

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

VALIDUS PHARMACEUTICALS, INC.,)	
)	
Plaintiff,)	
)	
v.)	C.A. No. _____
)	
ACTAVIS SOUTH ATLANTIC LLC, and)	
ACTAVIS, INC.,)	
)	
Defendants.)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Validus Pharmaceuticals, Inc. (“Validus”) by its attorneys, for its complaint against Actavis South Atlantic LLC and Actavis, Inc., alleges as follows:

The Parties

1. Plaintiff Validus Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of Delaware and has its principal place of business at 119 Cherry Hill Road - Suite 310, Parsippany, New Jersey 07054.

2. Upon information and belief, Defendant Actavis South Atlantic LLC (“Actavis South Atlantic”) is a limited liability company organized and existing under the laws of the State of Delaware, having a principal place of business at 13800 N.W. 2nd Street, Sunrise, Florida 33325. Upon information and belief, Actavis South Atlantic does business in Delaware.

3. Upon information and belief, Defendant Actavis, Inc. is a corporation organized and existing under the laws of the State of Delaware, and has a principal place of business at 14 Commerce Drive, Suite 301, Cranford, New Jersey 07207. Actavis, Inc. does business in the State of Delaware. Actavis, Inc. is the parent of Actavis South Atlantic, and Actavis South Atlantic is a wholly-owned subsidiary of Actavis, Inc.

4. Upon information and belief, Actavis South Atlantic and Actavis, Inc. (collectively, “Actavis”) are in the business of manufacturing, distributing, and selling generic pharmaceutical products, which are copies of products invented and developed by innovator pharmaceutical companies.

5. Upon information and belief, Actavis South Atlantic and Actavis, Inc. collaborated in the research and development of Actavis’s Abbreviated New Drug Application (“ANDA”) No. 79-180 for carbamazepine extended-release capsules, continue to collaborate in seeking approval of that application from the Food and Drug Administration (“FDA”), and intend to collaborate in the commercial manufacture, marketing, and sale of carbamazepine products, including commercial marketing and sale in the State of Delaware, in the event that FDA approves Actavis’s ANDA No. 79-180. Upon information and belief, Actavis South Atlantic and Actavis, Inc. collaborate in the manufacture, marketing, and sale of many pharmaceutical products, including numerous generic prescription drug products manufactured and sold pursuant to an approved abbreviated new drug application, that are marketed and sold to customers in the State of Delaware.

Jurisdiction and Venue

6. This is a civil action for patent infringement arising under the patent laws of the United States, Title 35 of the United States Code, for infringement of United States Patent No. 6,977,253 (“the ’253 patent”). This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

7. Actavis South Atlantic is subject to personal jurisdiction in this judicial district because it is a limited liability company organized and existing under the laws of the State of Delaware and, by virtue of, *inter alia*, its being organized in the State of Delaware,

having availed itself of the rights and benefits of Delaware law, and having engaged in substantial and continuing contacts with the State.

8. Actavis, Inc. is subject to personal jurisdiction in this judicial district because it is a corporation organized and existing under the laws of the State of Delaware and, by virtue of, *inter alia*, its being incorporated in the State of Delaware, having availed itself of the rights and benefits of Delaware law, and having engaged in substantial and continuing contacts with the State.

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

Regulatory Requirements for Approval of New and Generic Drugs

10. Any person wishing to market a pioneering drug – that is, a new drug that has not previously been approved by FDA – must first file a New Drug Application (“NDA”) with FDA demonstrating that the drug is safe and effective for its intended use. 21 U.S.C. § 355(b). To secure approval of a NDA, the NDA applicant must, among other things, collect and submit to FDA extensive animal and human clinical trial data at a substantial cost of time and money.

11. A person wishing to market a generic copy of a pioneering drug that previously has been approved by FDA may follow a truncated approval process by filing an abbreviated new drug application for a generic version of the drug. In the ANDA, the applicant must demonstrate, among other things, bioequivalence of the generic copy of the pioneering drug. 21 U.S.C. § 355(j)(2)(A)(iv). To demonstrate bioequivalence, the ANDA applicant must show that the rate and extent of absorption of the therapeutic ingredient in the generic drug does not significantly differ from that in the pioneering drug, or, if the rate of absorption differs, that

such difference is intentional, is reflected in the proposed labeling, is not essential to the attainment of effective body drug concentrations on chronic use, and is considered medically insignificant for the drug. 21 U.S.C. § 355(j)(8)(B).

12. However, unlike a NDA applicant, an ANDA applicant is not required to include safety and effectiveness data. The ANDA applicant is not required, for example, to conduct well-controlled clinical trials concerning the safety and effectiveness of the proposed drug. Instead, the ANDA applicant is permitted to piggy-back on the safety and effectiveness data developed and submitted by the approved NDA holder. 21 U.S.C. § 355(j).

13. Nor does an ANDA applicant establish any new conditions of use for the proposed drug product. Instead, an ANDA applicant may seek approval only for conditions of use that previously have been approved in connection with an approved NDA. 21 U.S.C. § 355(j)(2)(A)(i).

14. No person may market in the United States a new drug without an approved NDA or a generic version of a drug without an approved ANDA. 21 U.S.C. § 355(a).

Plaintiff's Approved Drug Product

15. Validus is the holder of an approved new drug application, NDA No. 21-710, for carbamazepine extended-release capsules. That NDA was approved by FDA on December 10, 2004 and covers three strengths of capsule – 100 mg, 200 mg, and 300 mg. The sole indication or condition of use for which carbamazepine extended-release capsules are approved in NDA No. 21-710 is the treatment of acute manic to mixed episodes associated with Bipolar I disorder.

16. Pursuant to FDA's approval, Validus currently markets carbamazepine extended-release capsules for the treatment of acute manic to mixed episodes associated with Bipolar I disorder under the trademark EQUETRO®.

17. FDA has listed the '253 patent in the Orange Book – formally known as Approved Drug Products With Therapeutic Equivalence Evaluations – in connection with NDA No. 21-710.

18. The '253 patent qualifies for listing in the Orange Book in connection with NDA No. 21-710 because it claims an approved use of the drug product that is the subject of that NDA. Actavis South Atlantic and Actavis have never challenged the listing of the '253 patent in the Orange Book.

Actavis's ANDA

19. Actavis has represented that on or before December 4, 2007, it submitted to FDA an ANDA (ANDA No. 79-180) and paragraph IV certifications under section 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 355(j)(2)(A)(vii)(IV), for carbamazepine extended-release capsules purportedly bioequivalent to Validus's EQUETRO® carbamazepine extended-release capsule products. The purpose of Actavis's ANDA and paragraph IV certifications, is to obtain approval under section 505(j) of the FDCA to engage in the commercial manufacture and sale of its proposed carbamazepine extended-release capsules before the expiration of the patents listed in the Orange Book for Validus's NDA No. 21-710. Hence, Actavis's purpose in submitting ANDA No. 79-180 is to market in the United States the carbamazepine products described therein before expiration of the '253 patent.

20. On or about December 4, 2007, Actavis sent a letter advising Validus of Actavis's paragraph IV certification relating to the '253 patent ("Actavis's Notice Letter"). Actavis's Notice Letter included an offer of confidential access that would permit Validus's outside counsel to review Actavis's ANDA.

21. Upon information and belief, the sole condition of use for which Actavis seeks approval in its ANDA No. 79-180 for its proposed carbamazepine extended-release capsules is the treatment of acute manic to mixed episodes associated with Bipolar I disorder, the same condition of use as that approved in Validus's NDA No. 21-710.

22. Upon information and belief, the sole indication set forth in the proposed labeling submitted by Actavis in its ANDA No. 79-180 for its proposed carbamazepine extended-release capsules is the treatment of acute manic to mixed episodes associated with Bipolar I disorder, the same indication as that set forth in the approved labeling for Validus's EQUETRO[®] carbamazepine extended-release capsule products.

Count 1: Patent Infringement

23. Validus realleges paragraphs 1 through 22 above as if fully set forth herein.

24. On December 20, 2005, the United States Patent and Trademark Office duly and legally issued the '253 patent, entitled "Methods For The Treatment Of Bipolar Disorder Using Carbamazepine." The term of the '253 patent runs through May 19, 2024. A true and correct copy of the '253 patent is attached hereto as Exhibit A.

25. Validus is the owner of the '253 patent.

26. Validus currently markets carbamazepine extended-release capsule products in the United States under the trademark EQUETRO[®]. The conditions of use for which EQUETRO[®] carbamazepine extended-release capsule products are approved fall within one or more of the claims of the '253 patent.

27. Actavis is liable for infringement of the '253 patent under 35 U.S.C. § 271(e)(2)(A) by virtue of its filing ANDA No. 79-180 with a paragraph IV certification seeking FDA approval of ANDA No. 79-180 prior to expiration of the '253 patent.

28. Upon information and belief, the conditions of use for which Actavis seeks approval in its ANDA No. 79-180 fall within one or more of the claims of the '253 patent. Upon information and belief, if approved, use of Actavis's proposed carbamazepine products in accordance with the proposed labeling submitted in ANDA No. 79-180 would infringe one or more of the claims of the '253 patent.

29. Upon information and belief, if ANDA No. 79-180 is approved, Actavis intends to manufacture, use, offer for sale, and sell in the United States, and import into the United States, the carbamazepine products for which approval is sought in Actavis's ANDA No. 79-180.

30. Upon information and belief, if approved, Actavis's carbamazepine products proposed in Actavis's ANDA No. 79-180 will be administered to human patients in a therapeutically effective amount for treatment of acute manic or mixed episodes of Bipolar I disorder, which administration would constitute direct infringement of one or more claims of the '253 patent. Upon information and belief, this infringement will occur at Actavis's behest, with its intent, knowledge, and encouragement, and Actavis will actively induce, encourage, aid, and

abet this administration with knowledge that it is in contravention of Validus's rights under the '253 patent.

31. Actavis's manufacture, use, offer for sale or sale in the United States, or importation into the United States, prior to expiration of the '253 patent, of the carbamazepine products for which approval is sought in ANDA No. 79-180, would actively induce and contribute to infringement of the '253 patent, and Actavis would be liable as an infringer under 35 U.S.C. §§ 271(b) and/or (c).

32. Validus will be irreparably harmed if Actavis is not enjoined from infringing or actively inducing or contributing to infringement of the '253 patent. Validus does not have an adequate remedy at law.

Prayer For Relief

WHEREFORE, Plaintiffs seek the following relief:

A. A judgment that Actavis has infringed one or more claims of the '253 patent under 35 U.S.C. § 271(e)(2)(A).

B. A judgment and order pursuant to 35 U.S.C. § 271(e)(4) providing that the effective date of any FDA approval of the Actavis ANDA No. 79-180 for carbamazepine extended-release 200 mg and 300 mg capsules be not earlier than the expiration date of the '253 patent;

C. A judgment declaring that Actavis's manufacture, use, offer for sale, or sale in the United States, or importation into the United States, of the carbamazepine products for which approval is sought in ANDA No. 79-180 would induce or contribute to infringement of the '253 patent, pursuant to 35 U.S.C. § 271 (b), and/or (c);

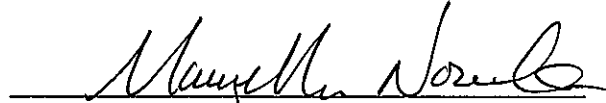
D. A permanent injunction enjoining Actavis and its officers, agents, servants, and employees, and those persons in active concert or participation with any of them, from making, using, selling, or offering to sell in the United States, or importing into the United States, the carbamazepine extended-release capsules for which approval is sought in ANDA No. 79-180, or any carbamazepine product that induces or contributes to the infringement of the '253 patent, until expiration of that patent;

E. A finding that this is an exceptional case, and an award of attorneys' fees in this action pursuant to 35 U.S.C. § 285;

F. An award of costs and expenses in this action; and

G. Such further and other relief as this Court determines to be just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP



Jack B. Blumenfeld (#1014)

Maryellen Noreika (#3208)

1201 North Market Street

P.O. Box 1347

Wilmington, DE 19899

(302) 658-9200

jblumenfeld@mnat.com

mnoreika@mnat.com

Attorneys for Plaintiff

Of Counsel:

George F. Pappas

Roderick R. McKelvie

Jeffrey B. Elikan

Steven P. Berman

Sarah J. Chickos

COVINGTON & BURLING LLP

1201 Pennsylvania Avenue, N.W.

Washington, D.C. 20004

(202) 662-6000

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