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

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

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

Plaintiffs,

v.

**SYNERX PHARMA, LLC;
KARALEX PHARMA, LLC; and
DPT LABORATORIES, LTD.,**

Defendants.

Civil Action No. _____

COMPLAINT

Plaintiffs Taro Pharmaceuticals North America, Inc., and Taro Pharmaceuticals U.S.A., Inc. (collectively "Plaintiffs" or "Taro"), for their Complaint against Defendants

Synerx Pharma, LLC, Karalex Pharma, LLC, and DPT Laboratories, Ltd., by and through their attorneys, allege as follows:

THE PARTIES

1. Taro Pharmaceuticals North America, Inc. is a corporation organized and existing under the laws of the Cayman Islands, having its principal place of business at 103 South Church Street, Grand Cayman, Cayman Islands.

2. Taro Pharmaceuticals U.S.A., Inc. is a corporation organized and existing under the laws of the State of New York, having a place of business at 3 Skyline Drive, Hawthorne, New York.

3. Upon information and belief, Defendant Synerx Pharma, LLC (“Synerx”) is a corporation organized and existing under the laws of the State of Pennsylvania, having a place of business at 100 North State Street, Newton, Pennsylvania.

4. Upon information and belief, Defendant Karalex Pharma, LLC (“Karalex”) is a corporation organized and existing under the laws of the State of New Jersey, having a place of business at 470 Chestnut Ridge Road, Woodcliff, New Jersey.

5. Upon information and belief, Karalex is registered to do business in New Jersey and has appointed Frank Fazio as its registered agent in New Jersey for receipt of service of process.

6. Upon information and belief, Defendant DPT Laboratories, Ltd. (“DPT”) is a corporation organized and existing under the laws of the State of Texas, having places of business at 1700 Oak Street, Lakewood, New Jersey, and 307 East Josephine Street, San Antonio, Texas.

JURISDICTION AND VENUE

7. This action arises under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.* This court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a).

8. Venue is proper in this judicial district pursuant to Title 28 of the United States Code, §§ 1391 and 1400(b).

9. This Court has personal jurisdiction over Synerx because it continuously and systematically transacts business in New Jersey, and committed acts within this judicial district that give rise to this action.

10. This Court has personal jurisdiction over Karalex because it continuously and systematically transacts business in New Jersey, it resides in the State of New Jersey, and committed acts within this judicial district that give rise to this action.

11. This Court has personal jurisdiction over DPT because it continuously and systematically transacts business in New Jersey, operates a facility in the State of New Jersey, and committed acts within this judicial district which give rise to this action.

CLAIM FOR PATENT INFRINGEMENT

12. On July 14, 2009, United States Patent No. 7,560,445 ("the '445 patent) entitled "Process for Preparing Malathion for Pharmaceutical Use," was duly and legally issued by the U.S. Patent and Trademark Office to Taro Pharmaceuticals North America, Inc. Taro Pharmaceuticals North America, Inc. is the owner of all right, title, and interest

in the '445 patent, including the right to sue for infringement. A copy of the '445 patent is attached hereto and incorporated herein as Exhibit A.

13. Taro Pharmaceuticals North America, Inc. holds an approved New Drug Application for 0.5% malathion topical lotion, which is sold under the registered trademark OVIDE®.

14. Taro Pharmaceuticals U.S.A., Inc., an affiliate of Taro Pharmaceuticals North America, Inc., distributes OVIDE® in the United States.

15. OVIDE® (malathion) Lotion, 0.5%, was originally approved on August 2, 1982, by the U.S. Food and Drug Administration (“FDA”) for treatment of patients infected with *Pediculus humanus capitis* (head lice and their ova) of the scalp hair.

16. Upon information and belief, Synerx obtained approval on March 6, 2009, for its Abbreviated New Drug Application No. 078743, covering 0.5% Malathion Topical Lotion, as a generic version of Taro's OVIDE® (malathion) Lotion.

17. Upon information and belief, Synerx’s generic version of OVIDE® (malathion) Lotion infringes one or more claims of the '445 patent.

18. Upon information and belief, Karalex is offering for sale, selling and/or distributing the Synerx generic version of Taro's OVIDE® (malathion) Lotion.

19. Upon information and belief, DPT is manufacturing the Synerx generic version of Taro's OVIDE® (malathion) Lotion.

20. Each of the Defendants has infringed and continues to infringe the '445 patent, either directly, by contributory infringement and/or by inducement of others to infringe. The infringing acts include, but are not limited to, the manufacture, use, sale,

importation, and/or offer for sale of products covered by the '445 patent. Each of the Defendants is liable for infringement of the '445 patent pursuant to 35 U.S.C. § 271.

21. Each of the Defendants' acts of infringement has caused damage to Taro, and Taro is entitled to recover from each Defendant the damages sustained by Taro as a result of each Defendants' individual wrongful acts in an amount subject to proof at trial. Each of the Defendants' infringement of Taro's exclusive rights under the '445 patent will continue to damage Taro's business, causing irreparable harm, for which there is no adequate remedy at law, unless it is enjoined by this Court.

22. Upon information and belief, Defendants' infringement of the '445 patent is willful and deliberate, entitling Taro to increased damages under 35 U.S.C. § 284 and to attorneys' fees and costs incurred in prosecuting this action under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Taro prays for judgment and seeks relief against each of the Defendants as follows:

- a) a judgment that the '445 patent has been and continues to be infringed by each Defendant;
- b) an accounting of all damages sustained by Taro as the result of acts of infringement by each Defendant;
- c) a preliminary and permanent injunction enjoining the aforesaid acts of infringement by each Defendant, their officers, agents, servants, employees, subsidiaries and attorneys, and those persons acting in concert with them, including related individuals and entities, customers, representatives, dealers and distributors;

- d) an award of damages and/or other monetary relief, including damages for willful infringement pursuant to 35 U.S.C. § 284, for the manufacture, use or sale of malathion compositions falling within the scope of one or more claims of the '445 patent prior to its expiration.
- e) an award of Plaintiffs' interest, costs, and reasonable attorneys' fees pursuant to 35 U.S.C. § 285 incurred in prosecuting this action; and
- f) such other and further relief as the Court may deem just and proper.

JURY DEMAND

Pursuant to Federal Rule of Civil Procedure 38(b), Plaintiffs hereby demands a trial by jury of all issues triable as of right in this action.

Respectfully submitted,

Dated: July 20, 2009

s/Arnold B. Calmann
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