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JUDGE NATHAN

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

BRAINTREE LABORATORIES, INC.,

Plaintiff,

v.

CYPRESS PHARMACEUTICAL, INC.,

Defendant.

Civil Action No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Braintree Laboratories, Inc. ("Braintree" or "Plaintiff") hereby alleges as follows:

NATURE OF THE ACTION

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 Abbreviated New Drug Application ("ANDA") No. 204135, filed by Cypress Pharmaceutical, Inc. with the U.S. Food and Drug Administration ("FDA") seeking approval to market a generic version of Braintree's SUPREP® drug product.

PARTIES

1. 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.

2. Upon information and belief, Cypress Pharmaceutical, Inc. ("Cypress") is a corporation organized and existing under the laws of the State of Mississippi, having a principal place of business at 135 Industrial Blvd., Madison, MS 39110.

3. Upon information and belief, following any FDA approval of ANDA No. 204135, Cypress will make, use, offer to sell, and/or sell the generic products that are the subject of ANDA No. 204135 throughout the United States, and/or import such generic products into the United States.

JURISDICTION AND VENUE

4. 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).

5. Upon information and belief, this Court has personal jurisdiction over Cypress, because, *inter alia*, Cypress has purposely availed itself of the rights and benefits of the laws of New York by engaging in persistent, systematic and continuous contacts with New York, such that it should reasonably anticipate being subject to suit here. In particular, Cypress selected New York County on its "Application for authority" to do business in New York as the "county…in which its office is to be located," and designated the New York Secretary of State as its "agent upon whom process against it may be served." ***See*** **Exhibit A** (New York State corporate status information for Cypress); New York Business Corporation Law §§ 1304(a)(5); (a)(6). New York County (Manhattan) is within the Southern District of New York.

6. Upon information and belief, Cypress regularly and continuously transacts business within the State of New York, including availing itself of the privilege of conducting business within New York by selling pharmaceutical products there. Upon information and

belief, Cypress derives substantial revenue from its New York drug sales. For instance, Cypress has numerous reimbursed products listed in the New York State Department of Health Medicaid system. *Available at* **https://www.emedny.org/info/fullform.pdf.**

7. Upon information and belief, Cypress will manufacture, market, and/or sell within the United States the generic version of Braintree's SUPREP® drug product described in Cypress' ANDA No. 204135 if FDA approval is granted. If ANDA No. 204135 is approved, the generic version of Braintree's SUPREP® charged with infringing the '149 Patent, would, upon information and belief, be marketed and distributed in New York, prescribed by physicians practicing in New York, dispensed by pharmacies located within New York, be listed as a reimbursed product in the New York State Department of Health Medicaid system, and/or used by persons in New York, all of which would have a substantial effect on New York.

8. In addition, upon information and belief, Cypress has previously availed itself of this forum for the purpose of litigating patent disputes. In *Glaxo Group Limited v. Cypress Pharmaceutical, Inc.*, Case No. 1:07-cv-06012-RJH (S.D.N.Y), Cypress admitted that it was subject to personal jurisdiction in this District and filed counterclaims seeking declaratory judgments of invalidity and non-infringement.

BACKGROUND

9. 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.

10. 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

11. 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 B**. The claims of the '149 patent are valid and enforceable.

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

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

14. 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 CYPRESS

15. By letter dated July 31, 2012 ("Cypress Notice Letter"), Cypress notified Braintree that Cypress had submitted ANDA No. 204135 to the FDA under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) seeking approval 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, prior to the expiration of the '149 patent.

16. By filing ANDA No. 204135, and upon information and belief, Cypress has represented to the FDA that the components of its proposed generic sodium sulfate, potassium sulfate and magnesium sulfate oral solution, respectively 17.5g/3.13g/1.6g per bottle, have the same active ingredients, the same route of administration, dosage form, and the same strengths as the corresponding components of SUPREP. Upon information and belief, Cypress has represented that its proposed generic sodium sulfate, potassium sulfate and magnesium sulfate oral solution is bioequivalent to SUPREP.

17. Cypress has committed an act of infringement pursuant to 35 U.S.C. § 271(e)(2) by filing ANDA No. 204135 under 21 U.S.C. § 355(j) seeking approval to engage in the commercial manufacture, use and/or sale of generic sodium sulfate, potassium sulfate, magnesium sulfate oral lavage solution before the expiration of the '149 patent.

18. Braintree is entitled under 35 U.S.C. § 271(e)(4) to full relief from Cypress's acts of infringement, including an Order by this Court ensuring that the effective date of any approval of ANDA No. 204135, relating to Cypress's proposed generic oral lavage solution, shall not be earlier than the expiration of the exclusivity afforded the '149 patent.

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

COUNT I (INFRINGEMENT OF THE '149 PATENT BY CYPRESS)

20. Each of the preceding paragraphs 1 through 19 is incorporated as if fully set forth.

21. Cypress's submission of ANDA No. 204135 to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of 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).

22. Upon information and belief, Cypress had actual and constructive knowledge of the '149 patent prior to filing ANDA No. 204135 and was aware that the filing of its ANDA with the FDA constituted an act of infringement of the '149 patent.

23. Upon information and belief, use of generic sodium sulfate, potassium sulfate and magnesium sulfate oral solution in accordance with and as directed by the proposed labeling in ANDA No. 204135 for that product would infringe one or more claims of the '149 patent.

24. Upon information and belief, Cypress knows that its 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 substantial noninfringing use. Upon information and belief, Cypress plans and intends to, and will induce and/or contribute to the infringement of the '149 patent immediately and imminently upon approval of ANDA No. 204135.

25. Upon FDA approval of Cypress's ANDA No. 204135, Cypress will infringe the '149 patent by making, using, offering to sell, and selling 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.

26. If infringement of the '149 patent by Cypress 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 Cypress's submission of ANDA No. 204135, and that the making, using, offering to sell, or selling in the United States, or importing into the United States, of generic sodium sulfate, potassium sulfate and magnesium sulfate oral solution by Cypress 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 ANDA No. 204135 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 Cypress, its affiliates, subsidiaries, and each of its officers, agents, servants and employees and those acting in privity or concert with it, from making, using, offering to sell, or selling in the United States, or importing into the United States, 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. Such further and other relief as this Court deems proper and just, including but not limited to any appropriate relief under Title 35 and recovery of Braintree's attorneys' and experts' fees and costs of this litigation.

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