IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SALIX PHARMACEUTICALS, INC., and NORGINE B.V., Plaintiffs, v. TARO PHARMACEUTICALS U.S.A., INC. and TARO PHARMACEUTICAL INDUSTRIES, LTD., Defendants.	)	CA. No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Salix Pharmaceuticals, Inc. and Norgine B.V. (collectively, "Plaintiffs") file this Complaint against Defendants Taro Pharmaceuticals U.S.A., Inc. and Taro Pharmaceutical Industries, Ltd. (collectively, "Taro" or "Defendants") and allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the Food and Drug Laws and Patent Laws of the United States, Titles 21 and 35 of the United States Code, respectively, arising from Taro's submission of an Abbreviated New Drug Application ("ANDA") to the Food and Drug Administration ("FDA") seeking approval to manufacture, use, and sell a generic version of Plaintiff Salix Pharmaceuticals, Inc.'s MOVIPREP® product prior to the expiration of United States Patent Nos. 7,169,381 ("the '381 patent") and 7,658,914 ("the '914 patent") (collectively, "the Patents-In-Suit").

THE PARTIES

2. Plaintiff Salix Pharmaceuticals, Inc. ("Salix") is a California corporation having a principal place of business at 8510 Colonnade Center Drive, Raleigh, North Carolina 27615.

3. Plaintiff Norgine B.V. ("Norgine") is a limited liability company organized under the laws of The Netherlands, with principal offices at Hogehilweg 7, 1101 CA, Amsterdam Zuid-Oost, The Netherlands.

4. On information and belief, Defendant Taro Pharmaceuticals U.S.A., Inc. ("Taro USA") is a New York corporation, with a principal place of business at 3 Skyline Drive, Hawthorne, New York 10532. On information and belief, Taro USA is in the business of making and selling generic pharmaceutical products, which it distributes, markets, and/or sells throughout the United States, including within the State of Delaware. On information and belief, Taro USA is an agent and wholly-owned subsidiary of Taro Pharmaceutical Industries, Ltd. ("Taro Ltd."). On information and belief, Taro USA acts under the direction, control, and influence of Taro Ltd., including with respect to the acts and conduct alleged in this Complaint.

5. On information and belief, Defendant Taro Ltd. is a corporation organized and existing under the laws of Israel, with a principal place of business at 14 Hakitor Street, Haifa Bay, Israel 2624761. On information and belief, Taro Ltd. is in the business of making and selling generic pharmaceutical products, which, through its subsidiaries including Taro USA, it distributes, markets, and/or sells throughout the United States, including within the State of Delaware.

JURISDICTION AND VENUE

6. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

7. On information and belief, Taro USA is subject to personal jurisdiction in Delaware because Taro USA itself and as the agent, wholly owned subsidiary and distributor of Taro Ltd., is in the business of making and selling generic pharmaceutical products, which it distributes throughout the United States including the State of Delaware. Specifically, Taro USA

has an active Pharmacy–Wholesale license in this District—license number A4-0001880. The license was issued on February 6, 2012, and does not expire until September 30, 2016. In addition, Taro USA also has an active Controlled Substances Distributor/Manufacturer CSR license in this District—license number DM-0008559. The license was issued on February 6, 2012, and does not expire until June 30, 2017. This Court has personal jurisdiction over Taro USA also because Taro USA has previously submitted to the jurisdiction of this Court and has purposefully availed itself of the jurisdiction of this Court by filing lawsuits, including the recently filed Civil Action Nos. 1:14-cv-00989-RGA and 1:15-cv-00859-RGA.

8. On information and belief, Taro Ltd. is subject to personal jurisdiction in Delaware because Taro Ltd. is in the business of making and selling generic pharmaceutical products, which through its agent and wholly owned subsidiary Taro USA, it distributes throughout the United States, including the State of Delaware.

9. Venue is proper in this district under 28 U.S.C. §§ 1391 and 1400.

THE PATENTS-IN-SUIT

10. The ’381 patent (a true and correct copy of which is attached hereto as Exhibit A), bearing the title “Colon Cleansing Compositions and Methods,” issued on January 30, 2007. Norgine is the owner by assignment of the ’381 patent. The ’381 patent claims, *inter alia*, certain compositions for use in colon cleansing.

11. Pursuant to an exclusive license between Salix and Norgine (“License Agreement”), Salix has the right to bring this suit for infringement of the ’381 patent.

12. The ’914 patent (a true and correct copy of which is attached hereto as Exhibit B), bearing the title “Colon Cleansing Compositions,” issued on February 9, 2010. Norgine is the owner by assignment of the ’914 patent. The ’914 patent claims, *inter alia*, certain compositions for use in colon cleansing.

13. Pursuant to an exclusive license between Salix and Norgine, Salix has the right to bring this suit for infringement of the ’914 patent.

MOVIPREP® Oral Solution

14. Plaintiff Salix is the holder of New Drug Application (“NDA”) No. 021-881 for a formulation comprising ascorbic acid, polyethylene glycol 3350, potassium chloride, sodium ascorbate, sodium chloride, and sodium sulfate, which it sells under the name MOVIPREP®.

15. On August 2, 2006, the FDA approved NDA No. 021-881 for the manufacture, marketing, and sale of MOVIPREP® for cleansing of the colon as a preparation for colonoscopy in adults 18 years of age or older.

16. The ’381 patent and the ’914 patent (*i.e.*, the Patents-In-Suit) are listed in the FDA’s Approved Drug Products with Therapeutic Equivalence Evaluations (the “Orange Book”) as covering MOVIPREP®.

TARO’S NOTICE LETTER AND PARAGRAPH IV CERTIFICATION

17. Plaintiffs received a letter on behalf of Taro USA and Taro Ltd. (collectively, “Taro”) dated August 25, 2015 (“Notice Letter”), stating that Taro submitted an ANDA to the FDA pursuant to 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95(c)(1), and that the FDA has received and assigned Taro’s ANDA No. 207498.

18. Taro’s Notice Letter also states that the established name of the drug product that is the subject of Taro’s ANDA (“Taro’s generic product”) is Ascorbic Acid; Polyethylene Glycol 3350; Potassium Chloride; Sodium Ascorbate; Sodium Chloride; and Sodium Sulfate Oral Solution.

19. Taro’s Notice Letter also states that the dosage form of Taro’s generic product is an oral solution with Ascorbic Acid (4.7 gm); Polyethylene Glycol 3350 (100 gm); Potassium

Chloride (1.015 gm); Sodium Ascorbate (5.9 gm); Sodium Chloride (2.691 gm); and Sodium Sulfate (7.5 gm).

20. Taro's Notice Letter also states that ANDA No. 207498 was submitted under 21 U.S.C. §§ 355(j)(1) and (2)(A), and includes a "paragraph IV certification" to obtain approval to engage in the commercial manufacture, use, or sale of Taro's generic product before the expiration of the Patents-In-Suit.

21. Taro's Notice Letter also states that Taro alleges, and has certified to the FDA, that each claim of the Patents-In-Suit is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of Taro's generic product.

COUNT I
(Infringement of the '381 Patent Under 35 U.S.C. § 271(e)(2))

22. Plaintiffs reallege paragraphs 1-21 above as if fully set forth herein.

23. Pursuant to 35 U.S.C. § 271(e)(2)(A), Taro's submission of ANDA No. 207498 to the FDA seeking approval to engage in the commercial manufacture, use, or sale of Taro's generic product was an act of infringement of the '381 patent.

24. On information and belief, Taro intends to engage in the commercial manufacture, use, sale, or offer for sale within the United States, or importation into the United States, of Taro's generic product upon receipt of final FDA approval of ANDA No. 207498.

25. Pursuant to 35 U.S.C. §§ 271(a), (b), and/or (c), Taro's commercial manufacture, use, sale, or offer for sale within the United States, or importation into the United States, of Taro's generic product will constitute infringement of the '381 patent.

26. Unless Taro is enjoined by the Court, Plaintiffs will be substantially and irreparably harmed by Taro's infringement of the '381 patent. Plaintiffs have no adequate remedy at law.

27. Taro was aware of the ’381 patent but nevertheless infringed and is continuing to infringe that patent by seeking FDA approval to engage in the commercial manufacture, use, sale, or offer for sale within the United States of Taro’s generic product.

COUNT II
(Infringement of the ’914 Patent Under 35 U.S.C. § 271(e)(2))

28. Plaintiffs reallege paragraphs 1-21 above as if fully set forth herein.

29. Pursuant to 35 U.S.C. § 271(e)(2)(A), Taro’s submission of ANDA No. 207498 to the FDA seeking approval to engage in the commercial manufacture, use, or sale of Taro’s generic product was an act of infringement of the ’914 patent.

30. On information and belief, Taro intends to engage in the commercial manufacture, use, sale, or offer for sale within the United States, or importation into the United States, of Taro’s generic product upon receipt of final FDA approval of ANDA No. 207498.

31. Pursuant to 35 U.S.C. §§ 271(a), (b), and/or (c), Taro’s commercial manufacture, use, sale, or offer for sale within the United States, or importation into the United States, of Taro’s generic product will constitute infringement of the ’914 patent.

32. Unless Taro is enjoined by the Court, Plaintiffs will be substantially and irreparably harmed by Taro’s infringement of the ’914 patent. Plaintiffs have no adequate remedy at law.

33. Taro was aware of the ’914 patent but nevertheless infringed and is continuing to infringe that patent by seeking FDA approval to engage in the commercial manufacture, use, sale, or offer for sale within the United States of Taro’s generic product.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment:

A. Declaring that Taro has infringed one or more claims of the ’381 patent and the ’914 patent;

B. Declaring that the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of Taro’s generic product will infringe one or more claims of the ’381 patent and the ’914 patent;

C. Ordering that the effective date of any approval of ANDA No. 207498 shall not be earlier than the expiration of the last to expire of the ’381 patent and the ’914 patent, including any extensions;

D. Preliminarily and permanently enjoining Taro, its officers, agents, servants, and employees, all other persons acting in privy or concert with them, and their successors and assigns, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of Taro’s generic product;

E. In the event that Taro engages in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of Taro’s generic product, awarding Plaintiffs damages to the full extent provided by 35 U.S.C. §§ 271(e)(4)(C) and 284;

F. Declaring this is an exceptional case within the meaning of 35 U.S.C. § 285 and awarding to Plaintiffs their reasonable attorneys’ fees, costs, and expenses;

G. Granting such other relief as the Court may deem just and proper.

Dated: October 8, 2015

Respectfully submitted,

/s/ Mary W. Bourke
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