signet Drive, Toronto, Ontario M9L 1T9, Canada.

3. Apotex Corp. is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326.

4. On information and belief, and based on the allegations in the Complaint, ARI is a corporation organized and existing under the laws of the State of New York, having its principal place of business at 5 Ramsey Road, Shirley, New York 20850.

JURISDICTION AND VENUE

5. The Court has jurisdiction over these counterclaims pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, 2202, and the Patent Laws of the United States, 35 U.S.C. §§ 1 *et. seq*.

6. This is an action based on an actual controversy between Apotex and Counterclaim Defendant concerning the noninfringement and invalidity of the '548 patent arising under the patent laws of the United States, 35 U.S.C. §§ 100 *et seq*., and Apotex's right to continue to seek

approval by the Food and Drug Administration ("FDA") of Abbreviated New Drug Application ("ANDA") No. 218576 (the "Apotex ANDA"), and upon FDA approval, to manufacture, use, sell, and offer to sell within, and/or import into, the United States the products that are the subject of the Apotex ANDA ("Apotex's ANDA Product(s)").

7. The Court has personal jurisdiction over Counterclaim Defendant because, on information and belief, Counterclaim Defendant transacts business within the State of New Jersey and/or has engaged in systematic and continuous business contacts within the State of New Jersey. Further, Counterclaim Defendant has subjected itself to the jurisdiction of this Court by virtue of filing the Complaint.

8. Venue is legally proper in this District under 28 U.S.C. § 1391, § 1400(b), 21 U.S.C. § 355(j)(5)(C)(i)(II), and/or by Counterclaim Defendant's choice of forum.

BACKGROUND

9. Apotex incorporates each of its responses to each paragraph of the Complaint, as well as the foregoing paragraphs 1–8 of the Counterclaims, as if fully set forth herein.

10. On or about October 17, 2023, according to the electronic records of the U.S. Patent and Trademark Office (the "USPTO"), the '548 patent, entitled "TRACE ELEMENT COMPOSITIONS, METHODS OF MAKING AND USE," issued, on its face, to Gopal Anyarambhatla, Richard Lawrence, and Jasmina Marinkovic. Counterclaim Defendant represented that a copy of the '548 patent was attached as Exhibit A to the Complaint.

11. On information and belief, Counterclaim Defendant caused the FDA to list the '548 patent in the FDA's Orange Book publication in connection with Tralement® and Multrys®.

12. On information and belief, Counterclaim Defendant purports to own, and/or to have the right to enforce, the '548 patent.

13. On information and belief, Counterclaim Defendant has not caused the FDA to remove the '548 patent from the Orange Book in connection with Tralement® or Multrys®.

14. By maintaining that listing of the patent in suit in the Orange Book, Counterclaim Defendant represents that the claims of infringement of the '548 patent "could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." *See* 21 U.S.C. § 355(b)(1)(A)(viii).

15. By letter dated January 25, 2024, Apotex timely notified Counterclaim Defendant that it had submitted ANDA No. 218576 to the FDA with a Paragraph IV certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '548 patent ("Notice Letter"). Apotex's Notice Letter met the statutory and regulatory requirements for such notice letters and included a detailed statement of the factual and legal bases for Apotex's opinion that the claims of the '548 patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, sale, offer for sale, and/or importation of Apotex's ANDA Products. Apotex incorporates by reference the positions set forth in its Notice Letter bur reserves the right to amend them.

16. Apotex's proposed ANDA Product is for Trace Elements Injection 4* USP, (*Adults: 3 mg Zn/mL, 0.3 mg Cu/mL, 55 mcg Mn/mL, and 60 mcg Se/mL) and (*Pediatric: 1,000 mcg Zn/mL, 60 mcg Cu/mL, 3 mcg Mn/mL, and 6 mcg Se/mL) single-dose vials.

17. On March 11, 2024, Counterclaim Defendant filed an infringement action in this Court against Apotex alleging infringement of the '548 patent.

18. In view of the foregoing, there has been, and is now, a definite and concrete, real and substantial, justiciable, and continuing case or controversy existing between Apotex and Counterclaim Defendant having sufficient immediacy and reality to warrant the issuance of a declaration of rights by the Court with respect to noninfringement and invalidity of the '548 patent,

and as to Apotex's right to obtain FDA approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of Apotex's ANDA Products.

COUNT I
Declaratory Judgment of Noninfringement of the '548 Patent

19. Apotex repeats and incorporates by reference each of the foregoing paragraphs 1–18 of its Counterclaims.

20. Counterclaim Defendant has accused Apotex of infringing claims of the '548 patent in connection with ANDA No. 218576.

21. Apotex denies infringement of any claim of the '548 patent and alleges that Apotex has not, does not, and would not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any claim of the '548 patent, including for at least the reasons set forth in the detailed statements included with Apotex's Notice Letter.

22. The manufacture, use, sale, or offer for sale within, and/or importation into, the United States of Apotex's ANDA Product will not constitute infringement (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), of any claim of the '548 patent.

23. Apotex is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of Apotex's ANDA Product does not, and would not if marketed, infringe any valid and/or enforceable claim of the '548 patent.

COUNT II
Declaratory Judgment of Invalidity of the Claims of the '548 Patent

24. Apotex repeats and incorporates by reference each of the foregoing paragraphs 1–23 of its Counterclaims.

25. Counterclaim Defendant has accused Apotex of infringing claims of the '548 patent in connection with ANDA No. 218576.

26. Apotex denies infringement of any claim of the '548 patent because all claims of the '548 patent are invalid for failure to meet one or more of the conditions of patentability specified in Title 35 of the United States Code. Given their invalidity, Apotex has cannot infringe invalid claims of the '548 patent, including for at least the reasons set forth in the detailed statements included with Apotex's Notice Letter.

27. The alleged inventions of the '548 patent do 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 no 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 inventions of the '548 patent and would have had a reasonable expectation of success in doing so.

28. The claims of the '548 patent are invalid at least under 35 U.S.C. §§ 102 and/or 103 in view of the prior art. The differences between the subject matter claimed in the '548 patent are such that the subject matter as a whole was either fully anticipated by the prior art or would have been obvious at the time the alleged invention(s) was (were) made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

29. The claims of the '548 patent are further invalid for failure to satisfy the requirements of 35 U.S.C. § 112.

30. Unless Counterclaim Defendant is enjoined, Apotex believes that Counterclaim Defendant will continue to assert that Apotex infringes the claims of the '548 patent and will continue to interfere with Apotex's business.

31. Apotex will be irreparably harmed if Counterclaim Defendant is not enjoined from continuing to assert the claims of the '548 patent and from interfering with Apotex's business.

32. A definite and concrete, real and substantial, justiciable controversy exists between Apotex and Counterclaim Defendant concerning the invalidity of the claims of the '548 patent which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

33. Apotex is entitled to a declaratory judgment that the asserted claims of the '548 patent are invalid.

EXCEPTIONAL CASE

This case is an exceptional one and Apotex is entitled to an award of its reasonable attorneys' fees and costs under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Apotex prays that the Court enter judgment in its favor and against Plaintiff/Counterclaim Defendant as follows:

a) Dismissing the Complaint with prejudice and denying each request for relief made by Plaintiff/Counterclaim Defendant therein;

b) Declaring that the manufacture, use, sale, offer for sale, importation, and/or marketing of the Apotex ANDA Products has not infringed, does not infringe, and will not infringe, either directly or indirectly, literally or under the doctrine of equivalents, any claims of the '548 patent;

c) Declaring that the claims of the '548 patent are invalid;

d) Granting Apotex judgment in its favor on Counterclaim Defendant's claims;

e) Granting Apotex judgment in its favor each and every of its own Counterclaims;

f) Declaring that this is an exceptional case in favor of Apotex pursuant to 35 U.S.C. § 285;

g) Declaring that Apotex is the prevailing party and awarding costs, attorneys' fees, and expenses to Apotex; and

h) Awarding Apotex such other and further relief to which it may be entitled.

MIDLIGE RICHTER LLC
Attorneys for Defendants, Apotex Inc. and Apotex Corp.

By: s/ James S. Richter
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Dated: May 2, 2024

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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 and the District of Delaware:

- American Regent, Inc. v. Somerset Therapeutics, LLC, et al., Civil Action No. 24 CV 1022 (BRM)(CLW)
- American Regent, Inc. v. Somerset Therapeutics, LLC, et al., Civil Action No. 24 CV 1031 (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. and Apotex Corp., 1:24-cv-00327-SB (D.D.E.), filed March 13, 2024.

Apotex 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: May 2, 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: May 2, 2024

CERTIFICATE OF SERVICE

The undersigned attorney certifies that a copy of Apotex's foregoing Answer, Separate Defenses, and Counterclaims was filed via ECF and served on all counsel of record by electronic mail on May 2, 2024.

s/ James S. Richter
James S. Richter

Dated: May 2, 2024