FILED

UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA

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CLERK, US DISTRICT COURT
MIDDLE DISTRICT OF FL
JACKSONVILLE FLORIDA

BRAINTREE LABORATORIES, INC.,

Plaintiff,

v.

Civil Action No. 3:13-cv-389-J-32MCR

GATOR PHARMACEUTICALS, INC.;
KVK-TECH, Inc.

Defendants.

COMPLAINT FOR PATENT INFRINGEMENT

INJUNCTIVE RELIEF SOUGHT

Plaintiff, Braintree Laboratories, Inc. ("Braintree" or "Plaintiff"), sues Defendants, Gator Pharmaceuticals, Inc. ("Gator") and KVK-TECH, Inc. ("KVK"), and alleges:

NATURE OF THE ACTION

1. This is an action for patent 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 505(b)(2) New Drug Application ("NDA") No. 204553, filed by Gator with the U.S. Food and Drug Administration ("FDA") seeking approval to market BC Powder for Oral Solution Kit, a generic powder version of Braintree's SUPREP® Bowel Prep Kit ("SUPREP") drug product.

PARTIES

2. 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, MA 02185-0929.

3. Upon information and belief, Gator is a corporation organized and existing under the laws of the State of Florida, having a principal place of business at 14 Inlet Drive, St. Augustine, FL 32080-3813.

4. Upon information and belief, KVK is a corporation organized and existing under the laws of the Commonwealth of Pennsylvania, having a principal place of business at 110 Terry Drive, Suite 200, Newtown, PA 18940.

5. Upon information and belief, following any FDA approval of NDA No. 204553, Gator and KVK will make, use, offer to sell, and/or sell the generic products that are the subject of NDA No. 204553 throughout the United States, and/or import such generic products into the United States.

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. Upon information and belief, this Court has personal jurisdiction over Gator, because, *inter alia*, Gator has purposely availed itself of the rights and benefits of the laws of Florida by engaging in persistent, systematic and continuous contacts with Florida, such that it should reasonably anticipate being subject to suit here. In particular, Gator is registered with the

Florida Department of State as a Florida Profit Corporation, and Gator's principal place of business is located in Florida.

8. Upon information and belief, this Court has personal jurisdiction over KVK, under FL. STAT. § 48.193 and other applicable law, because, *inter alia*, KVK regularly and continuously transacts business within the State of Florida, including availing itself of the privilege of conducting business within Florida by selling pharmaceutical products there for use by Florida citizens. Upon information and belief, KVK derives substantial revenue from its Florida drug sales. KVK is licensed in the state of Florida as a Non-Resident Prescription Drug Manufacturer, License Number 26707, expiring January 31, 2015. For instance, KVK sells at least one of its drugs, Promethazine Hydrochloride Tablets, through the State of Florida Department of Health Central Pharmacy. Furthermore, KVK has a pending Product Registration with the State of Florida. KVK is also listed as an approved drug labeler with Florida Medicaid.

9. Upon information and belief, Gator and KVK will manufacture, market, and/or sell within the United States the generic powder version of Braintree's SUPREP® drug product described in NDA No. 204553 if FDA approval is granted. If NDA No. 204553 is approved, the generic powder version of Braintree's SUPREP® charged with infringing the '149 patent, would, upon information and belief, be marketed and distributed in Florida, prescribed by physicians practicing in Florida, dispensed by pharmacies located within Florida, and/or used by persons in Florida, all of which would have a substantial effect on Florida.

BACKGROUND

10. Braintree holds approved NDA No. 22372 for 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.

11. Pursuant to 21 U.S.C. § 355 (b)(i) 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

12. Braintree is the lawful owner by assignment of the '149 patent, entitled "Salt Solution for Colon Cleansing," 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 was 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 determined to be patentable as amended, and claims 5, 11-12, 16, 19-20 and 22-23, each dependent on an amended claim, were also determined to be 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.

13. The '149 patent, *inter alia*, claims a composition and a method for use of the composition to cleanse the colon.

14. The '149 patent currently expires on March 7, 2023, which includes the associated patent term adjustment.

15. 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.

INFRINGEMENT BY GATOR AND KVK

16. By letter dated March 6, 2013 (the "Gator Notice Letter"), Gator notified Braintree that Gator had submitted an NDA to the FDA under Section 505(b)(2) of the Federal

Food, Drug, and Cosmetic Act, requesting approval to market its generic powder copy of SUPREP, BC Powder for Oral Solution Kit (sodium sulfate, potassium sulfate and magnesium sulfate), prior to the expiration of the '149 patent. The FDA assigned NDA No. 204553 to the application.

17. Upon information and belief, KVK participated and/or assisted in the drafting and filing of NDA No. 204553.

18. By filing NDA No. 204553, and upon information and belief, Gator and KVK have represented to the FDA that the components of BC Powder for Oral Solution Kit (sodium sulfate, potassium sulfate and magnesium sulfate), respectively 17.5g/3.13g/1.6g per reconstituted bottle, have the same active ingredients and the same strengths as the corresponding components of SUPREP. Upon information and belief, Gator and KVK have represented that BC Powder for Oral Solution Kit (sodium sulfate, potassium sulfate and magnesium sulfate) is bioequivalent to SUPREP.

19. Gator and KVK have committed an act of infringement pursuant to 35 U.S.C. § 271(e)(2) by filing NDA No. 204553 under 21 U.S.C. § 355(b)(2) seeking approval to engage in the commercial manufacture, use and/or sale of BC Powder for Oral Solution Kit (sodium sulfate, potassium sulfate and magnesium sulfate) before the expiration of the '149 patent.

20. Braintree is entitled under 35 U.S.C. § 271(e)(4) to full relief from Gator's and KVK's acts of infringement, including an Order by this Court ensuring that the effective date of any approval of NDA No. 204553, relating to Gator's and KVK's proposed BC Powder for Oral Solution Kit (sodium sulfate, potassium sulfate and magnesium sulfate), shall not be earlier than the expiration of the exclusivity afforded the '149 patent.

21. This Complaint is being filed before the expiration of the forty-five day period from the day after Braintree received the Gator Notice Letter.

COUNT I (INFRINGEMENT OF THE '149 PATENT BY GATOR AND KVK)

22. Each of the preceding paragraphs 1 through 21 is incorporated as if fully set forth.

23. Gator's and KVK's submission of NDA No. 204553 to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of BC Powder for Oral Solution Kit (sodium sulfate, potassium sulfate and magnesium sulfate) prior to the expiration of the '149 patent constitutes infringement of one or more of the claims of the '149 patent.

24. Upon information and belief, Gator and KVK had actual and constructive knowledge of the '149 patent prior to filing NDA No. 204553 and were aware that the filing of their NDA with the FDA constituted an act of infringement of the '149 patent.

25. Upon information and belief, use of BC Powder for Oral Solution Kit (sodium sulfate, potassium sulfate and magnesium sulfate), in accordance with and as directed by the proposed labeling in NDA No. 204553 for that product, would infringe one or more claims of the '149 patent.

26. Upon information and belief, Gator and KVK know that proposed BC Powder for Oral Solution Kit (sodium sulfate, potassium sulfate and magnesium sulfate), and the proposed labeling for that product, are especially made or adapted for use in infringing the '149 patent, and that BC Powder for Oral Solution Kit (sodium sulfate, potassium sulfate and magnesium sulfate) and the proposed labeling are not suitable for any substantial noninfringing use. Upon information and belief, Gator and KVK plan and intend to infringe, and will induce and/or contribute to the infringement of the '149 patent, immediately and imminently upon approval of NDA No. 204553.

27. Upon FDA approval of Gator's and KVK's NDA No. 204553, Gator and KVK will infringe the '149 patent by making, using, offering to sell, and selling BC Powder for Oral Solution Kit (sodium sulfate, potassium sulfate and magnesium sulfate) in the United States and/or importing such product 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.

28. If infringement of the '149 patent by Gator and KVK is not enjoined, Braintree will suffer substantial and irreparable harm for which there is no adequate remedy at law.

29. Braintree has retained the undersigned attorneys and is obligated to pay its attorneys a reasonable fee for their services.

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 Gator's and KVK's submission of NDA No. 204553, and that the making, using, offering to sell, or selling in the United States, or importing into the United States, of BC Powder for Oral Solution Kit (sodium sulfate, potassium sulfate and magnesium sulfate) by Gator and KVK 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 approval of NDA No. 204553 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 Gator and KVK, 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 BC Powder for Oral Solution Kit (sodium sulfate, potassium sulfate and magnesium sulfate) 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 reasonable 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.

Dated April 15, 2013.

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