IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

AMERICAN REGENT, INC., Plaintiff, v. APOTEX, INC. and APOTEX CORP. Defendants.	Civil Action No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff American Regent, Inc. ("ARI"), by its undersigned attorneys, for its Complaint against Defendants Apotex, Inc. and Apotex Corp. (collectively, "Apotex"), 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 Apotex's submission to the United States Food and Drug Administration ("FDA") of Abbreviated New Drug Application No. 218576 ("the 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").

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

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.

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

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.

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 Delaware and throughout the United States that are manufactured by Apotex, Inc.

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 Delaware.

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 Apotex, Inc. by virtue of, inter alia, its systematic and continuous contacts with this jurisdiction, as alleged herein.

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.

12. On information and belief, Apotex, Inc. makes pharmaceutical products for sale in Delaware, 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 Delaware and has availed itself of the privilege of conducting business within Delaware.

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 Delaware.

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 Delaware, 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 Delaware. 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 Delaware.

15. 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

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

limited to preparing and submitting abbreviated new drug applications 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.

16. This Court has personal jurisdiction over Apotex Corp. because, on information and belief, Apotex Corp. is a corporation organized and existing under the laws of the State of Delaware, has registered to do business in the State of Delaware, and has appointed a registered agent in Delaware to accept service of process. Apotex Corp. has thus consented to jurisdiction in Delaware.

17. 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 Delaware.

18. On information and belief, Apotex Corp. makes available pharmaceutical products for sale in Delaware, 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 Delaware and has availed itself of the privilege of conducting business within Delaware.

19. 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 Delaware.

20. 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 Delaware, 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 Delaware. 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 Delaware.

21. Apotex Inc. and Apotex Corp. have consented to jurisdiction in Delaware in one or more prior cases arising out of the filing of their drug applications, and they have filed counterclaims in such cases. *See, e.g., Senju Pharm. Co. v. Apotex Inc. & Apotex Corp.*, C.A. No. 12-159-SLR, D.I. 9 (D. Del. Mar. 16, 2012); *Alcon Pharm. Ltd. v. Apotex Inc. & Apotex Corp*., C.A. No. 12-960-SLR, D.I. 6 (D. Del. July 23, 2012); *Pfizer Inc. v. Apotex Inc. & Apotex Corp*., C.A. No. 12-809-SLR, D.I. 18 (D. Del. Aug. 27, 2012); *UCB, Inc. v. Apotex Corp. & Apotex Inc*., C.A. No. 13-1209-LPS, D.I. 12 (D. Del. Sept. 9, 2013); *Pfizer Inc. v. Apotex Inc. & Apotex Corp*., C.A. No. 13-1613-SLR, D.I. 8 (D. Del. Oct. 17, 2013); M*eda Pharm. Inc. v. Apotex Inc. & Apotex Corp*., C.A. No. 14-1453-LPS, D.I. 93 (D. Del. Mar. 9, 2016); *Salix Pharm., Inc. v. Apotex Inc. & Apotex Corp*., C.A. No. 15-880-GMS, D.I. 15 (D. Del. Mar. 14, 2016); *Forest Labs., LLC v. Apotex Corp. & Apotex Inc.*, C.A. No. 16-269-GMS, D.I. 8 (D. Del. May 4, 2016); *Amgen Inc. v. Apotex Inc. & Apotex Corp.*, C.A. No. 16-926-GMS, D.I. 13 (D. Del. Nov. 15, 2016); *Astellas Pharma Inc. v. Apotex Inc. & Apotex Corp*., C.A. No. 16-976-JFB, D.I. 17 (D. Del. Jan. 17, 2017); *Onyx Therapeutics, Inc. v. Apotex Inc. & Apotex Corp*., C.A. No. 16-1039-LPS, D.I. 14 (D. Del. Jan. 31, 2017); *Bristol-Myers Squibb Co. v. Apotex Inc. & Apotex Corp.*, C.A. No. 17-399-LPS, D.I. 8 (D. Del. May 4, 2017); *Bayer Healthcare LLC v. Apotex Inc. & Apotex Corp*., C.A. No. 17-334-LPS, D.I. 10 (D. Del. May 22, 2017); *Teva Pharms. Int'l GmbH, et al. v. Apotex Inc. & Apotex Corp*., C.A. No. 17-1164-CFC, D.I. 17 (D. Del. Nov. 27, 2017); Merck Sharp & Dohme Corp. v. Apotex

Inc. & Apotex Corp., C.A. No. 20-749-RGA, D.I. 7 (D. Del. Jun. 26, 2020); *Eagle Pharm. Inc. v. Apotex Inc. & Apotex. Corp.*, C.A. No. 21-1256-CFC, D.I. 12 (D. Del. Sept. 22, 2021).

22. 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]

23. 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.

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

25. 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

26. Venue is proper for Apotex Corp. under 28 U.S.C. §§ 1391 and/or 1400(b) at least because Apotex Corp. is incorporated in Delaware and therefore resides there for purposes of venue.

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

BACKGROUND

27. 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.

28. 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.

29. 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.

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

31. 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.

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

33. 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.

34. 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”).

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

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

37. 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 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.

38. 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.

39. 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 . . . .”

40. 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.

41. 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.

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

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

COUNT I: INFRINGEMENT OF THE ’548 PATENT

44. ARI realleges paragraphs 1-43 as if fully set forth herein.

45. 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.

46. 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.

47. 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.

48. 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.

49. 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).

50. 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 Apotex has infringed at least one claim of the ’548 patent through Apotex’s submission of the ANDA with a Paragraph IV Certification to FDA seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States the ANDA Products before the expiration of the ’548 patent;

(b) A judgment under 35 U.S.C. §§ 271(a), (b), and/or (c) that Apotex’s commercial manufacture, use, offer for sale, sale, and/or importation within or into the United States of the ANDA Products 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 Apotex, 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 Products, 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 Apotex, 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 Apotex engages in commercial manufacture, use, offers to sell, sale, and/or importation in or into the United States of the ANDA Products 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: March 13, 2024

GIBBONS P.C.

By: */s/ Christopher Viceconte*

Christopher Viceconte (No. 5568)
300 Delaware Avenue, Suite 1015
Wilmington, Delaware 198010
Tel: (302) 518-6322
Fax: (302) 397-2050
cviceconte@gibbonslaw.com

OF COUNSEL:

Dennies Varughese, Pharm. D.
Uma Everett

Adam LaRock
Alex Alfano
Ryan Conkin
Sterne, Kessler, Goldstein & Fox P.L.L.C.
1100 New York Avenue NW, Suite 600
Washington, DC 20005
(202) 371-2600
dvarughese@sternekessler.com
ueverett@sternekessler.com
alarock@sternekessler.com
aalfano@sternekessler.com
rconkin@sternekessler.com

Attorneys for Plaintiff
American Regent, Inc.