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

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

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	:	
TARO PHARMACEUTICALS NORTH	:	
AMERICA, INC. and TARO	:	Honorable
PHARMACEUTICALS U.S.A., INC.,	:	
	:	Civil Action No.
Plaintiffs,	:	
	:	
v.	:	
	:	COMPLAINT AND JURY DEMAND
SUVEN LIFE SCIENCES, LTD. and SUVEN	:	
LIFE SCIENCES USA, LLC,	:	
	:	
Defendant.	:	
	:	
	:	
_____		X

Plaintiffs Taro Pharmaceuticals North America, Inc., and Taro Pharmaceuticals U.S.A., Inc., for their Complaint against Defendants Suven Life Sciences, Ltd., and Suven Life Sciences USA, LLC, by and through their attorneys, allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement under the Hatch-Waxman Act, 35 U.S.C. § 271 (e)(2).

PARTIES

2. Plaintiff 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.

3. Plaintiff Taro Pharmaceuticals U.S.A., Inc., is a corporation organized and existing under the laws of the State of New York, having its principal place of business at 3 Skyline Drive, Hawthorne, New York. Taro Pharmaceuticals North America, Inc., and Taro Pharmaceuticals U.S.A., Inc., will be collectively referred to herein as “Taro.”

4. On information and belief, defendant Suven Life Sciences, Ltd., is a corporation organized and existing under the laws of India, having its principal place of business at Road No. 5, Avenue - 7, Banjara Hills, Hyderabad, India.

5. On information and belief, defendant Suven Life Sciences USA, LLC, is a wholly owned subsidiary of Suven Life Sciences, Ltd., organized and existing under the laws of the State of New Jersey, having its principal place of business at 1100 Cornwall Road, Monmouth Junction, New Jersey.

6. On information and belief, the acts of defendant Suven Life Sciences USA, LLC, complained of herein were done at the direction of, with authorization of, and with the cooperation, participation, and assistance of defendant Suven Life Sciences, Ltd. Suven Life Sciences USA, LLC, and Suven Live Sciences, Ltd., will be collectively referred to herein as “Suven.”

JURISDICTION AND VENUE

7. This action arises under the patent laws of the United States of America, Title 35, United States Code. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a).

8. On information and belief, Suven is subject to personal jurisdiction in this District because Suven maintains continuous and systematic contacts with the United States, including the State of New Jersey, and because it has committed the acts of patent infringement alleged herein within the United States. It is therefore subject to the Court’s general jurisdiction pursuant to Federal Rule of Civil Procedure 4(k).

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

FACTS COMMON TO ALL COUNTS

10. Taro holds approved New Drug Application No. 18-613 for malathion lotion, 0.5%, which it sells under the registered trademark OVIDE®.

11. Taro also is the owner of United States Patent No. 7,560,445 (the “’445 patent,” Exhibit A), entitled “Process for Preparing Malathion for Pharmaceutical Use.” The ’445 patent discloses and claims, *inter alia*, pharmaceutical grade malathion, a process for preparing highly purified malathion, pharmaceutical compositions containing malathion, and a method for treating an ectoparasite in a mammal. It was duly and legally issued on July 14, 2009, and remains in force.

12. Taro has caused the ’445 patent to be listed in the FDA’s *Approved Products with Therapeutic Equivalence Evaluations* (the “Orange Book”) for OVIDE® malathion lotion, 0.5%.

13. On or around March 16, 2011, Suven informed Taro by letter that it had submitted to the United States Food and Drug Administration an abbreviated new drug application (ANDA 091559) under the provisions of 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, or sale of malathion lotion, 0.5%.

14. Suven’s ANDA 091559 includes a Paragraph IV Certification pursuant to 21 U.S.C. § 355 (j)(2)(A)(vii)(IV), asserting that “no valid and enforceable claim of the ’445 patent will be infringed by the manufacture, use, or sale” of Suven’s proposed generic malathion lotion, 0.5%.

15. On information and belief, if ANDA 091559 is approved, Suven’s generic version of malathion lotion, 0.5%, will be commercially manufactured, used, marketed, sold, or distributed throughout the United States, in violation of Taro’s rights under the ’445 patent.

FIRST COUNT

(PATENT INFRINGEMENT)

16. Taro incorporates its factual allegations by reference.

17. The ’445 patent is valid and enforceable, and Taro has complied with all applicable regulations and laws.

18. By filing ANDA 091559 under 21 U.S.C. § 355(j) for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of its proposed drug products before the expiration of the `445 patent, Suven has committed an act of patent infringement under 35 U.S.C. § 271(e)(2).

19. On information and belief, Suven's ANDA seeks approval to manufacture, use or sell pharmaceutical formulations containing malathion, containing the precise compound described and claimed in the `445 patent, using the same process described and claimed in the `445 patent, and for treating mammals as claimed in the `445 patent.

20. Suven's proposed malathion product will infringe one or more claims of the `445 patent.

PRAYER FOR RELIEF

WHEREFORE, Taro respectfully requests the following relief:

A. Judgment that Suven has infringed one or more valid claims of the `445 patent by filing the aforesaid ANDA 091559;

B. A permanent injunction restraining and enjoining Suven 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, of generic malathion products as claimed in the `445 patent;

C. An order that the effective date of any approval of the aforementioned ANDA relating to Suven's generic malathion product be a date which is not earlier than the expiration dates of the `445 patent and any further exclusivity to which Taro is or becomes entitled;

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

E. Reasonable attorneys fees based on the exceptional nature of this case;

F. The costs and disbursements of this action; and

G. Such other and further relief as the Court may deem just and proper.

WINSTON & STRAWN LLP
Attorneys for Plaintiffs,
Taro Pharmaceuticals North America, Inc., and
Taro Pharmaceuticals U.S.A., Inc.

By: s/ James S. Richter
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Dated: April 28, 2011

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DEMAND FOR JURY TRIAL

Pursuant to Federal Rules of Civil Procedure Rule 38(b), Plaintiffs hereby demand a trial by jury as to all issues so triable.

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Taro Pharmaceuticals North America, Inc., and
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