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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

BRAINTREE LABORATORIES, INC., Plaintiff, v. PADDOCK LABORATORIES, INC., Defendant.	Civil Action No. _____ **COMPLAINT FOR PATENT INFRINGEMENT** **JURY TRIAL REQUESTED**

Plaintiff Braintree Laboratories, Inc. ("Braintree") 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. 203102, filed by Paddock Laboratories, 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 State of Massachusetts, with its principal place of business at 60 Columbian Street West, Braintree, MA 02185-0929.

2. Upon information and belief, Defendant Paddock Laboratories, Inc. ("Paddock") is a corporation organized and existing under the laws of the State of Minnesota, having a principal place of business at 3940 Quebec Avenue North, Minneapolis, MN 55427.

3. Upon information and belief, following any FDA approval of ANDA No. 203102, Paddock will make, use, offer to sell, and/or sell the generic products that are the subject of ANDA No. 203102 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. Based on the facts and causes alleged herein, and for additional reasons to be further developed through discovery, this Court has personal jurisdiction over Paddock.

6. This Court has personal jurisdiction over Paddock because, upon information and belief, Paddock regularly does business in New Jersey and has engaged in a

persistent course of conduct within New Jersey, by continuously and systematically placing goods into the stream of commerce for distribution throughout the United States, including in New Jersey, and/or by directly selling pharmaceutical products in New Jersey. On its company website, Paddock lists its "authorized distributors of record," which include companies that distribute pharmaceutical products throughout the country and in New Jersey, including, but not limited to, CVS Distribution Center, Walgreens, and Wal-Mart.

7. In addition, Paddock has previously submitted to the jurisdiction of this Court and has previously availed itself of this Court by seeking a declaratory judgment of non-infringement in another patent case it filed in this jurisdiction. *See Paddock Laboratories, Inc. v. Ethypharm S.A.*, Civil Action No. 3:09-cv-03779 (GEB) (LHG).

BACKGROUND

8. 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.

9. 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

10. 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 patentable as amended, and claims 5, 11-12, 16, 19-20 and 22-23, each dependent on an amended claim, were also 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.

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

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

13. 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 PADDOCK

14. By letter dated June 29, 2011 ("Paddock Notice Letter"), Paddock notified Braintree that Paddock had submitted ANDA No. 203102 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.

15. By filing ANDA No. 203102, Paddock has represented to the FDA that the components of its proposed generic sodium sulfate, potassium sulfate and magnesium sulfate oral solution, 17.5g/3.13g/1.6g per bottle, have the same active ingredients as those of the

corresponding components of SUPREP®, have the same route of administration, dosage form, and strengths as the corresponding components of SUPREP®, and are bioequivalent to the corresponding components of SUPREP®.

16. Paddock has committed an act of infringement pursuant to 35 U.S.C. § 271(e)(2) by filing ANDA No. 203102 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.

17. Braintree is entitled under 35 U.S.C. § 271(e)(4) to full relief from Paddock’s acts of infringement, including an Order by this Court ensuring that the effective date of any approval of ANDA No. 203102, relating to Paddock’s proposed generic oral lavage solution, shall not be earlier than the expiration of the exclusivity afforded the ‘149 patent.

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

COUNT I (INFRINGEMENT OF THE ’149 PATENT BY PADDOCK)

19. Each of the preceding paragraphs 1 through 18 is incorporated as if fully set forth.

20. Paddock’s submission of ANDA No. 203102 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).

21. Upon information and belief, Paddock had actual and constructive knowledge of the ’149 patent prior to filing ANDA No. 203102 and was aware that the filing of its ANDA with the FDA constituted an act of infringement of the ’149 patent.

22. 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. 203102 for that product, would infringe one or more claims of the '149 patent.

23. Upon information and belief, Paddock 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, Paddock 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. 203102.

24. Upon FDA approval of Paddock's ANDA No. 203102, Paddock 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.

25. If infringement of the '149 patent by Paddock is not enjoined, Plaintiff will suffer substantial and irreparable harm for which there is no remedy at law.

PRAYER FOR RELIEF

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

1. A judgment that one or more claims of the '149 patent are infringed by Paddock's submission of ANDA No. 203102, 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 Paddock 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. 203102 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 Plaintiff is or becomes entitled;

3. An order permanently enjoining Paddock, 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 Plaintiff is or becomes entitled;

4. Such further and other relief as this Court deems proper and just, including any appropriate relief under Title 35 and costs of this litigation.

JURY DEMAND

Plaintiff demands a trial by jury on all issues for which a right to a jury trial may exist.

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Dated: August 8, 2011

CERTIFICATION PURSUANT TO L. CIV. R. 11.2

I hereby certify that the matter in controversy may be deemed related to the following actions presently pending before this Court and other Courts:

Braintree Laboratories, Inc. v. Novel Laboratories, Inc.,
Civil Action No 3:11-cv-01341 (PGS) (LHG) (D.N.J.)

Braintree Laboratories, Inc. v. Amrutham, Inc.,
Civil Action No. 2:11-cv-01854-PD (E.D.P.A.)

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