IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NOVARTIS PHARMACEUTICALS CORPORATION, NOVARTIS AG, NOVARTIS PHARMA AG, NOVARTIS INTERNATIONAL PHARMACEUTICAL LTD. and LTS LOHMANN THERAPIE-SYSTEME AG	:	
Plaintiffs,	:	C.A. No. _____
v.	:	
ALVOGEN PINE BROOK, INC. and ALVOGEN GROUP, INC.	:	
Defendants.	:	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Novartis Pharmaceuticals Corporation, Novartis AG, Novartis Pharma AG, Novartis International Pharmaceutical Ltd. and LTS Lohmann Therapie-Systeme AG (hereinafter "Plaintiffs"), for their Complaint against defendants Alvogen Pine Brook, Inc. and Alvogen Group, Inc. allege as follows:

NATURE OF ACTION

1. This is an action for patent infringement.

PARTIES

2. Plaintiff Novartis Pharmaceuticals Corporation ("NPC") is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 59 Route 10, East Hanover, New Jersey 07936.

3. Plaintiff Novartis AG ("Novartis AG") is a corporation organized and existing under the laws of Switzerland, having an office and place of business at Lichtstrasse 35, CH-4056 Basel, Switzerland.

4. Plaintiff Novartis Pharma AG ("Pharma AG") is a corporation organized and existing under the laws of Switzerland, having an office and place of business at Lichtstrasse 35, CH-4056 Basel, Switzerland.

5. Plaintiff Novartis International Pharmaceutical Ltd. ("NIP") is a corporation organized and existing under the laws of Bermuda, having an office and place of business at 131 Front Street, Hamilton HM12, Bermuda.

6. Plaintiff LTS Lohmann Therapie-Systeme AG ("LTS") is a corporation organized and existing under the laws of Germany, having an office and place of business at Lohmannstraße 2, D-56626 Andernach, Germany.

7. On information and belief, defendant Alvogen Pine Brook, Inc. is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 10 Bloomfield Avenue, Building B, Pine Brook, New Jersey 07058.

8. On information and belief, defendant Alvogen Group, Inc. is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 10 Bloomfield Avenue, Building B, Pine Brook, New Jersey 07058.

9. On information and belief, Alvogen Pine Brook, Inc. is a subsidiary of Alvogen Group, Inc.

10. On information and belief, the acts of Alvogen Pine Brook, Inc. complained of herein were done at the direction of, with the authorization of, and with the cooperation, participation, and assistance of Alvogen Group, Inc.

11. Defendants Alvogen Pine Brook, Inc. and Alvogen Group, Inc. are referred to collectively as "Alvogen."

JURISDICTION AND VENUE

12. This action arises under the patent laws of the United States of America. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202.

13. On information and belief, Alvogen Group, Inc. is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. On information and belief, Alvogen Group, Inc. directly or through its affiliates and agents, including Alvogen Pine Brook, Inc., manufactures, markets and sells drug products throughout the United States and in this judicial district, is incorporated in Delaware, and has purposely availed itself of the rights and benefits of Delaware law and this Court.

14. On information and belief, Alvogen Pine Brook, Inc. directly or indirectly manufactures, markets and sells drug products throughout the United States and in this judicial district, is incorporated in Delaware, and has purposely availed itself of the rights and benefits of Delaware law and this Court.

15. This Court has personal jurisdiction over Alvogen by virtue of, *inter alia*, the above-mentioned facts.

16. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391(b) and (c) and 28 U.S.C. § 1400(b).

CLAIM FOR RELIEF – PATENT INFRINGEMENT

17. Plaintiff NPC holds an approved new drug application ("NDA") No. 22-083 for Exelon® Patch (rivastigmine transdermal system or extended release film) (4.6 mg/24 hr,

9.5 mg/24 hr and 13.3 mg/24 hr dosage strengths), which patch contains the active ingredient rivastigmine. Exelon® Patch (4.6 mg/24 hr and 9.5 mg/24 hr dosage strengths) was approved by the United States Food and Drug Administration ("FDA") on July 6, 2007, and Exelon® Patch (13.3 mg/24 hr dosage strength) was approved by the FDA on August 31, 2012. Exelon® Patch is indicated for the treatment of mild to moderate dementia of the Alzheimer's type and mild to moderate dementia associated with Parkinson's disease. Exelon® Patch (4.6 mg/24 hr, 9.5 mg/24 hr and 13.3 mg/24 hr dosage strengths) is sold in the United States by Plaintiff NPC.

18. Rivastigmine is known chemically as (S)-N-ethyl-3-[(1-dimethylamino)ethyl]-N-methylphenyl-carbamate.

19. Plaintiffs Novartis AG and LTS are the owners of United States Letters Patent No. 6,316,023 ("the '023 patent"). The '023 patent was duly and legally issued on November 13, 2001.

20. The '023 patent claims pharmaceutical compositions, *inter alia*, comprising 1 to 40 weight percent of (S)-N-ethyl-3-[(1-dimethylamino)ethyl]-N-methylphenyl-carbamate in the form of a free base or acid addition salt, 0.01 to 0.5 weight percent of an antioxidant, and a diluent or carrier, wherein the weight percents are based on the total weight of the pharmaceutical composition, as well as transdermal devices. A true copy of the '023 patent is attached hereto as Exhibit A.

21. Plaintiffs Novartis AG and LTS are the owners of United States Letters Patent No. 6,335,031 ("the '031 patent"). The '031 patent was duly and legally issued on January 1, 2002.

22. The '031 patent claims pharmaceutical compositions, *inter alia*, comprising: (a) a therapeutically effective amount of (S)-N-ethyl-3-[(1-dimethylamino)ethyl]-N-

methylphenyl-carbamate in free base or acid addition salt form; (b) about 0.01 to about 0.5 percent by weight of an antioxidant, based on the weight of the composition, and (c) a diluent or carrier, as well as transdermal devices and methods of stabilizing (S)-N-ethyl-3-[(1-dimethylamino)ethyl]-N-methylphenyl-carbamate in free base or acid addition salt form. A true copy of the '031 patent is attached hereto as Exhibit B.

23. The '023 and '031 patents were initially assigned to Novartis AG and LTS Lohmann Therapie-Systeme GmbH & Co. KG, which subsequently changed its legal form to become Plaintiff LTS.

24. On information and belief, Alvogen submitted to the FDA an abbreviated new drug application ("ANDA") under the provisions of 21 U.S.C. § 355(j) seeking approval to engage in the commercial manufacture, use, and sale of a rivastigmine transdermal system, 13.3 mg/24 hr dosage strength ("Alvogen's ANDA Product") before the expiration of the '023 and '031 patents.

25. On information and belief, Alvogen's ANDA Product consists of the same active ingredient and inactive ingredients, the same backing layer material, and the same release liner material as the rivastigmine transdermal system, 4.6 mg/24 hr and 9.5 mg/24 hr dosage strengths, for which Alvogen also seeks FDA approval and that are the subject of District of Delaware Civil Action No. 13-52-RGA (collectively "the 13-52 dosage strengths"). On information and belief, the active ingredient and inactive ingredients in Alvogen's ANDA Product are present in the same weight percentages (relative to the total combined weight of the active ingredient and inactive ingredients) as in the 13-52 dosage strengths. On information and belief, Alvogen's ANDA Product is manufactured from rollstock consisting of the same ingredients and materials in the same amounts as in the rollstock used to manufacture 13-52

dosage strengths. On information and belief, the ingredients and materials used in Alvogen's ANDA Product are from the same suppliers as the ingredients and materials used in the 13-52 dosage strengths.

26. On information and belief, Alvogen made and included in its ANDA a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that, in its opinion and to the best of its knowledge, the '023 and '031 patents are invalid and/or will not be infringed.

27. By filing its ANDA under 21 U.S.C. § 355(j) for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of Alvogen's ANDA Product before the expiration of the '023 and '031 patents, Alvogen has committed an act of infringement under 35 U.S.C. § 271(e)(2).

28. On information and belief, when Alvogen filed its ANDA, it was aware of the '023 and '031 patents and that the filing of its ANDA with the request for its approval prior to the expiration of the '023 and '031 patents was an act of infringement of those patents.

29. On information and belief, the commercial manufacture, use, offer for sale, sale and/or importation of Alvogen's ANDA Product will infringe one or more claims of the '023 and '031 patents.

30. On information and belief, the commercial manufacture of Alvogen's ANDA Product will involve direct infringement of the '023 patent. On information and belief, this will occur at Alvogen's active behest, and with Alvogen's intent, knowledge and encouragement. On information and belief, Alvogen will actively induce, encourage and abet this infringement with knowledge that it is in contravention of the rights under the '023 patent.

31. On information and belief, the commercial manufacture of Alvogen's ANDA Product will involve direct infringement of the '031 patent. On information and belief,

this will occur at Alvogen's active behest, and with Alvogen's intent, knowledge and encouragement. On information and belief, Alvogen will actively induce, encourage and abet this infringement with knowledge that it is in contravention of the rights under the '031 patent.

32. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of any approval of the aforementioned ANDA relating to Alvogen's ANDA Product be a date that is not earlier than January 8, 2019, the expiration date of the '023 and '031 patents, and an award of damages for any commercial sale or use of Alvogen's ANDA Product and any act committed by Alvogen with respect to the subject matter claimed in the '023 and '031 patents, which act is not within the limited exclusions of 35 U.S.C. § 271(e)(1).

33. On information and belief, Alvogen has taken and continues to take active steps towards the commercial manufacture, use, offer for sale, sale and/or importation of Alvogen's ANDA Product, including seeking approval of this product under Alvogen's ANDA.

34. There is a substantial and immediate controversy between Plaintiffs and Alvogen concerning the '023 and '031 patents. Plaintiffs are entitled to declaratory judgment under 28 U.S.C. §§ 2201 and 2202 that Alvogen will infringe and/or induce infringement of one or more claims of the '023 and '031 patents.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. Judgment that Alvogen has infringed and induced infringement of one or more claims of the '023 and '031 patents by filing the aforesaid ANDA relating to Alvogen's rivastigmine transdermal system, 13.3 mg/24 hr dosage strength;

B. A permanent injunction restraining and enjoining Alvogen 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 a rivastigmine transdermal system, 13.3 mg/24 hr dosage strength, as claimed in the '023 and '031 patents;

C. An order that the effective date of any approval of the aforementioned ANDA relating to Alvogen's rivastigmine transdermal system, 13.3 mg/24 hr dosage strength, be a date that is not earlier than the expiration of the right of exclusivity under the '023 and '031 patents;

D. Declaratory judgment that the commercial manufacture, use, offer for sale, sale and/or importation of Alvogen's rivastigmine transdermal system, 13.3 mg/24 hr dosage strength, will infringe one or more claims of the '023 and '031 patents and that Alvogen will induce infringement of one or more claims of the '023 and '031 patents;

E. Damages from Alvogen for the infringement and inducement of infringement of the '023 and '031 patents;

F. The costs and reasonable attorney fees of Plaintiffs in this action; and

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

Dated: March 7, 2013

McCARTER & ENGLISH, LLP

/s/ Daniel M. Silver

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