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

| | |
|---|---|
| CIMA LABS, INC. and SCHWARZ PHARMA, INC.,<br><br>Plaintiffs,<br>vs.<br><br>ACTAVIS GROUP hf, ACTAVIS, INC. and ACTAVIS ELIZABETH LLC,<br><br>Defendants. | **Civil Action No.: _____**<br><br>**DOCUMENT FILED ELECTRONICALLY** |

## COMPLAINT

Plaintiffs CIMA LABS, INC. ("CIMA") and Schwarz Pharma, Inc. ("Schwarz Pharma") (collectively, "Plaintiffs"), by their attorneys, for their Complaint against Actavis Group hf, Actavis, Inc. and Actavis Elizabeth LLC (collectively, "Actavis"), allege as follows:

## THE PARTIES

1. Plaintiff CIMA is a corporation organized and existing under the laws of Delaware, having its principal place of business at 10000 Valley View Road, Eden Prairie, Minnesota 55344.

2. Plaintiff Schwarz Pharma is a corporation organized and existing under the laws of the state of Delaware, and has a principal place of business at 6140 West Executive Drive, Mequon, Wisconsin 53092-4467.

3. Upon information and belief, defendant Actavis Group hf is a limited liability company organized under the laws of Iceland, having its principal place of business at Dalshrauni 1, 220 Hafnarfirdi, Iceland.

4. Upon information and belief, defendant Actavis, Inc. is a corporation organized and existing under the laws of Delaware, having its principal place of business at 200 Elmora Avenue, Elizabeth, New Jersey 07202. Upon information and belief, Actavis, Inc. is a wholly owned subsidiary, agent and alter-ego of defendant Actavis Group hf.

5. Upon information and belief, defendant Actavis Elizabeth LLC is a limited liability company organized under the laws of Delaware, having its principal place of business at 200 Elmora Avenue, Elizabeth, New Jersey 07202. Upon information and belief, Actavis Elizabeth LLC is a wholly owned subsidiary, agent and alter-ego of defendants Actavis, Inc. and/or Actavis Group hf.

6. Upon information and belief, Actavis Group hf manufactures numerous generic

drugs for sale and use throughout the United States, including this judicial district, through its wholly-owned subsidiary, agent and alter-ego defendants Actavis, Inc. and/or Actavis Elizabeth LLC.

## NATURE OF THE ACTION

7. This is a civil action for patent infringement arising under the Patent Laws of the United States, 35 U.S.C. 1 *et seq.*

## JURISDICTION AND VENUE

8. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202.

9. Actavis Elizabeth LLC is subject to personal jurisdiction in this judicial district by virtue of, *inter alia*, having its principal place of business in New Jersey, its conduct of business in this State, its purposeful availment of the rights and benefits of New Jersey law and its systematic and continuous contacts with the State.

10. Actavis, Inc. is subject to personal jurisdiction in this judicial district by virtue of, *inter alia*, having its principal place of business in New Jersey, its conduct of business in this State, its purposeful availment of the rights and benefits of New Jersey law and its systematic and continuous contacts with the State, including through its subsidiary, agent and alter-ego of defendant Actavis Elizabeth LLC.

11. Actavis Group hf is subject to personal jurisdiction in this judicial district by virtue of, *inter alia*, its presence through its subsidiary, agent and alter-ego of defendants Actavis, Inc. and/or Actavis Elizabeth LLC, and its systematic and continuous contacts with the State, including through its subsidiary, agent and alter-ego of defendants Actavis, Inc. and/or Actavis Elizabeth LLC.

12. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391(b), (c)

and/or (d) and 1400(b).

**ACTS GIVING RISE TO CLAIMS FOR PATENT INFRINGEMENT**

13. On February 15, 2000, the United States Patent and Trademark Office issued U.S. Patent No. 6,024,981, entitled "Rapidly Dissolving Robust Damage Form" (the "'981 patent"). A copy of the '981 patent is attached as Exhibit A.

14. An *ex parte* reexamination of the '981 patent was requested on or about August 22, 2005 (Control No. 90/007,684), and reexamination was ordered on or about October 7, 2005. A second *ex parte* reexamination of the '981 patent was filed on or about September 7, 2006 (Control No. 90/008,133), and reexamination was ordered on or about September 28, 2006. The two *ex parte* reexaminations of the '981 patent were consolidated on or about January 8, 2007.

15. By way of assignment, CIMA owns all rights, title and interest in and to the '981 patent, including the right to sue and recover for patent infringement.

16. On April 24, 2001, the United States Patent and Trademark Office issued U.S. Patent No. 6,221,392, entitled "Rapidly Dissolving Robust Damage Form" (the "'392 patent"). A copy of the '392 patent is attached as Exhibit B.

17. An *inter partes* reexamination of the '392 patent was filed on July 28, 2006 (Control No. 95/000,160), and reexamination was ordered on or about September 13, 2006.

18. By way of assignment, CIMA owns all rights, title and interest in and to the '392 patent, including the right to sue and recover for patent infringement.

19. Schwarz Pharma is the exclusive licensee to the '981 and '392 patents for alprazolam orally disintegrating tablets in the United States. Under the exclusive license, CIMA manufactures NIRAVAM™, an alprazolam product, for Schwarz Pharma.

20. The '981 patent and '392 patent (sometimes collectively referred to as the

"patents in suit") are listed in a publication known as the Orange Book (formerly entitled *Approved Drug Products with Therapeutic Equivalence Evaluations*) as covering NIRAVAM™, alprazolam orally disintegrating tablets in 0.25 mg, 0.5 mg, 1 mg and 2 mg dosages.

21. Upon information and belief, Actavis Elizabeth LLC submitted to the United States Food and Drug Administration ("FDA") Abbreviated New Drug Application ("ANDA") No. 78-561 under the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j). Through this ANDA, Actavis seeks the approval of the FDA necessary to engage in the commercial manufacture, use, offer for sale and sale of generic versions of alprazolam orally disintegrating tablets in 0.25 mg, 0.5 mg, 1 mg and 2 mg dosages. ANDA No. 78-561 specifically seeks FDA approval of the proposed generic versions prior to the expiration of the patents in suit.

22. No earlier than January 12, 2007, Plaintiffs received a letter from Actavis notifying them that ANDA No. 78-561 containing a Paragraph IV Certification had been submitted to the FDA ("Paragraph IV Notice Letter"). The Paragraph IV Notice Letter and, upon information and belief, ANDA No. 78-561, allege that the '981 patent and the '392 patent are invalid, unenforceable and/or will not be infringed by the manufacture, use or sale of the generic versions of alprazolam orally disintegrating products for which Actavis seeks FDA approval.

23. Plaintiffs have commenced this action within forty-five (45) days of receipt of the Paragraph IV Notice Letter.

## COUNT ONE

## INFRINGEMENT OF THE '981 PATENT

24. Plaintiffs repeat and reallege each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

25. Upon information and belief and subject to F.R.C.P. 11(b)(3), defendants'

submission of ANDA No. 78-561 to the FDA constitutes infringement of the '981 patent under 35 U.S.C. § 271(e)(2)(A).

26. Upon information and belief and subject to F.R.C.P. 11(b)(3), defendants' manufacture, use, offer for sale and/or sale of its proposed generic versions for which defendants seek approval from the FDA under ANDA No. 78-561 will infringe, contribute to the infringement of and induce the infringement of one or more of the claims of the '981 patent.

27. Upon information and belief and subject to F.R.C.P. 11(b)(3), defendants were aware at the time of submission of ANDA No. 78-561 and continue to be aware that the proposed generic versions for which defendants seek approval from the FDA under ANDA No. 78-561, if approved, will be made, used and/or sold in contravention of Plaintiffs' rights in and to the '981 patent.

28. Upon information and belief and subject to F.R.C.P. 11(b)(3), the conduct by Actavis renders this case "exceptional" as described in 35 U.S.C. § 285.

29. Plaintiffs will be irreparably harmed if the infringing activities of Actavis in relation to the '981 patent are not enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

## COUNT TWO

## INFRINGEMENT OF THE '392 PATENT

30. Plaintiffs repeat and reallege each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

31. Upon information and belief and subject to F.R.C.P. 11(b)(3), defendants' submission of ANDA No. 78-561 to the FDA constitutes infringement of the '392 patent under 35 U.S.C. § 271(e)(2)(A).

32. Upon information and belief and subject to F.R.C.P. 11(b)(3), defendants'

manufacture, use, offer for sale and/or sale of its proposed generic versions for which defendants seek approval from the FDA under ANDA No. 78-561 will infringe, contribute to the infringement of and induce the infringement of one or more of the claims of the '392 patent.

33. Upon information and belief and subject to F.R.C.P. 11(b)(3), defendants were aware at the time of submission of ANDA No. 78-561 and continue to be aware that the proposed generic versions for which defendants seek approval from the FDA under ANDA No. 78-561, if approved, will be made, used and/or sold in contravention of Plaintiffs' rights in and to the '392 patent.

34. Upon information and belief and subject to F.R.C.P. 11(b)(3), the conduct by Actavis renders this case "exceptional" as described in 35 U.S.C. § 285.

35. Plaintiffs will be irreparably harmed if the infringing activities of Actavis in relation to the '392 patent are not enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

**PRAYER FOR RELIEF**

WHEREFORE, Plaintiffs respectfully request the following relief:

A. A judgment that defendants have infringed the patents in suit by submission of ANDA No. 78-561 and that the manufacture, use, offer for sale or sale of the generic versions proposed by defendants to the FDA in ANDA No. 78-561, if marketed, would infringe, induce or contribute to the infringement of the patents in suit;

B. An order pursuant to 35 U.S.C. § 271(e)(4)(A) decreeing the effective date of any approval of ANDA No. 78-561 be subsequent to the date of the last to expire of the patents in suit;

C. A preliminary and permanent injunction pursuant to 35 U.S.C. § 271(e)(4)(B) prohibiting Actavis, its officers, agents, attorneys, and employees and those acting in active

concert or participation with any of them, from engaging in the commercial manufacture, use, offer for sale, sale or importation of the generic versions proposed by defendants to the FDA in ANDA No. 78-561 or any other product that infringes, induces or contributes to the infringement of one or more of any of the claims in the patents in suit prior to expiration, including any extensions;

D. Monetary relief and damages, including damages for willful infringement, pursuant to 35 U.S.C. § 284, if any defendant commercially manufactures, uses, offers for sale or sells the generic versions proposed by defendants to the FDA in ANDA No. 78-561 or any other product that infringes, induces or contributes to the infringement of one or more of any of the claims in the patents in suit prior to expiration, including any extensions;

E. A declaration that this case is exceptional under 35 U.S.C. § 271(e)(4)(C) and 35 U.S.C. § 285 and an award of attorneys' fees, costs and expenses to Plaintiffs;

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

Dated: February 23, 2007

Respectfully submitted,

**MCCARTER & ENGLISH, LLP**

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