UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BRAINTREE LABORATORIES, INC.,

Plaintiff,

v. Civil Action No. _____

ALKEM LABORATORIES LIMITED,
and ASCEND LABORATORIES, LLC

Defendants.

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Braintree Laboratories, Inc. ("Braintree" or "Plaintiff"), brings this Complaint for Patent Infringement against Defendants Alkem Laboratories Limited ("Alkem") and Ascend Laboratories, LLC ("Ascend") (collectively, "Defendants"), and alleges:

NATURE OF THE ACTION

1. This is an action for infringement of U.S. Patent No. 6,946,149, as reexamined ("the '149 patent"), arising under the patent laws of the United States, Title 35, United States Code, 35 U.S.C. §§ 271 and 281. This action relates to Abbreviated New Drug Application ("ANDA") No. 213924 filed by Defendants with the U.S. Food and Drug Administration ("FDA") and seeking approval to market a generic version of Braintree's SUPREP® Bowel Prep Kit ("SUPREP") drug product.

PARTIES

2. Plaintiff Braintree is a corporation organized and existing under the laws of the Commonwealth of Massachusetts, with its principal place of business at 60 Columbian Street West, Braintree, Massachusetts 02185-0929.

3. Upon information and belief, defendant Alkem is a corporation organized and existing under the laws of India, having a principal place of business at Alkem House, Senapati Bapat Marg, Lower Parel, Mumbai, 400 013, Maharashtra, India.

4. Upon information and belief, defendant Ascend is a corporation organized and existing under the laws of the State of New Jersey, having a principal place of business at 339 Jefferson Road, Parsippany, New Jersey 07054.

5. Upon information and belief, following any FDA approval of ANDA No. 213924, Defendants will make, use, offer to sell, and/or sell the generic products that are the subject of ANDA No. 213924 throughout the United States, and/or import such generic products into the United States, including in this judicial district.

JURISDICTION AND VENUE

6. This action arises under the patent laws of the United States, 35 U.S.C. §§ 100, *et seq*, and this Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a). Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b).

7. Based on the facts and causes alleged herein, and for additional reasons to be further developed through discovery, this Court has personal jurisdiction over Defendants.

8. Upon information and belief, this Court has personal jurisdiction over Alkem, under 10 Del. C. § 3104 and other applicable law, because, *inter alia*, upon information and belief, Alkem has purposefully availed itself of the rights and benefits of the laws of Delaware, such that it should reasonably anticipate being subject to suit here.

9. Upon information and belief, Alkem, for example, regularly does business in Delaware and has engaged in a persistent course of conduct within Delaware directly and/or indirectly through its affiliates, including Ascend. Upon information and belief, Defendants work in concert either directly or indirectly through one or more of their wholly-owned subsidiaries,

agents and/or alter egos, with respect to the regulatory approval, development, manufacturing, marketing, sale and distribution of generic pharmaceutical products throughout the United States, including in this judicial district.

10. For example, Alkem notes on its website at https://www.alkemlabs.com/us.php that the United States is "the focal point of our international operations," and that Alkem "manufacture[s] and suppl[ies] a wide-range of generics and branded formulations in the United States."

11. In addition, Alkem has regularly submitted to the jurisdiction of courts in this judicial district and has previously availed itself of courts in this district for the purpose of litigating business disputes. For example, in *Pfizer Inc. v. Alkem Laboratories Ltd.*, No. 13-1110-GMS (D. Del.), Alkem admitted that it was subject to personal jurisdiction in this district for that litigation. *See also, e.g., Biogen Int'l GmbH, Inc. et al. v. Alkem Labs. Ltd. et al.*, No. 1:17-cv-00850-LPS (D. Del.); *Shire Dev. LLC v. Alkem Labs. Ltd.*, No. 16-cv-00747 (D. Del.); *Acorda Therapeutics, Inc. v. Alkem Labs. Ltd.*, No. 14-cv-00917 (D. Del.).

12. In the alternative, this Court may exercise personal jurisdiction over Alkem pursuant to Federal Rule of Civil Procedure 4(k)(2) because: (i) Braintree's claims arise under federal law; (ii) Alkem would be a foreign defendant not subject to personal jurisdiction in the courts of any state; and (iii) Alkem has sufficient contacts with the United States as a whole, including but not limited to filing over 100 ANDAs with the FDA and 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 Alkem would satisfy due process.

13. Upon informiaton and belief, this Court has personal jurisdiction over Ascend, under 10 Del. C. § 3104 and other applicable law, because, *inter alia*, upon information and belief, Ascend regularly does business in Delaware and has engaged in a persistent course of conduct

within Delaware by continuously and systematically placing goods into the stream of commerce for distribution throughout the United States, including Delaware, and/or by directly selling pharmaceutical products in Delaware.

14. Upon information and belief, Ascend acts at the direction, and for the benefit, of Alkem, and is controlled and/or dominated by Alkem. Upon information and belief, Ascend and Alkem operate as a single integrated business. For example, Alkem states on its website at https://www.alkemlabs.com/us.php that Ascend is its "primary subsidiary" in the United States. Ascend also states on its website at http://www.ascendlaboratories.com/Home/Background that prior to realizing Ascend and Alkem should become "one company rather than two," Ascend acted as the "exclusive agent for all of [Alkem's] FDA approved drugs," and that now Ascend manufacturers and supplies over 100 SKU's "thought [sic] the USA." Upon information and belief, Ascend's sales throughout the United States include sales within this district. Upon information and belief, following any FDA approval of ANDA No. 213924, Asecend will use, offer to sell, and/or sell the generic product that is the subject of ANDA No. 213924 in this judicial district.

15. In addition, Ascend has regularly submitted to the jurisdiction of courts in this judicial district and has previously availed itself of courts in this district for the purpose of litigating business disputes. For example, in *Teijin Limited et al. v. Alkem Laboratories Limited and Ascend Laboratories, LLC*, C.A. No. 19-cv-768-RGA (D. Del.), Ascend admitted that it was subject to personal jurisdiction. *See, e.g., Acorda Therapeutics, Inc. et al. v. Alkem Labs. Ltd. et al.*, 14-0917 (D. Del.); *Sanofi et al. v. Alkem Labs. Ltd. et al.*, 14-292 (D. Del.); *Medicis Pharm. Corp. v. Alkem Labs. Ltd.*, 12-1663 (D. Del.).

16. Defendants derive substantial revenue from drug sales in the United States, including, upon information and belief, deriving substantial revenue from sales in Delaware. For

example, United States sales, including upon information and belief, Delaware sales, made up 27.2% of Alkem's total sales in its most recent fiscal quarter. *Investor Presentation Q3FY20* (Feb. 7, 2020), Alkem Laboratories Ltd., https://www.alkemlabs.com/pdf/investor-presentation/Q3FY20_Investor_Presentation.pdf.

17. Upon information and belief, Defendants will, either directly or through one or more wholly-owned subsidiaries, agents, and/or alter egos, develop, manufacture, market, and/or sell within the United States a generic version of Braintree's SUPREP drug product described in ANDA No. 213924 if FDA approval is granted. If ANDA No. 213924 is approved, the generic version of Braintree's SUPREP charged with infringing the '149 patent, would, upon information and belief, be manufactured, marketed and distributed in Delaware, prescribed by physicians practicing in Delaware, dispensed by pharmacies located within Delaware, be listed as a reimbursed product in the Delaware Department of Health and Social Services Medicaid system, and/or used by persons in Delaware, all of which would have a substantial effect on Delaware.

18. Braintree enjoys sales in Delaware of its SUPREP drug product, which is covered by the claims of the '149 patent. If the FDA approves ANDA No. 213924, Defendants' manufacturing, marketing and/or sales of the accused generic version of Braintree's SUPREP will cause Braintree substantial injury in Delaware.

BACKGROUND

19. Braintree holds approved New Drug Application ("NDA") No. 22372 for SUPREP® Bowel Prep Kit ("SUPREP"). SUPREP is a sodium sulfate, potassium sulfate and magnesium sulfate osmotic laxative and was approved by the FDA on August 5, 2010. SUPREP is indicated for bowel cleansing prior to an adult patient having a colonoscopy procedure.

20. Pursuant to 21 U.S.C. § 355 (b)(1) and attendant FDA regulations, the '149 patent has been listed in connection with SUPREP in the FDA's publication, *Approved Drug Products*

with Therapeutic Equivalence Evaluations, which is referred to as the "Orange Book." SUPREP, or its use or formulation, is covered by one or more claims of the '149 patent.

THE '149 PATENT

21. Braintree is the lawful owner by assignment of the '149 patent, entitled "Salt Solution for Colon Cleansing," which was duly and legally issued by the U.S. Patent and Trademark Office on September 20, 2005. The '149 patent was the subject of an *ex parte* reexamination procedure that Braintree requested on October 15, 2008. A reexamination certificate was issued by the U.S. Patent and Trademark Office on June 30, 2009. As a result of the reexamination, it was determined that claims 1, 6, 8-9, 13-14, 17 and 21 were cancelled, claims 2-4, 7, 10, 15 and 18 were patentable as amended, and claims 5, 11-12, 16, 19-20 and 22-23, each dependent on an amended claim, were patentable. A true and correct copy of the '149 patent and its reexamination certificate are attached hereto as Exhibit A. The claims of the '149 patent are valid and enforceable.

22. The '149 patent, *inter alia*, claims compositions and methods for use of the compositions for inducing purgation of the colon.

23. The '149 patent will expire no earlier than March 7, 2023.

24. Braintree, as the owner of the entire right, title and interest in the '149 patent, possesses the right to sue for infringement of the '149 patent. The Federal Circuit has affirmed the validity of the '149 patent. *See Braintree Labs., Inc. v. Novel Labs., Inc.*, 749 F.3d 1349, 1358-60 (Fed. Cir. 2014).

INFRINGEMENT BY DEFENDANTS

25. By letter dated January 31, 2020 ("Alkem Notice Letter"), Alkem notified Braintree that Alkem had submitted ANDA No. 213924 to the FDA under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)), seeking approval, prior to the expiration of

the ’149 patent, to engage in the commercial manufacture, use, or sale and/or importation of the sodium sulfate, potassium sulfate and magnesium sulfate oral lavage solution currently listed in the Orange Book for SUPREP.

26. By filing ANDA No. 213924, Alkem has represented to the FDA that the components of its proposed generic sodium sulfate, potassium sulfate and magnesium sulfate oral solution, 17.5g/bot; 3.13g/bot; 1.6g/bot, have the same active ingredients, the same route of administration, dosage form, and the same strengths as the corresponding components of SUPREP. Alkem’s Notice Letter states that Alkem submitted its ANDA, which included “bioavailability or bioequivalence data or information” to establish bioequivalence of its proposed generic version of SUPREP.

27. Alkem has committed an act of infringement, pursuant to 35 U.S.C. § 271(e)(2), by filing ANDA No. 213924 under 21 U.S.C. § 355(j) seeking approval to engage in the commercial manufacture, use and/or sale of such generic sodium sulfate, potassium sulfate and magnesium sulfate oral solution before the expiration of the ’149 patent.

28. Upon information and belief, Ascend and Alkem operate as a single business entity and Ascend will engage with Alkem in the commercial manufacture, use, and/or sale of the proposed generic product. Therefore, upon information and belief, Ascend will infringe the ’149 patent upon approval of ANDA No. 213924.

29. Braintree is entitled under 35 U.S.C. § 271(e)(4) to full relief from Defendants’ acts of infringement, including an Order by this Court ensuring that the effective date of any approval by the FDA of ANDA No. 213924, relating to Alkem’s proposed generic oral solution, shall not be earlier than the expiration of the exclusivity afforded the ’149 patent.

30. This Complaint is being filed before the expiration of the forty-five day period from the day after Braintree received the Alkem Notice Letter. Braintree received the Alkem Notice Letter, which was dated January 31, 2020, on February 3, 2020.

COUNT I (INFRINGEMENT OF THE '149 PATENT BY ALKEM AND ASCEND)

31. Each of the preceding paragraphs 1 through 30 is incorporated as if fully set forth herein.

32. Defendants' submission of ANDA No. 213924 to obtain approval to engage in the commercial manufacture, use, and/or sale of such sodium sulfate, potassium sulfate and magnesium sulfate oral solution prior to the expiration of the '149 patent constitutes infringement of one or more of the claims of the '149 patent under 35 U.S.C. § 271(e)(2)(A).

33. Specifically, the composition and the way it is proposed to be made, used and sold as described in Alkem's Notice Letter and, upon information and belief, ANDA No. 213924, will, if marketed and sold, infringe every limitation of at least claims 15, 18, 19, 20, and 23 of the '149 patent. According to Alkem's Notice Letter, and upon information and belief, the components of Defendants' proposed generic product have the same active ingredients, the same route of administration, the same dosage form, and the same strengths as the corresponding components of SUPREP. Upon information and belief, Ascend and Alkem operate as a single business entity and Ascend will engage with Alkem in the commercial manufacture, use, and/or sale of the proposed generic product.

34. Defendants' generic product described in Alkem's Notice Letter will practice each and every limitation of at least claim 15, for example. Claim 15 recites:

> A composition for inducing purgation of the colon of a patient, the composition comprising from about 100 ml to about 500 ml of an aqueous hypertonic solution comprising an effective amount of Na_2SO_4, an effective amount of $MgSO_4$, and an effective amount of K_2SO_4, wherein the composition does not produce any clinically significant electrolyte shifts and does not include phosphate.

35. Upon information and belief, Defendants' proposed generic product described in Alkem's Notice Letter and, upon information and belief, ANDA No. 213924, is a composition for inducing purgation of the colon of a patient. Alkem's Notice Letter states that Alkem submitted its ANDA, which included "bioavailability or bioequivalence data or information" to establish bioequivalence to Braintree's SUPREP.

36. Upon information and belief, Defendants' proposed generic product described in Alkem's Notice Letter is a composition comprising from about 100 ml to about 500 ml of an aqueous hypertonic solution comprising an effective amount of Na_4SO_4, an effective amount of $MgSO_4$, and an effective amount of K_2SO_4, and does not produce any clinically significant electrolyte shifts. Alkem's Notice Letter states that Defendants' ANDA product is "formulated as an oral solution" containing active ingredients "sodium sulfate, potassium sulfate, and magnesium sulfate," respectively 17.5g/3.13g/1.6g per bottle. Upon information and belief, Defendants' proposed generic product: 1) will induce purgation of a colon of a patient because it will be administered, upon information and belief, using the same dosing regime as SUPREP; 2) will be a composition comprising 100 ml to 500 ml of an aqueous hypertonic solution because it will be administered, upon information and belief, using the same dosing regime as SUPREP and will be a hypertonic solution like SUPREP; 3) will comprise effective amounts of sodium sulfate, potassium sulfate and magnesium sulfate to induce purgation of a colon because, upon information and belief, it will be administered using the same dosing regime as SUPREP; and 4) will not cause clinically significant electrolyte shifts because, upon information and belief, it will be administered using the same dosing regime as SUPREP.

37. The only purported basis for noninfringement of claim 15 in Alkem's Notice Letter is that its proposed generic product contains phosphate.

38. Defendants' proposed generic product does not include phosphate within the meaning of the claims of the '149 patent. Alkem's Notice Letter identifies the active ingredients in its proposed drug product as sodium sulfate, potassium sulfate and magnesium sulfate. It does not identify phosphate as an active ingredient. Therefore, and upon information and belief, to the extent phosphate is alleged to be in Defendants' proposed generic product, the presence of phosphate does not exclude the proposed generic product from the claimed compositions because any such phosphate is different from the sulfate salts and phosphate recited in at least, for example, claim 15 of the '149 patent. Accordingly, Defendants' proposed generic product contains each and every element of at least, for example, claim 15 of the '149 patent.

39. Upon information and belief, Defendants had actual and constructive knowledge of the '149 patent prior to filing ANDA No. 213924, and were aware that the filing of its ANDA with the FDA constituted an act of infringement of the '149 patent.

40. Upon information and belief, use of such generic sodium sulfate, potassium sulfate and magnesium sulfate oral solution would infringe one or more claims of the '149 patent.

41. Upon information and belief, Defendants know that their generic sodium sulfate, potassium sulfate and magnesium sulfate oral solution, and the proposed labeling for that product, are especially made or adapted for use in infringing the '149 patent, and that the generic sodium sulfate, potassium sulfate and magnesium sulfate oral solution and the proposed labeling are not suitable for any substantial noninfringing use. Upon information and belief, Defendants plan and intend to infringe, and will induce and/or contribute to the infringement of, the '149 patent, immediately and imminently upon FDA approval of ANDA No. 213924.

42. Upon FDA approval of ANDA No. 213924, Defendants will infringe the '149 patent by making, using, offering to sell, and selling such generic sodium sulfate, potassium sulfate and magnesium sulfate oral solution in the United States and/or importing such solution into the

United States, and by actively inducing and contributing to infringement by others, in violation of 35 U.S.C. § 271 (a)-(c), unless enjoined by the Court.

43. If infringement of the ’149 patent by Defendants is not enjoined, Braintree will suffer substantial and irreparable harm for which there is no adequate remedy at law.

REQUEST FOR RELIEF

WHEREFORE, Braintree requests that this Court grant the following relief:

1. A judgment that one or more claims of the ’149 patent are infringed by the submission of ANDA No. 213924, and that the making, using, offering to sell, or selling in the United States, or importing into the United States, of the proposed generic sodium sulfate, potassium sulfate and magnesium sulfate oral solution by Defendants will infringe, actively induce infringement, and/or contribute to the infringement of the ’149 patent;

2. An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of ANDA No. 213924 shall be a date which is not earlier than the expiration date of the ’149 patent, including any extensions and/or additional periods of exclusivity to which Braintree is or becomes entitled;

3. An order permanently enjoining Defendants, their affiliates, subsidiaries, and each of their officers, agents, servants and employees, and those acting in privity or concert with them, from making, using, offering to sell, or selling in the United States, or importing into the United States, such generic sodium sulfate, potassium sulfate and magnesium sulfate oral solution until after the expiration date of the ’149 patent, including any extensions and/or additional periods of exclusivity to which Braintree is or becomes entitled;

4. That Braintree be awarded its attorneys’ and experts’ fees and costs of this litigation; and

5. Such further relief as this Court deems proper and just, including but not limited to any appropriate relief under Title 35.

Date: March 13, 2020

/s/ Frederick L. Cottrell, III

Frederick L. Cottrell, III (#2555)
Tyler E. Cragg (#6398)
Richards, Layton & Finger PA
One Rodney Square
920 North King Street
Wilmington, DE 19801
cottrell@rlf.com
cragg@rlf.com
(302) 651-7700

Attorneys for Plaintiff
Braintree Laboratories, Inc.