Eric I. Abraham
Christina L. Saveriano
HILL WALLACK, LLP
202 Carnegie Center
Princeton, NJ 08540
Phone: (609) 734-6358
Fax: (609) 452-1888
eia@hillwallack.com
cls@hillwallack.com

Attorneys for Defendants,
Suven Life Sciences USA, LLC

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

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

Plaintiff,

v.

SUVEN LIFE SCIENCES, LTD. and SUVEN LIFE SCIENCES USA, LLC,

Defendant.

Honorable Joel A. Pisano, U.S.D.J.
Civil Action No. 11 CV 2452 (JAP) (DEA)

ANSWER, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS TO PLAINTIFFS' AMENDED COMPLAINT AND JURY DEMAND

Defendant Suven Life Sciences USA, LLC, ("Suven USA") by and through its attorneys, answers Plaintiffs Taro Pharmaceuticals North America, Inc.'s and Taro Pharmaceuticals U.S.A., Inc.'s (collectively "Plaintiffs") Amended Complaint as follows:

All averments not expressly admitted are denied.

NATURE OF THE ACTION

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

ANSWER:

Suven USA admits that Plaintiffs' Amended Complaint purports to state 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.

ANSWER:

Admitted upon information and belief.

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."

ANSWER:

The allegations contained within the first sentence of paragraph 3 are admitted upon information and belief. The second sentence of paragraph 3 contains no allegation to which an answer is required.

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.

ANSWER:

Suven USA admits upon information and belief that 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. To the best of Suven USA's information and belief, Suven Life Sciences, Ltd. has not been served in this action.

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.

ANSWER:

Admitted.

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 Life Sciences, Ltd., will be collectively referred to herein as "Suven."

ANSWER:

Suven USA admits that Suven Life Sciences, Ltd. participated in the preparation and filing of ANDA No. 091559. All remaining allegations contained within the first statement of paragraph 6 are denied. The second sentence of paragraph 6 contains allegations to which no answer is required.

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).

ANSWER:

The allegations in paragraph 7 state legal conclusions to which no answer is required. To the extent that an answer is required, Suven USA states that it does not contest subject matter jurisdiction in this Court for purposes of this case.

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).

ANSWER:

The allegations in paragraph 8 state legal conclusions to which no answer is required. To the extent that an answer is required, Suven USA does not contest personal jurisdiction

for purposes of this case. Suven USA denies all other allegations in paragraph 8.

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

ANSWER:

The allegations in paragraph 9 state legal conclusions to which no answer is required. To the extent that an answer is required, Suven USA states that it does not contest venue in this Court for purposes of this case.

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®.

ANSWER:

Suven USA admits upon information and belief that Taro Pharmaceuticals North America is listed in the FDA's publication, *Approved Drug Products With Therapeutic Equivalence Evaluations* (commonly referred to as the "Orange Book") as the applicant holding New Drug Application ("NDA") No. 18-613 for malathion lotion 0.5%, brand name OVIDE®. Suven USA is without knowledge or information sufficient to form a belief about the truth of all other allegations in paragraph 10 and therefore denies them.

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.

ANSWER:

The allegations in paragraph 11 state legal conclusions to which no answer is

required. To the extent an answer is required, Suven USA admits that what purports to be a copy of U.S. Patent No. 7,560,445 ("the '445 patent") is attached to the Amended Complaint as Exhibit A. Suven USA further admits that on its face Exhibit A is purportedly entitled "Process for Preparing Malathion for Pharmaceutical Use," and lists July 14, 2009 as the issue date. Suven USA further admits that "Taro Pharmaceuticals North America, Inc." is listed on the face of Exhibit A as a purported "assignee." Suven USA denies that the '445 patent was "duly and legally issued" and that the '445 patent "remains in force." Suven USA is without knowledge or information sufficient to form a belief about the truth of all other allegations in paragraph 11 and therefore denies them.

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%.

ANSWER:

Suven USA admits upon information and belief that the '445 patent is listed in the Orange Book in connection with NDA. No. 18-613 for malathion lotion 0.5%, brand name OVIDE®. Suven USA denies all other allegations in paragraph 12.

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%.

ANSWER:

Suven USA admits that Suven Life Sciences, Ltd. transmitted a letter dated on March 16, 2011 to Plaintiffs pursuant to 21 U.S.C. § 355(j)(2)(B)(ii) regarding Suven Life Sciences, Ltd.'s ANDA No. 091559. Suven USA denies all other allegations in paragraph 13.

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%.

ANSWER:

Suven USA admits that Suven Life Sciences, Ltd's ANDA No. 091559 includes a 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 Life Sciences, Ltd.'s proposed generic malathion lotion, 0.5%. Suven USA denies all other allegations in Paragraph 14.

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. On or about April 28, 2011, Taro filed its complaint for patent infringement of the '445 patent by Suven.

ANSWER:

Suven USA admits that Taro filed its complaint for patent infringement of the '445 patent against Suven USA on or about April 28, 2011. Suven USA denies all other allegations in paragraph 15.

16. Taro also is the owner of United States Patent No. 7,977,324 (the "'324 patent," Exhibit B), entitled "Process for Preparing Malathion for Pharmaceutical Use." The '324 patent discloses and claims, *inter alia*, pharmaceutical formulations containing pharmaceutical grade malathion. It was duly and legally issued on July 12, 2011, and remains in force.

ANSWER:

The allegations in paragraph 16 state legal conclusions to which no answer is required. To the extent an answer is required, Suven USA admits that what purports to be a copy of U.S. Patent No. 7,977,324 ("the '324 patent") is attached to the Amended Complaint as Exhibit B. Suven USA further admits that on its face Exhibit B is purportedly entitled

"Process for Preparing Malathion for Pharmaceutical Use," and lists July 12, 2011 as the issue date. Suven USA further admits that "Taro Pharmaceuticals North America, Inc." is listed on the face of Exhibit B as a purported "assignee." Suven USA denies that the '324 patent was "duly and legally issued" and that the '324 patent "remains in force." Suven USA is without knowledge or information sufficient to form a belief about the truth of all other allegations in paragraph 16 and therefore denies them.

17. 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 '324 patent.

ANSWER:

Denied.

FIRST COUNT

(PATENT INFRINGEMENT OF THE '445 PATENT)

18. Taro incorporates its factual allegations by reference.

ANSWER:

Suven USA repeats and reasserts its answers to the allegations in paragraphs 1-17 as though fully set forth herein.

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

ANSWER:

Denied.

20. 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).

ANSWER:

Denied.

21. 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.

ANSWER:

Denied.

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

ANSWER:

Denied.

SECOND COUNT

(PATENT INFRINGEMENT OF THE '324 PATENT)

23. Taro incorporates its factual allegations by reference.

ANSWER:

Suven USA repeats and reasserts its answers to the allegations in paragraphs 1-22 as though fully set forth herein.

24. The '324 patent is valid and enforceable, and Taro has complied with all applicable regulations and laws.

ANSWER:

Denied.

25. 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 '324 patent, Suven has committed an act of patent infringement under 35 U.S.C. § 271(e)(2).

ANSWER:

Denied.

26. 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 '324 patent.

ANSWER:

Denied.

27. Suven's proposed malathion product will infringe one or more claims of the '324 patent.

ANSWER:

Denied.

PRAYER FOR RELIEF

Suven USA specifically denies that Plaintiffs are entitled to the general or specific relief requested against Suven USA, or to any relief whatsoever, and prays for judgment in favor of Suven USA dismissing this action with prejudice, and awarding Suven USA its reasonable attorneys' fees pursuant to 35 U.S.C. § 285, interest, and costs of this action, and such other or further relief as this Court may deem just and proper.

AFFIRMATIVE DEFENSES

Without prejudice to the denials set forth in its Answer and without admitting any allegations of the Amended Complaint not otherwise expressly admitted, Suven Life Sciences USA, LLC, ("Suven USA") avers and asserts the following Affirmative Defenses to Plaintiffs Taro Pharmaceuticals North America, Inc.'s and Taro Pharmaceuticals U.S.A., Inc.'s (collectively "Plaintiffs'") Amended Complaint.

FIRST AFFIRMATIVE DEFENSE
(Noninfringement of U.S. Patent No. 7,560,445)

The manufacture, use, sale, offer to sell or importation into the United States of Suven Life Science, Ltd.'s proposed malathion lotion, 0.5% that is the subject matter of ANDA No. 091559 would not and will not directly infringe, induce infringement, or contributorily infringe

any valid claim of U.S. Patent No. 7,560,445 ("the '445 patent") either literally or under the doctrine of equivalents.

SECOND AFFIRMATIVE DEFENSE
(Invalidity of U.S. Patent No. 7,560,445)

Upon information and belief, one or more of the claims of the '445 patent are invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, Sections 101, 102, 103 and/or 112.

THIRD AFFIRMATIVE DEFENSE
(Noninfringement of U.S. Patent No. 7,977,324)

The manufacture, use, sale, offer to sell or importation into the United States of Suven Life Science, Ltd.'s proposed malathion lotion, 0.5% that is the subject matter of ANDA No. 091559 would not and will not directly infringe, induce infringement, or contributorily infringe any valid claim of U.S. Patent No. 7,977,324 ("the '324 patent") either literally or under the doctrine of equivalents.

FOURTH AFFIRMATIVE DEFENSE
(Invalidity of U.S. Patent No. 7,977,324)

Upon information and belief, one or more of the claims of the '324 patent are invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, Sections 101, 102, 103 and/or 112.

FIFTH AFFIRMATIVE DEFENSE
(Uneforceability of U.S. Patent No. 7,560,445)

Upon information and belief, the claims of the '445 patent are unenforceable based on the patent applicants' and prosecuting attorneys' inequitable conduct and/or unclean hands in prosecuting the patent for the reasons set forth below in paragraphs numbers 8-71 and 82-97 of Suven USA's Counterclaims, which are incorporated by reference herein in their entirety.

SIXTH AFFIRMATIVE DEFENSE
(Uneforceability of U.S. Patent No. 7,977,324)

Upon information and belief, the claims of the '324 patent are unenforceable based on the patent applicants' and prosecuting attorneys' inequitable conduct and/or unclean hands in prosecuting the patent for the reasons set forth below in paragraphs numbers 8-71 and 82-97 of Suven USA's Counterclaims, which are incorporated by reference herein in their entirety.

COUNTERCLAIMS

Counterclaimant Suven Life Sciences USA, LLC, by and through its undersigned attorneys, for its Counterclaims against Counterclaim Defendants Taro Pharmaceuticals North America, Inc. and Taro Pharmaceuticals U.S.A., Inc. (collectively "Counterclaim Defendants") alleges as follows:

PARTIES

1. Counterclaimant Suven Life Sciences USA, LLC ("Suven USA") is a corporation 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.

2. Counterclaim Defendant Taro Pharmaceuticals North America, Inc. ("Taro NA"), 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. Counterclaim Defendant 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.

JURISDICTION AND VENUE

4. As a consequence of Counterclaim Defendants' Amended Complaint against

Suven USA, there is now an existing, continuing actual controversy between Counterclaim Defendants and Suven USA regarding the alleged infringement, validity, and enforceability of U.S. Patent Nos. 7,560,445 ("the '445 patent") and 7,977,324 ("the '324 patent").

5. This Court has jurisdiction over the subject matter of these Counterclaims pursuant to §§ 1331 and 1338 (a) of Title 28 of the U.S. Code because they involve substantial claims arising out of the United States Patent Act, 35 U.S.C. § 1, et. seq.

6. This Court may declare the rights and legal relation of the parties pursuant to §§ 2201 and 2202 of Title 28 of the U.S. Code and § 271(e)(5) of Title 35 of the U.S. Code because the Counterclaims present an actual controversy within the Court's jurisdiction that the patents asserted by Counterclaim Defendants against Suven USA are not infringed and/or are invalid and/or are unenforceable.

7. Venue for these counterclaims is proper within this District in which Counterclaim Defendants' Amended Complaint is pending.

GENERAL ALLEGATIONS

8. Malathion is an organophosphate composition first used as a pesticide in the 1950's.

9. The Food and Drug Administration ("FDA") first approved malathion for use in topical pharmaceutical compositions on August 2, 1982 in response to New Drug Application ("NDA") No. 18-613, now held by Taro NA.

10. The product described in NDA No. 18-613 is malathion lotion, 0.5%, which has been marketed by various manufacturers, including Taro NA and Medicis Pharmaceutical

Corporation ("Medicis"), under the brand name OVIDE® since 1982.

11. Taro NA acquired the right to market OVIDE® under NDA No. 18-613 from Medicis in 2003.

12. Cheminova A/S ("Cheminova") supplies the malathion active pharmaceutical ingredient ("API") contained in OVIDE® products sold under NDA No. 18-613, including the products sold by both Medicis and Taro NA.

13. Highly pure malathion is desirable because malathion's impurities, in particular isomalathion, are highly toxic.

14. Malathion contained in pesticide compositions is typically technical grade with a purity of approximately 96%, while malathion contained in topical pharmaceutical compositions, such as OVIDE®, is pharmaceutical grade with a much higher purity.

15. Malathion made by Cheminova and used by Medicis to produce OVIDE® beginning in the late 1990's was of an extremely high purity, as reflected in certificates of analysis, stability test results, and product specifications contained in the prosecution history for the '445 patent.

16. The certificates of analysis, stability test results, and product specifications contained in the prosecution history for '445 patent (and submitted in the '324 patent prosecution history) show that malathion contained within OVIDE® batches sold between 1998 and 2004 had purity levels at least as high as 99.8% (w/w) and an impurity profile showing extremely low levels of known impurities, in particular levels of isomalathion as low as 0.1% and 0.01% (w/w).

17. On June 30, 2006, U.S. Patent Application No. 11/427,863 ("the '863 application") was filed by Michael A. Davitz ("Davitz") of Taro Pharmaceuticals U.S.A., Inc. on behalf of listed inventors Daniella Gutman ("Gutman") and Wael Baidussi (Baidussi"). The '863 application later issued as the '445 patent. The '863 application claims priority to U.S. Provisional Patent Applications Nos. 60/743,741, 60/741,360, and 60/697,010, which also list Gutman and Baidussi as inventors.

18. On January 15, 2008, Gutman and Baidussi filed a declaration appointing Venable LLP as prosecuting attorneys for the '863 application and declaring as follows:

> As a below named inventor, I hereby declare…that I believe I am…an original, first and joint inventor…of the subject matter which is claimed and for which a patent is sought on the invention [described in the '863 application]…
>
> * * *
>
> I hereby state that I have reviewed and understand the contents of the ['863 application], including the claims, as amended by any amendment…
>
> I acknowledge the duty to disclose to the Patent and Trademark Office all information known to me to be material to patentability as defined in Title 37, Code of Federal Regulations, 1.56.
>
> * * *
>
> I declare that all statements made herein of own knowledge are true and that all statements made on information and belief are believed to be true; and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under [section] 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

19. Gutman, Baidussi, Davitz, and the prosecuting attorneys at Venable, including Keith G. Haddaway ("Haddaway"), had a duty of candor when dealing with the Patent Office

pursuant to 37 C.F.R. § 1.56(b).

20. The '863 application states on page 3 that:

> The malathion prepared by the methods of this invention has significantly lower levels of toxic impurities such as isomalathion when compared with other, commercially available malathion preparations that are currently used for pharmaceutical purposes.

21. The '863 application states on page 19 that:

> When compared with malathion from Cheminova, malathion prepared by the methods of the present invention has less isomalathion, <0.02% (w/w) versus 0.2% (w/w) isomalathion from Cheminova.

22. The statements described in paragraphs 20 and 21 of these Counterclaims, were made by Gutman, Baidussi, Davitz, and/or their attorneys at Venable LLP to support the patentability of the methods and compositions claimed in the '863 application.

23. On March 26, 2009, Haddaway filed an Amendment to the '863 application. On page 12 of that Amendment, Haddaway states that "[s]ubmitted herewith is an [Information Disclosure Statement] citing additional material identified during review of Applicants' files." The Information Disclosure Statement ("IDS") submitted with the March 26, 2009 Amendment contained certificates of analysis for batches of malathion produced by Cheminova during the year 1999 ("1999 Cheminova Certificates of Analysis") and product specifications for OVIDE® dated almost two years before the '863 application's filing.

24. Haddaway possessed the 1999 Cheminova Certificates of Analysis and OVIDE® product specifications during the prosecution of the '445 patent.

25. The 1999 Cheminova Certificates of Analysis disclose batches of pharmaceutical grade malathion produced by Cheminova and sold in the United States to Medicis containing

malathion that was 99.8% pure with low levels of toxic impurities, including isomalathion levels as low as 0.01% (w/w).

26. Based on the OVIDE® product specifications, OVIDE® released for sale in the United States contained less that 0.1% (w/w) isomalathion.

27. The 1999 Cheminova Certificates of Analysis and OVIDE® product specifications show that the statements described in paragraphs 20 and 21 of these Counterclaims were false.

28. The statements described in paragraphs 20 and 21 of these Counterclaims were misrepresentations material to the patentability of one of more claims contained in the '863 application.

29. The '863 application also includes Table III on page 18 presented below:

Table III: HPLC Analysis of Malathion Prepared by the Process of the Invention after Drying and Comparison with Malathion from the USP and Cheminova***

Batch	Malathion	MeOOSPO	MeOSSPO	Malaxon	MeOOSPS	Diethyl Fumarate	Dimethyl Malathion	Methyl Malathion	O,O methyl, ethyl S-(1,2-dicarboethoxy)ethyl phosphorodithioate	Tetraethyl dithiodisuccinate	Isomalathion	Malathion Carboxylic Acids	Mercapto Succinate	Tetraethyl thiodisuccinate
A	99.3	<0.04	<0.02	<0.05	0.1	<0.01	<0.02	0.07	0.1	0.05	<0.02	<0.03	0.01	ND*
B	99.2	<0.04	<0.02	<0.05	0.1	<0.01	<0.02	0.07	0.1	0.06	<0.02	<0.03	0.01	ND
C	99.2	<0.04	<0.02	<0.05	0.2	<0.01	<0.02	0.06	0.1	0.05	<0.02	<0.03	0.01	ND
USP		<0.04	0.04	<0.05	0.09	0.05	<0.02	0.17	0.14	<0.03	0.27	0.77	0.04	ND
I***		0.05	<0.02	<0.05	0.05	0.02	<0.02	0.2	-	-	0.2	-	-	-
II***		0.05	<0.02	0.07	0.06	<0.02	<0.02	0.1	-	-	0.2	-	-	-
III***		0.06	<0.02	<0.05	0.04	0.02	<0.02	0.2	-	-	0.2	-	-	-

* ND – not detected
** all numbers are presented as (w/w)%
*** I – III commercial sample of pharmaceutical grade malathion obtained from Cheminova. Samples were stored for at least 1 year under proper storage conditions prior to analysis

30. The '863 application describes Table III on pages 17 and 18 as follows:

> In Table III...three different batches of malathion prepared by the process of the invention (these batches are noted in the table as A, B and C) were analyzed after drying by HPLC for malathion purity and for the presence of impurities…As a comparison, the following samples of malathion were analyzed, malathion approved for pharmaceutical use from the United States Pharmacopeia ("USP") and malathion used for pharmaceutical preparations obtained from Cheminova (referred to herein as, Cheminova A/S, Thyborønvej 78 DK-7673 Harboøre, Denmark). The purity of these samples, USP and Cheminova, was compared with the purity of the malathion prepared by the process of the invention.

31. Table III represents that the three Cheminova samples analyzed by the patent applicants were found to contain 0.2% (w/w) isomalathion. These results are footnoted with three asterisks (***) indicating that the "[s]amples were stored for at least 1 year under proper storage conditions."

32. Table III of the '863 application was presented by Gutman, Baidussi, Davitz, and/or the attorneys at Venable LLP to support the patentability of the methods and compositions claimed in the '863 application.

33. The 1999 Cheminova Certificates of Analysis disclose batches of pharmaceutical grade malathion produced by Cheminova and sold in the United States to Medicis containing malathion that was 99.8% pure with low levels of toxic impurities, including isomalathion levels as low as 0.01% (w/w).

34. Based on the OVIDE® product specifications, OVIDE® released for sale in the United States contained less that 0.1% (w/w) isomalathion.

35. The 1999 Cheminova Certificates of Analysis and OVIDE® product specifications show that Table III's description of isomalathion levels in the Cheminova samples is false.

36. The '863 application states on page 3 that "because malathion is known to be unstable, the level of toxic impurities, e.g., isomalathion, are known to increase over time…"

37. The 1999 Cheminova Certificates of Analysis and OVIDE® product specifications in combination with the statement described in paragraph 36 of these Counterclaims show that Table III makes a misleading comparison between the level of toxic impurities, in particular isomalathion, contained in compositions made pursuant to the methods described in '863 application and the level of toxic impurities, in particular isomalathion, contained in the Cheminova malathion samples.

38. Table III contained misrepresentations material to patentability of one or more claims contained in the '863 application.

39. The 1999 Cheminova Certificates of Analysis and OVIDE® product specifications are also material to patentability. Several of the claims of the '445 patent, including independent claims 1 and 12, contain limitations that require the claimed malathion to be 98.5% pure and to have "less than about 0.1% isomalathion," and the certificates of analysis and/or product specifications directly anticipate at least claims 12, 13, 15, 17-24, 31, 35 and 39.

40. Upon reviewing the '863 application and claims, Gutman and/or Baidussi had a duty under 37 C.F.R. § 1.56 to inform the Patent Office that the 1999 Cheminova Certificates of Analysis and OVIDE® product specifications in Gutman and/or Baidussi's files showed that Cheminova's malathion was highly pure and contained lower isomalathion levels than represented in the '863 patent application and claims.

41. Upon submitting the 1999 Cheminova Certificates of Analysis and OVIDE®

product specifications, Haddaway had a duty under 37 C.F.R. § 1.56 to inform the Patent Office that the Certificates of Analysis and product specifications showed that Cheminova's malathion was highly pure and contained lower isomalathion levels than represented in the '863 patent application and claims.

42. Upon reviewing the '863 application, Gutman and/or Baidussi had a duty under 37 C.F.R. § 1.56 to inform the Patent Office that the 1999 Cheminova Certificates of Analysis and OVIDE® product specifications in Gutman and/or Baidussi's files showed that the data within Table III was misleading and needed to be corrected.

43. Upon submitting the 1999 Cheminova Certificates of Analysis and OVIDE® product specifications, Haddaway had a further duty under 37 C.F.R. § 1.56 to inform the Patent Office that the Certificates of Analysis and product specifications showed that the data within Table III was misleading and needed to be corrected.

44. Gutman, Baidussi, and Haddaway, also had a duty under 37 C.F.R. § 1.56 to provide the Patent Office with a corrected version of Table III to allow the patent examiner the opportunity to assess the accuracy of statements made in the application supporting patentability of one or more claims of the '863 application, in light of the full data.

45. Gutman, Baidussi, and Haddaway, also had a duty under 37 C.F.R. § 1.56 to withdraw or amend any claim pending in the '863 application that was anticipated by the 1999 Cheminova Certificates of Analysis and OVIDE® product specifications, including claims 12, 13, 15, 17-24, 31, 35 and 39 and inform the Patent Office of the reason for the withdrawal or amendment.

46. Gutman, Baidussi, Haddaway, and other prosecuting attorneys at Venable LLP breached their duties under 37 C.F.R. § 1.56 by failing to inform the Patent Office about the falsity of statements made within the '863 application to support patentability.

47. Gutman, Baidussi, Haddaway, and other prosecuting attorneys at Venable LLP breached their duties under 37 C.F.R. § 1.56 by failing to take corrective action regarding material contained within the '863 application that was false and/or misleading.

48. Gutman, Baidussi, Haddaway, and other prosecuting attorneys at Venable LLP breached their duties under 37 C.F.R. § 1.56 by failing to amend or withdraw claims that were anticipated the 1999 Cheminova Certificates of Analysis and OVIDE® product specifications.

49. Upon information and belief, Gutman, Baidussi, Haddaway, and other prosecuting attorneys at Venable LLP made highly material misrepresentations regarding the patentability of the subject matter contained in the '863 application and claims, knowing the falsity of their misrepresentations, with an intent to deceive the Patent Office.

50. Upon information and belief, Gutman, Baidussi, Haddaway, and other prosecuting attorneys at Venable LLP breached their duties under 37 C.F.R. § 1.56 with respect to the patentability of one or more claims of the '445 patent, while fully aware of their breach of duty, with an intent to deceive the Patent Office.

51. Upon information and belief, Haddaway intentionally concealed the nature of the 1999 Cheminova Certificates of Analysis and OVIDE® product specifications by mischaracterizing their significance in the March 26, 2009 Amendment.

52. On page 12 of the March 26, 2009 Amendment to the '863 application,

Haddaway states:

> As discussed with the Examiner, the present invention is directed to malathion for use in a pharmaceutical composition for topical application. The previously cited reference applies to a method of making technical grade malathion such as used for agriculture. While technical grade malathion contains a number of impurities, malathion for use in a pharmaceutical composition, for example the formerly available material from Cheminova (See Example 6 of the specification) previously used in Ovide™ malathion lotion (See paragraph [0057]), must have higher purity. *Submitted herewith is an IDS citing additional material identified during review of Applicants' files. This material is submitted for completeness, although it is believed to be cumulative of references already of record.*
> The present application is directed to a new pharmaceutical grade composition.
>
> Per the telephone conversation with the Examiner, the present claims distinguish the invention from the prior art of record. (emphasis added)

53. In the statements described in paragraph 52 of the Counterclaims, Haddaway described the 1999 Cheminova Certificates of Analysis and OVIDE® product specifications that he submitted as "cumulative of references already of record" in the prosecution.

54. Haddaway statements described in paragraph 52 of the Counterclaims, were made to support the patentability of one or more claims contained in the '863 application.

55. The 1999 Cheminova Certificates of Analysis and OVIDE® product specifications show that one or more claims of the '863 application pending on March 26, 2009 were invalid for anticipation.

56. The 1999 Cheminova Certificates of Analysis and OVIDE® product specifications show other statements made in the '863 application to support patentability to be false.

57. The 1999 Cheminova Certificates of Analysis and OVIDE® product specifications

also show the that the content and comparisons made in Table III of the '863 application were false and misleading.

58. Haddaway's characterization of the 1999 Cheminova Certificates of Analysis and OVIDE® product specifications as "cumulative of references already of record" was false and misleading.

59. Haddaway's characterization of the 1999 Cheminova Certificates of Analysis and OVIDE® product specifications as "cumulative of references already of record" was a misrepresentation material to patentability of one or more claims contained in the '863 application.

60. Haddaway breached his duty under 37 C.F.R. § 1.56 by characterizing the1999 Cheminova Certificates of Analysis and OVIDE® product specifications as "cumulative of references already of record."

61. Upon information and belief, Haddaway intentionally concealed and mischaracterized the information contained within the 1999 Cheminova Certificates of Analysis and OVIDE® product specifications, knowing the falsity of his misrepresentations, with an intent to deceive the patent examiner.

62. On January 14, 2009, U.S. Patent Application No. 12/353,691 ("the '691 application") was filed as a continuation of the '863 application also listing Gutman and Baidussi as inventor. The '691 application later issued as the '324 patent.

63. The '691 application was transmitted by Haddaway and contains the same declaration of Gutman and Baidussi as the '863 application.

64. On November 11, 2009, Haddaway submitted a Preliminary Amendment to the '691 application seeking claims to pharmaceutical formulations of pharmaceutical grade malathion "comprising pharmaceutical grade malathion containing…0.1% or less (w/w) isomalathion."

65. Haddaway possessed the 1999 Cheminova Certificates of Analysis and OVIDE® product specifications when he submitted the November 11, 2009 Preliminary Amendment to the Patent Office.

66. The 1999 Cheminova Certificates of Analysis and OVIDE® product specifications would have directly anticipated one or more of the claims submitted in the November 11, 2009 Preliminary Amendment.

67. At least one of the claims submitted in the November 11, 2009 Preliminary Amendment that was directly anticipated by the 1999 Cheminova Certificates of Analysis and OVIDE® product specifications, claim 22, issued as a claim in the '324 patent, claim 1.

68. Haddaway had a duty under 37 C.F.R. § 1.56 to withdraw or amend any claim pending in the '691 application that was anticipated by the 1999 Cheminova Certificates of Analysis and OVIDE® product specifications, including claim 22, and inform the Patent Office of the reason for the withdrawal or amendment.

69. Haddaway breached his duty under 37 C.F.R. § 1.56 by failing to withdraw or amend any claim pending in the '691 application that was anticipated by the 1999 Cheminova Certificates of Analysis and OVIDE® product specifications .

70. Haddaway's breach of his duty under 37 C.F.R. § 1.56 was material to the

patentability of one or more claims of the '324 patent.

71. Upon information and belief, Haddaway breached his duty under 37 C.F.R. § 1.56 with respect to the patentability of one or more claims of the '324 patent, while fully aware of his breach, with an intent to deceive the Patent Office.

COUNT I

(Declaratory Judgment Of Noninfringement Of The '445 Patent)

72. Suven USA repeats and reasserts its allegations in paragraphs 1-71 as though fully set forth herein.

73. The manufacture, use, sale, offer to sell or importation into the United States of Suven Life Science, Ltd.'s proposed malathion lotion, 0.5% that is the subject matter of ANDA No. 091559 would not and will not directly infringe, induce infringement, or contributorily infringe any valid claim of U.S. Patent No. 7,560,445 ("the '445 patent") either literally or under the doctrine of equivalents.

COUNT II

(Declaratory Judgment Of Invalidity Of The '445 Patent)

74. Suven USA repeats and reasserts its allegations in paragraphs 1-73 as though fully set forth herein.

75. By asserting their claim against Suven USA for infringement of the '445 patent, Counterclaim Defendants have created a case or controversy regarding the validity of the '445 patent for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, Sections 101, 102, 103 and/or 112.

76. Upon information and belief, one or more of the claims of the '445 patent are

invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, Sections 101, 102, 103 and/or 112.

COUNT III

(Declaratory Judgment Of Noninfringement Of The '324 Patent)

77. Suven USA repeats and reasserts its allegations in paragraphs 1-76 as though fully set forth herein.

78. The manufacture, use, sale, offer to sell or importation into the United States of Suven Life Science, Ltd.'s proposed malathion lotion, 0.5% that is the subject matter of ANDA No. 091559 would not and will not directly infringe, induce infringement, or contributorily infringe any valid claim of U.S. Patent No. 7,977,324 ("the '324 patent") either literally or under the doctrine of equivalents.

COUNT IV

(Declaratory Judgment Of Invalidity Of The '324 Patent)

79. Suven USA repeats and reasserts its allegations in paragraphs 1-78 as though fully set forth herein.

80. By asserting their claim against Suven USA for infringement of the '324 patent, Counterclaim Defendants have created a case or controversy regarding the validity of the '324 patent for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, Sections 101, 102, 103 and/or 112.

81. Upon information and belief, one or more of the claims of the '324 patent are invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, Sections 101, 102, 103 and/or 112.

COUNT V

(Unenforceability Of The '445 Patent)

82. Suven USA repeats and reasserts its allegations in paragraphs 1-81 as though fully set forth herein.

83. Upon information and belief, Gutman, Baidussi, Haddaway, and/or other Venable prosecuting attorneys intentionally submitted false and misleading statements and evidence in support of the '863 application's patentability.

84. The false and misleading statements and evidence submitted by Gutman, Baidussi, Haddaway, and/or other Venable prosecuting attorneys were misrepresentations material to the patentability of one or more claims of the '445 patent.

85. Upon information and belief, Gutman, Baidussi, Haddaway, and/or other Venable prosecuting attorneys submitted these material misrepresentations with an intent to deceive the Patent Office.

86. But for Gutman's, Baidussi's, Haddaway's, and/or other Venable prosecuting attorneys' material misrepresentations one or more claims of the '445 patent would not have issued.

87. The material misrepresentations submitted by Gutman, Baidussi, Haddaway, and/or other Venable prosecuting attorneys amounted to affirmative egregious misconduct in dealing with the Patent Office.

88. By submitting material misrepresentations in the form of false and misleading statements and evidence with an intent to deceive the Patent Office, Gutman, Baidussi,

Haddaway, and/or other Venable prosecuting attorneys committed inequitable conduct in the form of affirmative egregious misconduct that renders the '445 patent unenforceable.

89. By committing affirmative egregious misconduct during prosecution of the '445 patent, Gutman, Baidussi, Haddaway, and/or other Venable prosecuting attorneys came to the prosecution with unclean hands rendering the '445 patent unenforceable.

COUNT VI

(Unenforceability Of The '324 Patent)

90. Suven USA repeats and reasserts its allegations in paragraphs 1-89 as though fully set forth herein.

91. As the '324 patent issued from a continuation of the '861 application any inequitable conduct and/or unclean hands committed during the '861 application's prosecution also renders the '324 patent unenforceable.

92. Upon information and belief, Haddaway submitted one or more claims within a Preliminary Amendment known to be invalid with knowledge of their invalidity.

93. Haddaway's failure to withdraw one or more claims within a Preliminary Amendment that were invalid breached his duty of candor to the Patent Office.

94. Upon information and belief, Haddaway breached his duty of candor with an intent to deceive the Patent Office.

95. But for Haddaway's breach of his duty of candor to the Patent Office, one or more claims of the '324 patent would not have issued.

96. By submitting claims known to be invalid with an intent to deceive the Patent

Office about their patentability, Haddaway committed inequitable conduct in the form of affirmative egregious misconduct that renders the '324 patent unenforceable.

97. By committing affirmative egregious misconduct during prosecution of the '324 patent, Haddaway came to the prosecution with unclean hands rendering the '324 patent unenforceable.

PRAYER FOR RELIEF

WHEREFORE, Counterclaimant Suven Life Sciences USA, LLC, respectfully request the Court to enter judgment against Counterclaim Defendants Taro Pharmaceuticals North America, Inc. and Taro Pharmaceuticals U.S.A., Inc. as follows:

A. Declaring that Suven Life Science, Ltd.'s proposed malathion lotion, 0.5% that is the subject matter of ANDA No. 091559 would not and will not directly infringe, induce infringement, or contributorily infringe any valid claim of U.S. Patent No. 7,560,445 either literally or under the doctrine of equivalents;

B. Declaring that U.S. Patent No. 7,560,445 is invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to Sections 101, 102, 103 and/or 112;

C. Declaring that Suven Life Science, Ltd.'s proposed malathion lotion, 0.5% that is the subject matter of ANDA No. 091559 would not and will not directly infringe, induce infringement, or contributorily infringe any valid claim of U.S. Patent No. 7,977,324 either literally or under the doctrine of equivalents;

D. Declaring that U.S. Patent No. 7,977,324 is invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to Sections 101, 102, 103 and/or 112;

E. Declaring that all claims of U.S. Patent No. 7,560,445 are unenforceable as a result of inequitable conduct and/or unclean hands committed during the patent's prosecution;

F. Declaring that all claims of U.S. Patent No. 7,977,324 are unenforceable as a result of inequitable conduct and/or unclean hands committed during the patent's prosecution;

G. Awarding Suven Life Sciences USA, LLC its reasonable costs and attorneys' fees incurred in connection with this action pursuant to 35 U.S.C. § 285; and

H. Awarding all such other and further relief as this Court may deem just and proper.

PLAINTIFF'S JURY DEMAND

As pled, Plaintiffs' Amended Complaint does not present any issue triable by jury, and thus the Jury Demand should be stricken.

Dated: September 28, 2011

Respectfully Submitted

/s/Eric I. Abraham

Eric I. Abraham
Christina L. Saveriano
HILL WALLACK, LLP
202 Carnegie Center
Princeton, NJ 08540
Phone: (609) 734-6358
Fax: (609) 452-1888
eia@hillwallack.com
cls@hillwallack.com

Of Counsel:
Michael J. Gaertner
Keith D. Parr, P.C.
David B. Abramowitz
LOCKE LORD LLP
111 South Wacker Drive
Chicago, IL 60606

Tel: (312) 443-0700
Fax: (312) 443-0336
mgaertner@lockelord.com
kparr@lockelord.com
dabramowitz@lockelord.com

LOCAL CIVIL RULE 11.2 CERTIFICATION

I hereby certify pursuant to Local Civil Rule 11.2, that to the best of my knowledge, information and belief the patents at issue in this action are not at issue in any other actions.

_/s/Eric I. Abraham_____

Eric. I. Abraham

Dated: September 28, 2011

CERTIFICATE OF SERVICE

I hereby certify that on September 28, 2011, copies of the foregoing **ANSWER, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS TO PLAINTIFFS' AMENDED COMPLAINT AND JURY DEMAND** were served by ECF upon the following counsel:

James S. Richter
jrichter@winston.com
Jeffrey P. Catenacci
jcatenacci@winston.com
WINSTON & STRAWN LLP
The Legal Center
One Riverfront Plaza, Suite 730
Newark, New Jersey 07102

I certify that the foregoing statements made by me are true. I am aware that if any of the foregoing statements are willfully false, I am subject to punishment.

_/s/Eric I. Abraham__