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,	:	Case No.
v.	:	
ACTAVIS, INC., WATSON PHARMACEUTICALS, INC., WATSON LABORATORIES, INC., and WATSON PHARMA, INC.,	:	
Defendants.	:	

PLAINTIFFS' COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Novartis Pharmaceuticals Corporation, Novartis AG, Novartis Pharma AG, Novartis International Pharmaceutical Ltd. and LTS Lohmann Therapie-Systeme AG (collectively "Plaintiffs"), for their Complaint herein against defendants Actavis, Inc., Watson Pharmaceuticals, Inc., Watson Laboratories, Inc. and Watson Pharma, Inc. (collectively "Actavis") 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, Actavis, Inc. is a corporation organized and existing under the laws of the State of Nevada, having a place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey.

8. On information and belief, Watson Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of Nevada, having a place of business at

Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey. On information and belief, Watson Pharmaceuticals, Inc. changed its name to Actavis, Inc. on January 24, 2013. On information and belief, apart from that name change, the corporation formerly known as Watson Pharmaceuticals, Inc. and currently known as Actavis Inc., has not undergone any change of corporate form, state of incorporation and/or place(s) of business. Any reference herein to Actavis, Inc. shall be considered a reference to Watson Pharmaceuticals, Inc. and vice versa.

9. On information and belief, Watson Laboratories, Inc. ("Watson Laboratories") is a corporation organized and existing under the laws of the State of Nevada, having a place of business at 311 Bonnie Circle, Corona, California, and another place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey.

10. On information and belief, Watson Pharma, Inc. ("Watson Pharma") is a corporation organized and existing under the laws of the State of Delaware, having a place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey.

11. On information and belief, Watson Laboratories and Watson Pharma are wholly owned subsidiaries of Actavis, Inc.

12. On information and belief, the acts of Watson Laboratories complained of herein, were done at the direction of, with the authorization of, and with the cooperation, participation, and assistance of Actavis, Inc. and Watson Pharma.

13. Defendants Actavis, Inc., Watson Laboratories and Watson Pharma are referred to collectively as "Actavis."

JURISDICTION AND VENUE

14. 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.

15. On information and belief, Actavis, Inc. organizes its operations by divisions—Generic, Brand, and Distribution—and reports its financial results in its Securities and Exchange Commission ("SEC") filings by reference to these divisions. Actavis, Inc. consolidates its financial results with its subsidiaries in its SEC filings at least for 2007 to date and does not separate financial reports to the SEC for each subsidiary.

16. On information and belief, the Generic Division is involved in the development, manufacture, marketing, sale, and distribution of generic pharmaceuticals. On information and belief, Actavis, Inc., Watson Laboratories and Watson Pharma each act as agents of each other and/or work in concert with each other to further the aims of the Generic Division. On information and belief, the Generic Division, which is responsible for, *inter alia*, developing and submitting abbreviated new drug applications ("ANDAs") to the U.S. Food and Drug Administration ("FDA"), relies on contributions from Actavis, Inc., Watson Laboratories and Watson Pharma.

17. On information and belief, the head of the Generic Division is an employee of Actavis, Inc., the Generic Division's ANDAs are submitted by Watson Laboratories, the Generic Division's products are manufactured also by Watson Laboratories, and the Generic Division's products are marketed and sold throughout the United States, including in Delaware, by Watson Pharma.

18. On information and belief, Actavis, Inc., Watson Laboratories and Watson Pharma share a common place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey.

19. On information and belief, Actavis, Inc., Watson Laboratories and Watson Pharma each share with the others common employees, officers, and directors.

20. On information and belief, Watson Laboratories has purposely availed itself of the rights and benefits of Delaware law and this Court. This Court previously determined in *Cephalon, Inc. v. Watson Pharmaceuticals, Inc*., 629 F. Supp. 2d 338, 348 D. Del. 2009), that Watson Laboratories "'regularly does or solicits business' in Delaware or engages in a 'persistent course of conduct' in Delaware."

21. On information and belief, Watson Pharma, a Delaware corporation, is the distributor of drugs for which Watson Laboratories is the named applicant in the FDA's Approved Drug Product List. On information and belief, Watson Pharma, acting as the agent of Watson Laboratories and Actavis, Inc., markets and sells these drugs throughout the United Stated, including in Delaware.

22. On information and belief, Watson Pharma is licensed to do business in Delaware and has sales personnel assigned to cover Delaware for the purpose of marketing and selling Generic Division products of Actavis, Inc., including Watson Laboratories' products.

23. On information and belief, Watson Laboratories and Watson Pharma are parties to one or more contractual agreements for distributing drugs manufactured under Watson Laboratories' ANDAs.

24. On information and belief, Actavis, Inc., through its own actions and the actions of one or more of its subsidiaries, actively engages in a concerted effort to sell generic products throughout the United States, including in Delaware.

25. This Court has personal jurisdiction over defendants Actavis, Inc., Watson Laboratories and Watson Pharma by virtue of, *inter alia*, the above-mentioned facts. They demonstrate that Actavis, Inc., Watson Laboratories and Watson Pharma either directly or through an agent, including each other, regularly do or solicit business in Delaware, engage in other persistent courses of conduct in Delaware, and/or derive substantial revenue from services or things used or consumed in Delaware. These activities further demonstrate that Actavis, Inc., Watson Laboratories and Watson Pharma have continuous and systematic contacts in Delaware.

26. On information and belief, Actavis, Inc., Watson Laboratories and Watson Pharma have acted or will act as agents of each other, and/or have worked or will work in concert with respect to the development, regulatory approval, marketing, sale and distribution of pharmaceutical products, including a rivastigmine transdermal system, 13.3 mg/24 hr dosage strength.

27. On information and belief, each of Actavis, Inc., Watson Laboratories and Watson Pharma, as part of Actavis, Inc.'s Generic Division, would manufacture, market, and/or sell within the United States Actavis's rivastigmine transdermal system, 13.3 mg/24 hr dosage strength, if FDA approval is granted.

28. On information and belief, if approved by the FDA, Actavis's rivastigmine transdermal system, 13.3 mg/24 hr dosage strength, would be marketed and distributed in Delaware, prescribed by physicians practicing in Delaware, dispensed by pharmacies located

within Delaware, and/or used by persons in Delaware, all of which would have a substantial effect on Delaware.

29. 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

30. 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.

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

32. 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.

33. 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.

34. 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.

35. 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 B.

36. 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.

37. On information and belief, Actavis submitted to the FDA an 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 ("Actavis's ANDA Product") before the expiration of the '023 and '031 patents.

38. On information and belief, Actavis'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 Actavis also seeks FDA approval and that are the subject of District of Delaware Civil Action No. 11-1112-RGA (collectively "the 11-1112 dosage strengths"). On

information and belief, the active ingredient and inactive ingredients in Actavis'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 11-1112 dosage strengths. On information and belief, Actavis'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 11-1112 dosage strengths. On information and belief, the ingredients and materials used in Actavis's ANDA Product are from the same suppliers as the ingredients and materials used in the 11-1112 dosage strengths.

39. 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 Product before the expiration of the '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 Product, for which Actavis seeks approval in its ANDA, will also infringe one or more claims of the '023 and '031 patents.

40. 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 '023 and '031 patents are invalid and/or will not be infringed.

41. On information and belief, Actavis's ANDA seeks approval to manufacture and sell Actavis's ANDA Product, which infringes the '023 and '031 patents.

42. 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 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 Actavis's ANDA Product, and any act committed by Actavis 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).

43. On information and belief, when Actavis 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 these patents.

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

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

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

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

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, 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 Actavis'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 Actavis's rivastigmine transdermal system, 13.3 mg/24 hr dosage strength, will infringe one or more claims of the '023 and '031 patents;

E. Damages from Actavis for the 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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