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,	:	Case No. _____
Plaintiffs,	:	
v.	:	
ACTAVIS SOUTH ATLANTIC LLC and ACTAVIS, 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 herein against defendants Actavis South Atlantic LLC and Actavis, 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 Pharmaceuticals Ltd. ("NIP") is a corporation organized and existing under the laws of Bermuda, having an office and place of business at Hurst Holme, 12 Trott Road, Hamilton HM LX, 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, Actavis South Atlantic LLC is a limited liability company organized and existing under the laws of the State of Delaware, having a place of business at 13800 NW 2nd Street, Suite 190, Sunrise, Florida.

8. On information and belief, Actavis, Inc. is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 60 Columbia Road, Building B, Morristown, New Jersey.

9. On information and belief, Actavis South Atlantic LLC is a wholly owned subsidiary of Actavis, Inc.

10. On information and belief, the acts of Actavis South Atlantic LLC complained of herein, were done at the direction of, with the authorization of, and with the cooperation, participation, and assistance of Actavis, Inc.

11. Defendants Actavis South Atlantic LLC and Actavis, Inc. are referred to collectively as "Actavis."

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 and 1338(a).

13. On information and belief, Actavis, Inc. is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. On information and belief, Actavis, Inc. directly, or through its affiliates and agents, including Actavis South Atlantic LLC, 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, Actavis South Atlantic LLC directly, or indirectly, manufactures, markets and sells drug products, including generic drug products manufactured by Actavis, Inc., 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 Actavis 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 and 9.5 mg/24 hr dosages), which patch contains the active ingredient rivastigmine. Exelon® Patch (4.6 mg/24 hr and 9.5 mg/24 hr) was approved by the United States Food and Drug Administration ("FDA") on July 6, 2007, and 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 and 9.5 mg/24 hr) is sold in the United States by Plaintiff NPC.

18. The active ingredient in the Exelon® Patch, rivastigmine, is known chemically as (S)- 3-[1-(dimethylamino) ethyl]phenyl ethylmethylcarbamate or (S)-[N-ethyl-3[(1-dimethylamino)ethyl]-N-methyl-phenyl-carbamate].

19. Plaintiff Novartis AG is the owner of United States Letters Patent No. 5,602,176 ("the '176 patent"). The '176 patent was duly and legally issued on February 11, 1997.

20. Plaintiff Novartis AG was formed as a result of the merger of Ciba-Geigy AG and Sandoz Ltd., both of Basel, Switzerland. The '176 patent was initially assigned to Sandoz Ltd. on January 29, 1988, which subsequently became Novartis AG after the merger.

21. The '176 patent claims the (S)-[N-ethyl-3-[(1-dimethylamino)ethyl]-N-methyl-phenyl-carbamate] enantiomer substantially free of its (R) isomer in free base or acid addition form, as well as pharmaceutical compositions and methods of treating

conditions such as Alzheimer's disease. A true copy of the '176 patent is attached hereto as Exhibit A.

22. 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.

23. 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 B.

24. 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.

25. 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. A true copy of the '031 patent is attached hereto as Exhibit C.

26. 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.

27. On information and belief, Actavis 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, 4.6 mg/24 hr and 9.5 mg/24 hr dosages ("Actavis's ANDA Products").

28. On information and belief, Actavis submitted its ANDA to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of Actavis's ANDA Products before the expiration of the '176, '023, and '031 patents.

29. 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 Actavis's ANDA Products before the expiration of the '176, '023, and '031 patents, Actavis has committed an act of infringement under 35 U.S.C. § 271(e)(2). Further, on information and belief, the commercial manufacture, use, offer for sale, sale and/or importation of Actavis's ANDA Products, for which Actavis seeks approval in its ANDA will also infringe one or more claims of the '176, '023, and '031 patents.

30. On information and belief, Actavis's ANDA Products, if approved, will be administered to human patients in a therapeutically effective amount for treatment of mild to moderate dementia of the Alzheimer's type, which administration constitutes direct infringement of the '176 patent. On information and belief, this will occur at Actavis's active behest, and with Actavis's intent, knowledge and encouragement. On information and belief, Actavis will actively induce, encourage and abet this administration with knowledge that it is in contravention of the rights under the '176 patent.

31. On information and belief, Actavis made, and included in its ANDA, a certification under 21 U.S.C. § 355(j)(2)(vii)(IV) that, in its opinion and to the best of its knowledge, the ’176, ’023, and ’031 patents are invalid, unenforceable and/or will not be infringed.

32. On information and belief, Actavis’s ANDA seeks approval to manufacture and sell Actavis’s ANDA Products, which infringe the ’176, ’023, and ’031 patents.

33. 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 Actavis’s ANDA Products, be a date that is not earlier than February 11, 2014, the expiration date of the ’176 patent, and 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 Actavis’s ANDA Products, and any act committed by Actavis with respect to the subject matter claimed in the ’176, ’023, and ’031 patents, which act is not within the limited exclusions of 35 U.S.C. § 271(e)(1).

34. On information and belief, when Actavis filed its ANDA, it was aware of the ’176, ’023, and ’031 patents and that the filing of its ANDA with the request for its approval prior to the expiration of the ’176, ’023, and ’031 patents was an act of infringement of these patents.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. Judgment that Actavis has infringed one or more claims of the ’176, ’023, and ’031 patents by filing the aforesaid ANDA relating to Actavis’s rivastigmine transdermal system, 4.6 mg/24 hr and 9.5 mg/24 hr dosages;

B. A permanent injunction restraining and enjoining Actavis 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, 4.6 mg/24 hr and 9.5 mg/24 hr dosages, as claimed in the ’176, ’023, and ’031 patents;

C. An order that the effective date of any approval of the aforementioned ANDA relating to Actavis’s rivastigmine transdermal system, 4.6 mg/24 hr and 9.5 mg/24 hr dosages, be a date that is not earlier than the expiration of the right of exclusivity under the ’176, ’023, and ’031 patents;

D. Damages from Actavis for the infringement of the ’176, ’023, and ’031 patents;

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

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

Dated: November 3, 2011 McCARTER & ENGLISH, LLP

/s/ Daniel M. Silver
Michael P. Kelly (#2295)
Daniel M. Silver (#4758)
Renaissance Centre
405 N. King Street, 8th Floor
Wilmington, DE 19801
mkelly@mccarter.com
dsilver@mccarter.com

Attorneys for Plaintiffs

Of Counsel:

Nicholas N. Kallas
Filko Prugo
FITZPATRICK, CELLA, HARPER & SCINTO
1290 Avenue of the Americas
New York, New York 10104-3800
Telephone: (212) 218-2100
Facsimile: (212) 218-2200