IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

ARBOR PHARMACEUTICALS, LLC Plaintiff, v. TARO PHARMACEUTICALS U.S.A., INC. and TARO PHARMACEUTICAL INDUSTRIES, LTD. Defendants.	)	C.A. No._____

COMPLAINT

Plaintiff Arbor Pharmaceuticals, LLC ("Arbor" or "Plaintiff") for its Complaint against Defendants Taro Pharmaceuticals U.S.A., Inc. ("Taro USA") and Taro Pharmaceutical Industries, Ltd. ("Taro Ltd.") (collectively, "Taro" or "Defendants"), hereby alleges as follows:

The Parties

1. Arbor is a limited liability company organized and existing under the laws of the state of Delaware, having a principal place of business at 6 Concourse Parkway, Suite 1800, Atlanta, GA 30328.

2. On information and belief, Defendant Taro USA is a corporation organized and existing under the laws of the State of New York, with a place of business at 3 Skyline Drive, Hawthorne, NY 10532.

3. On information and belief, Defendant Taro Ltd. is a corporation organized and existing under the laws of the State of Israel, with a place of business at 14 Hakitor Street, Haifa Bay 2624761, Israel.

4. On information and belief, Taro USA is a wholly-owned subsidiary of Taro Ltd. and is controlled by Taro Ltd.

Nature of the Action

5. This is a civil action for infringement of United States Patent Nos. 8,791,153 ("the '153 patent") and 8,927,595 ("the '595 patent") (collectively, "the patents-in-suit"). (Exhibits A–B.) This action arises under the Patent Laws of the United States, 35 U.S.C. §§ 100 *et seq*.

Jurisdiction & Venue

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

7. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

8. This Court has personal jurisdiction over Defendants, and venue is proper in this district, by virtue of the facts that, *inter alia*, Taro USA is a New York corporation and thus resides in New York, and Defendants have committed, aided, abetted, contributed to, and/or participated in the commission of a tortious act of patent infringement under 35 U.S.C. § 271(e)(2) that has led and/or will lead to foreseeable harm and injury to Plaintiff, including in the State of New York. Defendants have indicated that they intend to engage in the commercial manufacture, use, or sale of an Ivermectin Lotion, 0.5% product ("the ANDA Product") under Abbreviated New Drug Application No. 210720 ("the '720 ANDA") before the expiration of the patents-in-suit, throughout the United States, including in the State of New York.

9. Upon information and belief, Taro Ltd. is in the business of, *inter alia*, manufacturing and selling generic pharmaceutical products that are distributed throughout the

United States, including in the State of New York, through its own actions, and through the actions of its agents and affiliates, including, at least, Taro USA.

10. Upon information and belief, Taro USA is in the business of, *inter alia*, manufacturing and selling generic pharmaceutical products that are distributed throughout the United States, including in the State of New York, through its own actions, and through the actions of its agents and affiliates.

11. Upon information and belief, Taro Ltd and Taro USA have participated and collaborated in the preparation, filing, and seeking FDA approval of the '720 ANDA for the ANDA Product; continue to participate and collaborate in seeking FDA approval of the '720 ANDA; and intend to participate and collaborate in the commercial manufacture, marketing, offer for sale, and sale of the ANDA Product throughout the United States including the State of New York.

12. Defendants' infringing activities with respect to the filing of the '720 ANDA and intent to commercialize the ANDA Product have led and/or will lead to foreseeable harm and injury to Plaintiff.

Arbor's NDA and the Patents-In-Suit

13. Arbor holds New Drug Application ("NDA") No. 202736 on SKLICE® (ivermectin lotion), and is the exclusive distributor of SKLICE® in the United States.

14. On July 29, 2014, the '153 patent, entitled "Topical avermectin formulations and methods for elimination and prophylaxis of susceptible and treatment-resistant strains of head lice" was duly and legally issued. A copy of the '153 patent is attached as Exhibit A.

15. Arbor owns the '153 patent.

16. On January 6, 2015, the '595 patent, entitled "Topical avermectin formulations and methods for elimination and prophylaxis of susceptible and treatment resistant strains of head lice" was duly and legally issued. A copy of the '595 patent is attached as Exhibit B.

17. Arbor owns the '595 patent.

18. The patents-in-suit are listed in the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book") for SKLICE®.

Taro's ANDA and Paragraph IV Notification

19. Upon information and belief, Taro USA, with the collaboration or assistance of Taro Ltd., submitted the '720 ANDA to the FDA under § 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)), including a certification with respect to the patents-in-suit under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act, seeking approval to engage in the commercial manufacture, use, sale, or offer for sale within the United States, or importation into the United States, of the ANDA Product prior to the expiration of the patents-in-suit.

20. Plaintiff received written notification of Taro's ANDA and its accompanying § 505(j)(2)(A)(vii)(IV) certification by a letter ("Paragraph IV Notification"), dated November 3, 2017, and sent via Federal Express.

21. This action is being commenced by Plaintiff within 45 days of the date of their receipt of the Paragraph IV Notification.

22. The Paragraph IV Notification was accompanied by an Offer of Confidential Access ("OCA") to certain confidential information regarding the ANDA Product. Arbor subsequently negotiated with Taro in an effort to agree on reasonable terms for such confidential access. As of the time of filing of this Complaint, however, the parties have not able to reach an

agreement with respect to reasonable revisions that Plaintiff proposed to the OCA. For example, Taro refused to allow any outside expert review of any aspects of the ANDA irrespective of terms for such review, notwithstanding that such provisions are routinely used in confidentiality provisions in litigation.

23. To date, Taro has not provided Plaintiff with a copy of any portions of the '720 ANDA or any information regarding the ANDA Product, beyond the information set forth in the Paragraph IV Notification.

24. The limited information relating to the ANDA Product that was provided in Taro's Paragraph IV Notification does not demonstrate that the ANDA Product, which Taro is asking the FDA to approve for sale in the U.S., will not fall within the scope of issued claims of the patents-in-suit.

Taro's Infringement of the Patents-In-Suit

25. Plaintiff re-allege paragraphs 1–24 as if fully set forth herein.

26. By seeking FDA approval of the '720 ANDA to engage in the commercial manufacture, use, sale, or offer for sale within the United States, or importation into the United States, of the ANDA Product prior to the expiration of the patents-in-suit, Defendants have infringed those patents under 35 U.S.C. § 271(e)(2)(A).

27. Upon information and belief, the '720 ANDA contains a certification under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act that the claims of the patents-in-suit are not infringed and invalid. Taro notified Arbor of that certification and provided a statement of the alleged bases for it its claims.

28. Defendants are jointly and severally liable for infringement of the patents-in-suit under 35 U.S.C. § 271(e)(2)(A). Upon information and belief, Defendants actively and

knowingly caused to be submitted, assisted with, participated in, contributed to, or directed the submission of the '720 ANDA seeking to engage in the commercial manufacture, use, sale, or offer for sale within the United States, or importation into the United States, of the ANDA Product prior to the expiration of the patents-in-suit.

29. Moreover, if Defendants manufacture, use, offer for sale, or import into the United States any of the ANDA Product, or induce or contribute to any such conduct, prior to the expiration of the patents-in-suit, including any applicable exclusivities or extensions, they would infringe one or more claims of those patents-in-suit under 35 U.S.C. § 271(a), (b) and/or (c).

30. Plaintiff is entitled to relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of the '720 ANDA be a date that is not earlier than the expiration date of the patents-in-suit, or any later expiration of any patent term extension or exclusivity for the patents-in-suit to which Plaintiff becomes entitled.

31. Plaintiff will be irreparably harmed by Taro's infringing activities unless those activities are enjoined by this Court. Plaintiff does not have an adequate remedy at law.

Prayer for Relief

Plaintiff requests that the Court grant the following relief:

A. An order that Defendants have infringed the patents-in-suit by submitting the '720 ANDA to the FDA;

B. An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of the '720 ANDA will not be earlier than the expiration date of the patents-in-suit, or any later expiration of any patent term extension or exclusivity for the aforementioned patents-in-suit to which Plaintiff is or becomes entitled;

C. An order permanently enjoining Defendants, their directors, officers, agents, attorneys, affiliates, divisions, successors and employees, and those acting in privity or concert with them, from manufacturing, using, offering to sell, selling, marketing, distributing, or importing the ANDA Product identified in this Complaint, or any product that infringes the patents-in-suit, prior to the expiration of the patents-in-suit, including any extensions to which Plaintiff is or becomes entitled;

D. That Plaintiff be awarded monetary relief to the extent Defendants commercially manufacture, use, offer for sale, or sell within the United States, or import into the United States any product that infringes or induces or contributes to the infringement of the patents-in-suit, within the United States prior to the expiration of the aforementioned patents, including any later expiration of any patent term extension or exclusivity for the patents to which Plaintiff is or will become entitled, and that any such monetary relief be awarded to Plaintiff with prejudgment interest; and

E. Such other and further relief as this Court may deem just and proper.

PAUL HASTINGS LLP

/s Chad J. Peterman
Bruce M. Wexler
Chad J. Peterman
200 Park Avenue
New York, NY 10166
(212) 318-6000
Attorneys for Plaintiff

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