IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF MICHIGAN

TARO PHARMACEUTICALS U.S.A., INC. and TARO PHARMACEUTICALS NORTH AMERICA, INC.,

Plaintiffs,

v.

PERRIGO ISRAEL PHARMACEUTICALS LTD.,

Defendant.

Case No.

Hon.

JURY DEMAND

COMPLAINT AND JURY DEMAND

Plaintiffs Taro Pharmaceuticals U.S.A., Inc. ("Taro USA") and Taro Pharmaceuticals North America, Inc. ("Taro North Am.") (together, "Taro") hereby state the following claims for relief against Defendant Perrigo Israel Pharmaceuticals Ltd. ("Perrigo Israel"):

NATURE OF THE ACTION

1. This is an action for patent infringement under the patent laws of the United States, 35 U.S.C. § 100, *et seq.*, the Hatch-Waxman Act, 35 U.S.C. § 271(e)(2), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

2. This action arises from Perrigo Israel's filing of an Abbreviated New Drug Application ("ANDA") with the U.S. Food and Drug Administration ("FDA") seeking approval to commercially market a generic version of Taro's

Topicort® (desoximetasone) Topical Spray, 0.25% before the expiration of U.S. Patent Nos. 8,277,780 (the "'780 patent," attached as Exhibit A) and 8,715,624 (the "'624 patent," attached as Exhibit B).

PARTIES

3. Taro USA is a company organized and existing under the laws of the State of New York, with a principal place of business at 3 Skyline Drive, Hawthorne, New York 10532.

4. Taro North Am. is a company organized and existing under the laws of the Cayman Islands, with a principal place of business at 190 Elgin Avenue, George Town, Grand Cayman, KY1-9005, Cayman Islands.

5. On information and belief, Perrigo Israel is a wholly owned subsidiary of Perrigo Company that is organized and exists under the laws of Israel, having a principal place of business at 29 Lehi Street, Bnei Brak 51200, Israel. Perrigo Company has its principal place of business in the United States at 515 Eastern Avenue, Allegan, MI 49010.

JURISDICTION AND VENUE

6. Taro seeks to enforce its federal patent rights under Title 35, United States Code. This Court has subject matter jurisdiction over this action under 28 U.S.C. §§ 1331, 1338, 2201 and 2202.

7. This Court has personal jurisdiction over Perrigo Israel because, among other reasons, it has substantial and continuous contacts with the United States, including this District, and because it has committed the acts of patent infringement alleged herein in the United States. In addition, Perrigo Israel has authorized service of process for this suit on Andrew M. Solomon, Vice President and Assistant General Counsel, Perrigo Company, 515 Eastern Ave., Allegan, MI 49010. Also, Perrigo Israel has not contested personal jurisdiction in this District. (Case No. 08-cv-539).

8. Venue is proper in this Court under 28 U.S.C. § 1391.

FACTUAL BACKGROUND

A. The FDA Marketing Approval Process

9. The Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.*, as amended by the Hatch-Waxman Amendments, sets forth the rules that the FDA follows when considering the approval of applications for both brand-name and generic drugs.

10. Under the Hatch-Waxman Amendments, an applicant seeking to market a new brand-name drug must prepare a New Drug Application ("NDA") for consideration by the FDA. *See* 21 U.S.C. § 355.

11. An NDA must include, among other things, the patent number of any patent that claims the drug or a method of using such drug, for which the applicant

submitted the NDA and for which a claim of patent infringement could reasonably be asserted against an unauthorized party. *See* 21 U.S.C. § 355(b)(1) and (c)(2); 21 C.F.R. §§ 314.53(b) and (c)(2).

12. Upon approval of the NDA, the FDA publishes patent information for the approved drug in its publication, Approved Drug Products with Therapeutic Equivalence Evaluation ("Orange Book"). *See* 21 U.S.C. § 355(j)(7)(A)(iii).

13. A pharmaceutical company may seek to market a generic version of the innovator's brand drug by submitting an ANDA under 21 U.S.C. § 355(j). The generic company may then rely on the studies the innovator includes in its NDA.

B. Taro's Topicort® Product

14. On April 11, 2013, the FDA approved Taro's NDA for Topicort® (desoximetasone), NDA No. 204141. Taro began marketing Topicort® shortly after that approval.

15. Topicort® is a corticosteroid indicated for the treatment of plaque psoriasis in patients 18 years of age or older. Psoriasis is a systemic inflammatory disease of immune dysfunction that affects an estimated 2%-3% of the U.S. population.

C. Taro's Patents Covering Topicort®

16. The United States Patent & Trademark Office ("PTO") legally issued the '780 patent, titled "Stable Liquid Desoximetasone Compositions with Reduced

Oxidized Impurity" on October 2, 2012. Taro North Am. owns the '780 patent, which lists Srinivasa Rao, Suresh Dixit, Avraham Yacobi, and Arthur Bailey as its inventors. The invention provides a liquid formulation that contains specific ranges of desoximetasone, isopropyl myristate, a C_2-C_4 alcohol, and a stabilizing agent.

17. The PTO legally issued the '624 patent, titled "Stable Liquid Desoximetasone Compositions with Reduced Oxidized Impurity" on May 6, 2014. Taro North Am. owns the '624 patent, which lists Srinivasa Rao, Suresh Dixit, Avraham Yacobi, and Arthur Bailey as its inventors. The invention provides a liquid formulation that contains specific ranges of desoximetasone, isopropyl myristate, a C_2-C_4 alcohol, and a stabilizing agent.

18. Both the '780 and '624 patents are listed in the Orange Book listing for Topicort® under 21 C.F.R. § 314.53(b)(1) as "patent[s] that claim[] the drug or a method of using the drug that is the subject of the new drug application or amendment or supplement to it and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug product."

D. Perrigo Israel's Infringing ANDA

19. On information and belief, Perrigo Israel made and included in ANDA No. 206441 a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV)

("Paragraph IV certification") that, in its opinion and to the best of its knowledge, the '780 and '624 patents are invalid, unenforceable, and/or will not be infringed.

20. Perrigo Israel sent Taro a "Notice of Certification" letter explaining that it filed ANDA No. 206441 for Desoximetasone Topical Spray, 0.25% ("Perrigo Israel's ANDA Product") seeking approval to manufacture, use, sell, or import Perrigo Israel's ANDA Product before the '780 patent expires. This letter provides notice of Perrigo Israel's Paragraph IV certification and alleges that the claims of the '780 patent are invalid, unenforceable, and/or will not be infringed by the activities described in Perrigo Israel's ANDA.

21. Perrigo Israel sent Taro another "Notice of Certification" letter, which explains that ANDA No. 206441 also sought approval to manufacture, use, sell or import Perrigo Israel's ANDA Product before the '624 patent expires. This letter provides notice of Perrigo Israel's Paragraph IV certification and alleges that the claims of the '624 patent are invalid, unenforceable, and/or will not be infringed by the activities described in Perrigo Israel's ANDA.

COUNT 1: INFRINGEMENT OF THE '780 PATENT

22. Paragraphs 1 to 21 are incorporated as if fully set forth herein.

23. Perrigo Israel submitted an ANDA with a Paragraph IV certification to obtain FDA approval to manufacture, use, offer for sale, or sell Perrigo Israel's

ANDA Product before expiration of the ’780 patent — an act of infringement under 35 U.S.C. § 271(e)(2)(A).

24. Unless enjoined by the Court, if and when Perrigo Israel’s ANDA No. 206441 is approved, Perrigo Israel will further infringe the ’780 patent by making, using, offering for sale, or selling Perrigo Israel’s ANDA Product before expiration of the ’780 patent in violation of 35 U.S.C. §§ 271(a), (b) or (c).

25. Accordingly, Taro is entitled to a judicial declaration that ANDA No. 206441 infringes one or more valid, enforceable claims of the ’780 patent.

COUNT 2: INFRINGEMENT OF THE ’624 PATENT

26. Paragraphs 1 to 25 are incorporated as if fully set forth herein.

27. Perrigo Israel submitted an ANDA with a Paragraph IV certification to obtain FDA approval to manufacture, use, offer for sale, or sell Perrigo Israel’s ANDA Product before expiration of the ’624 patent — an act of infringement under 35 U.S.C. § 271(e)(2)(A).

28. Unless enjoined by the Court, if Perrigo Israel’s ANDA No. 206441 is approved, Perrigo Israel will further infringe the ’624 patent by making, using, offering for sale, or selling Perrigo Israel’s ANDA Product before expiration of the ’624 patent in violation of 35 U.S.C. §§ 271(a), (b) or (c).

29. Accordingly, Taro is entitled to a judicial declaration that ANDA No. 206441 infringes one or more valid, enforceable claims of the ’624 patent.

PRAYER FOR RELIEF

WHEREFORE, Taro prays for judgment from this Court against Perrigo Israel and respectfully requests the following relief:

a. Judgment that Perrigo Israel has infringed one or more valid claims of the '780 and '624 patents by filing ANDA No. 206441;

b. Judgment that the making, using, selling, offering to sell, or importing into the United States Perrigo Israel's ANDA Product will infringe one or more claims of the '780 and '624 patents;

c. A permanent injunction restraining and enjoining Perrigo Israel and its officers, agents, attorneys and employees, and those acting in privity or concert with it, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, Perrigo Israel's ANDA Product, as claimed in the '780 and '624 patents, until the expiration of those patents or any later date of exclusivity to which Taro is or becomes entitled;

d. An order that the effective date of any FDA approval of ANDA No. 206441 relating to Perrigo Israel's ANDA Product be a date that is not earlier than the expiration dates of the '780 and '624 patents, or any later date of exclusivity to which Taro is or becomes entitled;

e. Monetary relief to the extent that Perrigo Israel has committed or does commit any act outside the scope of 35 U.S.C. § 271(e)(1);

f. Reasonable attorney's fees based on the exceptional nature of this case;

g. Costs and expenses in this action; and

h. Such other and further relief as the Court deems just and appropriate.

JURY DEMAND

Plaintiffs Taro Pharmaceuticals U.S.A., Inc. and Taro Pharmaceuticals North America, Inc. hereby demand a trial by jury.

Respectfully submitted,

/s/ Morley Witus
Morley Witus (P30895)
BARRIS SOTT DENN & DRIKER PLLC
211 W. Fort Street, 15th Floor
Detroit, Michigan 48226-3281
(313) 965-9725
mwitus@bsdd.com

James F. Hurst
WINSTON & STRAWN LLP
35 W. Wacker Drive
Chicago, Illinois 60601-9703
(312) 558-5600
jhurst@winston.com

Charles B. Klein
John K. Hsu
Neema Kumar
Christopher M. Bruno
WINSTON & STRAWN LLP
1700 K Street, N.W.
Washington, DC 20006
(202) 282-5000
cklein@winston.com
jhsu@winston.com
nkumar@winston.com
cmbruno@winston.com

Attorneys for Plaintiffs Taro Pharmaceuticals U.S.A., Inc. and Taro Pharmaceuticals North America, Inc.

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