UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

BRAINTREE LABORATORIES, INC.,

Plaintiff,

v. Civil Action No. _____

TARO PHARMACEUTICALS USA, INC.;
TARO PHARMACEUTICAL
INDUSTRIES, LTD.

Defendants.

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff, Braintree Laboratories, Inc. ("Braintree" or "Plaintiff"), sues Defendants, Taro Pharmaceuticals USA, Inc. ("Taro USA") and Taro Pharmaceutical Industries, Ltd. ("TPI") (collectively, "Taro"), 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 Abbreviated New Drug Application ("ANDA") No. 206431, filed by Taro USA and TPI with the U.S. Food and Drug Administration ("FDA") and seeking approval to market a generic version of Braintree's 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, Taro USA is a corporation organized and existing under the laws of the State of New York, having a principal place of business at 3 Skyline Drive, Hawthorne, New York 10532.

4. Upon information and belief, TPI is a corporation organized and existing under the laws of Israel, having a principal place of business at 14 Hakitor Street, Haifa Bay 2624761, Israel.

5. Upon information and belief, following any FDA approval of ANDA No. 206431, Taro USA and TPI will make, use, offer to sell, and/or sell the generic products that are the subject of ANDA No. 206431 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 Taro USA, because, *inter alia*, Taro USA 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, Taro

USA is registered with the New York Department of State as a Domestic Business Corporation, and Taro USA's principal place of business is located in New York.

8. Upon information and belief, Taro USA regularly and continuously transacts business within the State of New York, including availing itself of the privilege of conducting business within New York by developing, manufacturing, marketing, and selling pharmaceutical products there. Upon information and belief, Taro USA derives substantial revenue from its New York drug sales. For instance, Taro USA has numerous reimbursed products listed in the New York State Department of Health Medicaid system. Available at **https://www.emedny.org/info/fullform.pdf**.

9. Upon information and belief, this Court has personal jurisdiction over TPI, under N.Y. C.P.L.R. § 302 (McKinney) and other applicable law, because, *inter alia*, TPI regularly and continuously transacts business within the State of New York, including availing itself of the privilege of conducting business within New York by developing, manufacturing and marketing prescription and over-the-counter pharmaceutical products there for use by New York citizens. TPI is a publicly-traded company traded on the New York Stock Exchange. Upon information and belief, TPI and Taro USA share the same Chief Financial Officer, whom TPI lists on the face of its United States Securities and Exchange Commission filings as its Interim Chief Financial Officer, with a United States address of TPI c/o Taro USA, 3 Skyline Drive, Hawthorne, NY 10532. *See* TPI Form 20-F (2014), at 1, available at **https://www.sec.gov/Archives/edgar/data/906338/000119312514259627/d739586d20f.htm**. Upon information and belief, TPI derives substantial revenue from its subsidiary Taro USA's New York drug sales. *E.g., id.* at 10. TPI lists its agent for service of process in the United States as Taro USA, at the same Hawthorne, NY address. *Id.* at 20.

10. Upon information and belief, Taro USA and TPI will develop, manufacture, market, and/or sell within the United States the generic version of Braintree's SUPREP® drug product described in ANDA No. 206431 if FDA approval is granted. If ANDA No. 206431 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 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.

11. Braintree enjoys substantial sales in New York of its SUPREP® drug product, which is covered by the claims of the '149 patent. If the FDA approves ANDA No. 206431, Taro USA's and TPI's manufacturing, marketing and sales of their generic version of Braintree's SUPREP® will cause Braintree substantial injury in New York.

12. Upon information and belief, TPI has previously availed itself of this forum for the purpose of litigating business disputes. In *Morris v. Taro Pharmaceuticals Industries, Ltd.*, Case No. 1:11-cv-00470-KBF (S.D.N.Y.), TPI waived any argument that it was not subject to personal jurisdiction in this District, pursuant to Federal Rules of Civil Procedure 12(g)(2) and (h)(1)(A), by moving to dismiss for failure to state a claim but not moving to dismiss for lack of personal jurisdiction. In *Taro Pharmaceutical Industries Ltd. et al v. Sun Pharmaceutical Industries Ltd.*, Civ. No. 1:09-cv-08262-PGG (S.D.N.Y.), TPI selected this District to file suit against a Michigan corporation, with its principal place of business in Detroit, Michigan, and three corporations organized under foreign laws with principal places of business in foreign countries. These cases were both assigned to the Manhattan Court in this District.

BACKGROUND

13. 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.

14. 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

15. 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 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 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.

16. The '149 patent, *inter alia*, claims compositions and methods for use of the compositions to cleanse the colon.

17. The '149 patent will expire no earlier than March 7, 2023; Braintree has applied for a patent term extension until August 5, 2024.

18. 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 TARO USA AND TPI

19. By letter dated September 2, 2014 ("Taro Notice Letter"), Taro USA and TPI notified Braintree that Taro USA and TPI had submitted ANDA No. 206431 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.

20. By filing ANDA No. 206431, and upon information and belief, Taro USA and TPI have represented to the FDA that the components of their 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, Taro USA and TPI have represented that their proposed generic sodium sulfate, potassium sulfate and magnesium sulfate oral solution is bioequivalent to SUPREP.

21. Taro USA and TPI have committed an act of infringement, pursuant to 35 U.S.C. § 271(e)(2), by filing ANDA No. 206431 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, magnesium sulfate oral lavage solution before the expiration of the '149 patent.

22. Braintree is entitled under 35 U.S.C. § 271(e)(4) to full relief from Taro USA's and TPI's acts of infringement, including an Order by this Court ensuring that the effective date of any approval from the FDA of ANDA No. 206431, relating to Taro USA's and

TPI's proposed generic oral lavage solution, shall not be earlier than the expiration of the exclusivity afforded the '149 patent.

23. This Complaint is being filed before the expiration of the forty-five day period from the day after Braintree received the Taro Notice Letter. Braintree received the Taro Notice Letter on September 3, 2014.

COUNT I (INFRINGEMENT OF THE '149 PATENT BY TARO USA AND TPI)

24. Each of the preceding paragraphs 1 through 23 is incorporated as if fully set forth.

25. Taro USA's and TPI's submission of ANDA No. 206431 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).

26. Upon information and belief, Taro USA and TPI had actual and constructive knowledge of the '149 patent prior to filing ANDA No. 206431, and were aware that the filing of their ANDA with the FDA constituted an act of infringement of the '149 patent.

27. Upon information and belief, use of such generic sodium sulfate, potassium sulfate and magnesium sulfate oral solution, in accordance with and as directed by the proposed labeling in ANDA No. 206431 for that product, would infringe one or more claims of the '149 patent.

28. Upon information and belief, Taro USA and TPI 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, Taro USA and TPI plan and intend to infringe, and will induce and/or contribute to the infringement of, the '149 patent, immediately and imminently upon approval of ANDA No. 206431.

29. Upon FDA approval of Taro USA's and TPI's ANDA No. 206431, Taro USA and TPI 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.

30. If infringement of the '149 patent by Taro USA and TPI 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 Taro USA's and TPI's submission of ANDA No. 206431, 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 Taro USA and TPI 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. 206431 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 Taro USA and TPI, 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.

Dated: October 9, 2014.

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